Taiwan Herbal Pharmacopeia
4th Edition English Version

臺灣中藥典第四版
英文版

Ministry of Health and Welfare
Taiwan, Republic of China
December, 2022

Taiwan Herbal Pharmacopeia
4th Edition English Version

臺灣中藥典第四版
英文版

Ministry of Health and Welfare
Taiwan, Republic of China

Preface

The Taiwan Herbal Pharmacopeia (THP) with records of the specification and inspection standards of TCM (Traditional Chinese Medicine) herbs is the national basis for the quality control of TCM products. After the promulgation of the 3rd edition of the THP in 2018, the Ministry of Health and Welfare (MOHW) started editing the 4th THP and establishing sound quality specifications of TCM herbs to further promote the quality consistency in TCM herbs and to assure the safety of medicines taken by the public. Accessing the executed quality control and the use of TCM herbs in Taiwan in recent years, the content of the 4th edition of the THP was comprehensively reviewed and revised accordingly.

For compiling the 4th edition of the THP, the MOHW has successively entrusted Tajen University, Da-Yeh University, China Medical University, Hungkuang University, Kaohsiung Medical University, I-Shou University together with the National Research Institute of Chinese Medicine, to carry out joint a coule of researches, focusing on the revision and addition of the specifications for TCM herbs and herbal preparations.

Following the running mechanism of editing the 3rd THP, four sub-committees, including, "Source origin research group", "Chemical specifications group", "TCM preparation group" and "Clinical Chinese medicine group", were formed to edit the 4th THP. Each sub-committee provided a platform to operate the reviews and discussions on the related issues through regular meetings. After a total of 42 meetings contributing to the editing work, the 4th edition of the THP was completed.

The 4th edition of the THP covered a total of 394 items including 355 monographs of TCM herbs, 30 items of decoction pieces, and 9 monographs of TCM preparations. Three new TCM herb monographs (Lonicerae Flos, Schisandrae Sphenantherae Fructus and Puerariae Thomsonii Radix), 30 decoction pieces, and 7 TCM preparations (Rhubarb Concentrated Preparation, Siaocinglong Tang Concentrated Preparation, Bansia Xiesin Tang Concentrated Preparation, Liquorice Root and Rhizome Concentrated Preparation, Corydalis Tuber Concentrated Preparation, Ge Gen Tang Concentrated Preparation and Puerariae Radix Concentrated Preparation) were added. In contrast, 3 existed monographs of TCM herbs (Trogopterori Faeces, Malvae Fructus and Photiniae Folium) were deleted. Among those covered items, 330 items were of plant sources, 11 items were of animal sources, 6 items were of fungi sources, 4 items were of insect sources and 4 items were of mineral sources. Based on the TCM clinical literatures and clinical experiences, the “Administration and dosage” of each monograph was revised. The functions of each of the 355 TCM herbs were added. Hydrargyri Oxydum Rubrum was added to the List of poisonous Chinese Materia Medica. The General rules of concentrated TCM pill preparation, a Table of code numbers of columns, and a comparison table of the new and old Latin names of the herb species were added. The code numbers and wording description of the General rules were revised, and some general rules were merged. In order to improve the inspection methods and in line with the international

trends of pharmacopeia, the thin layer chromatographic identification methods of 41 TCM herbs had been added or revised, consequently the percentage of the monographs with TLC specification has been increased to 91%. The assay of high-performance liquid chromatography of 48 TCM herbs had been added or revised and the percentage of the monographs with HPLC specification had been increased to 62%. The calculation equations of the assay of 214 TCM herbs, were added. The limits of abnormal substances such as heavy metals, sulfur dioxide, pesticide residues, aflatoxin and microorganisms promulgated by the MOHW previously were added in the related monographs. With the continuously scientific and systematic improvement of the quality control specifications of TCM herbs, we aim to promote the development of Chinese medicine industry in Taiwan and facilitate the globalization of Chinese medicine.

I am delighted to see the completion of the editorial work and the printing of the 4th edition of the THP and is happy to write the preface for the work. I would like to heartily thank those experts engaged in the establishment of the specifications, compilation and review for devoting their time, efforts and precious recommendation. With the publishing of the 4th edition of the THP, I sincerely welcome comments from TCM communities, related organizations and academic institutes.

Jui-Yuan Hsueh (薛瑞元)
Minister of Ministry of Health and Welfare
September, 2022

The Development of the Compilation of the 4th Edition of the Taiwan Herbal Pharmacopeia

The Pharmacopeia is the national standards of the pharmaceutical products. It is the legal basis for the production, inspection, supplement, usage, and supervision of marketing drugs and elaborated and promulgated by the government. The Herbal Pharmacopeia contains the national inspection specifications and detection methods of herbal medicines, also is the basis of the national standards for quality assurance to Traditional Chinese medicines (TCM). The Chinese Herbal Pharmacopeia (CHP) with 200 herb items was proclaimed on March 9, 2004 by the government and implemented on May 1, 2004. In each individual monograph, the Chinese name, scientific name, source, description, identification, limits of impurities, assay, storage, usage, dosage, precaution and warning of each item were recorded. Later, the “CHP” was renamed as “Traditional Taiwan Pharmacopeia” on August 31, 2005.

The compilation of the second edition of the Traditional Taiwan Pharmacopoeia was initiated in 2010 and completed in December 2012. A total of 300 of TCM herb items were covered with 101 new items added and deletion of Granati Radicis Cortex due to seldom use. The “Traditional Taiwan Pharmacopeia” was then renamed as “Taiwan Herbal Pharmacopeia (THP)” and implemented on April 1, 2013. In 2016, the English CD version of the second edition of the THP was published and is helpful for promoting the internationalization of the THP. The English version provided a good reference for international experts, scholars and TCM pharmaceutical companies in exporting their products. It also strengthened the international influence of the THP.

In order to meet the advanced specifications applied to the quality control for medicine and to catch up with the innovative techniques involved in the detection methods accepted by the herbal pharmacopoeia in the world and the newly developing herbal regulations, the Ministry of Health and Welfare (MOHW) established the working groups for compilation of the third edition of the THP in 2015. Based on the objetives of editing works, four sub-committees, including, "Source origin research group", "Chemical specifications group", "TCM preparation group" and "Clinical Chinese medicine group" were formed. The " Source origin research group " was responsible for the application and the review of new items recruited from Taiwan's native species. It also reviewed the origin, the used part, Latin names, microscopic description of each current and new monograph. The "Chemical specifications group" was responsible for addition of new items of the processed Chinese herbs in the THP, the detection methods which have not yet been validated or established. The group also edited the General Rules of detection methods. The " TCM preparation group " was responsible for establishing the detection methods of the new TCM preparations, assay limit, and the limits of abnormal substances. The group also edited the General Rules of TCM preparations. The " Clinical Chinese medicine group " was responsible for reviewing and adding "Property and Flavor", “Meridians and Tropism”, and the toxicity classification of each monograph. The group was also responsible for reviewing the usage, dosage, precaution and warning of each monograph. To strengthen the local characteristics of the THP, meet the actual needs and the expectation of the related communities, the MOHW promulgated “The guidance of

incorporating Taiwan local or endemic species into the THP*"* in 2016 as reference to applicants and reviewers.

The 3rd edition of the THP was promulgated on November 2, 2018 and implemented on June 1, 2019. A total of 357 TCM herbs were covered, including 55 new herbal items and 2 items of the concentrated TCM preparations (Jiawei Xiaoyao San Concentrated Preparation and Scutellaria Root Concentrated Preparation). Six new species originated from Taiwan native species were added (*Dendrobium tosaense* Makino, *Bletilla formosana* (Hayata) Schltr., *Orthosiphon aristatus* (Blume) Miq., *Pteris multifida* Poir., *Litsea cubeba* (Lour.) Pers. and U*ncaria lanosa* Wall. var. *appendiculata* (Benth.) Ridsale). The "Property and Flavor " and "Meridians and Tropism" of all 355 TCM herbs, the General rules of concentrated TCM preparations and concentrated TCM tablets were added. Hydrargyri Oxydum Rubrum was added to the List of poisonous Chinese Materia Medica. The current limits of abnormal substances such as heavy metals, sulfur dioxide, pesticide residues, aflatoxin and microorganisms promulgated by the MOHW previously were added to their related monographs. To provide the international references, the English version of the 3rd THP was published in December 2019.

Following the editing methods of the 3rd THP, a total of 78 experts were invited to join the editorial work of the 4th THP. Dependent on their expertise, four sub-committees, including, "Source origin research group", "Chemical specifications group", "TCM preparation group" and "Clinical Chinese medicine group" were formed.

Following the current plant nomenclature systems, such as The Plant List (TPL), The International Plant Names Index (IPNI), Plants of the World Online (POWO), Medicinal Plant Names Services (MPNS), taxonomic research, and the priority rules etc., the "Source origin research group" revised some Latin genus names and species names of the plant species. A comparison table of the new and old Latin names was provided. Meanwhile, it elaborated the principles for adding and deleting the monograph or the selected species and explored the techniques applied to the harvest and the process of herbal medicines. Summarily, the official name (Latin names of the crude drugs) of 53 TCM herbs and 47 Latin names of the plant species were revised and descriptions of the 30 new decoction pieces were added. Additionally, the sources and descriptions of 3 new items (Lonicerae Flos, Schisandrae Sphenantherae Fructus and Puerariae Thomsonii Radix) were also added.

The "Chemical specifications group" revised the General rules, the detection specifications for TCM herbs and decoction pieces. Besides coping with the code numbers of General rules in the Taiwan Pharmacopeia. Several General rules were merged together as considering the necessity, for instances, the merged Determination of extractives (6011), Microscopic identification (6503), and Heavy metal determination (6301), etc. The Code number of Column (8999) and three test solutions (artificial gastric juice, etc.) described in the General rules were added. In the part of TCM herb monographs, 41 TLC methods, 48 HPLC methods, 13 impurities limits, and other requirements were revised. The specification of 30 decoction pieces and the calculation equations

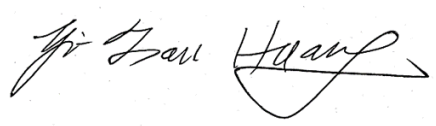
of the assay described in 214 TCM monographs were added. The lack of flow rate and temperature used in the assay test for some TCM item were supplemented and the type of the chosen column is expressed in code numbers.

The "TCM preparation group" compiled the specifications of concentrated TCM preparations. The preparations that are used in large quantity will be incorporated in the priority order. Seven concentrated TCM preparations were added in the 4th THP including 3 compound formula concentrated TCM preparations (Siaocinglong Tang Concentrated Preparation, Bansia Xiesin Tang Concentrated Preparation and Ge Gen Tang Concentrated Preparation) and 4 monocomponent herb concentrated TCM preparations (Rhubarb Concentrated Preparation, Liquorice Root and Rhizome Concentrated Preparation, Corydalis Tuber Concentrated Preparation and Puerariae Radix Concentrated Preparation). For concentrated TCM preparations, the identification of the ingredient herbs and the assays methods and limits were confirmed by three accredited laboratories. The limits of the markers and the pharmacopeia specifications for the concentrated TCM Preparations were established based on the levels of the analytical markers determined by reference to the analytical results obtained from the selected samples, including the standard decoctions and 10 batches of commercial products.

The "Clinical Chinese medicine group" revised the text of usage, property and flavor, meridians and tropism, function, dosage, precaution and warning described in each individual monograph of TCM herbs, decoction pieces and concentrated TCM preparations. The "eighteen antagonisms" of the herbs were added to the section of precaution and warning. Plumbum Rubrum (for external use) was added to the "List of poisonous Chinese Materia Medica". This group also worked with the "Source origin research group" to set up general principles for adding and deleting items from the content of theTHP. Following the international trend and due to seldom use, three TCM herb items were deleted (Trogopterori Faeces, Malvae Fructus and Photiniae Folium).

Looking back to the first edition of the THP which was published in 2004, 4 editions had been published. Of them, the number of collected items had been increased up to 394. In the 4th THP, the range of collected items covered from commonly used TCM herbs, decoction pieces to concentrated TCM preparations, provides a guideline for the quality control of TCM herbs and herbal preparations to TCM communities. The MOHW will continue to perfact the THP through reviewing the compilation mechanism of the THP, with scientific and systematic methods to establish a sound quality control specification of TCM herbs and herbal preparations, scrolling inspection of the specification and detection methods exploited to TCM. Through confirmation with repetitive experiments, the feasibility of the developed methods is assured. We will also consult specifications and detection methods of other herbal pharmacopeias in the world and incorporated the useful parts into the the latest edition of the THP. In addition, we will also take initiatives to attend the international herbal pharmacopeia meetings to understand the international trends of herbal pharmacopeia and the quality controls of TCM herbs, and collect the newest editing information of the international herbal pharmacopeias, providing references for the compilation of the THP. It will also help to increase the visibility of quality control of TCM in

Taiwan and will help to promote the internationalization of Chinese medicine and the development of TCM industry.



Yi-Tsau Huang (黃怡超)
Director-General
Department of Chinese Medicine and Pharmacy
Ministry of Health and Welfare

List of Editorial Members of Taiwan Herbal Pharmacopeia, Fourth Edition

Editor in Chief：Jui-Yuan Hsueh (薛瑞元)

Deputy Editor in Chief：Chung-Liang Shih (石崇良)、Yi-Tsau Huang (黃怡超)、Yi-Chang Su (蘇奕彰)

Origin of Source group 中藥基原小組

Chairperson：Chieh-Fu Chen (陳介甫)

Vice chairman：Ih-Sheng Chen (陳益昇)

Members：Chia-Jung Lee (李佳蓉)、Wei-Chu Li (李威著)、Ya-Ching Shen (沈雅敬)、Fang-Rong Chang (張芳榮)、Hsun-Shuo Chang (張訓碩)、Wen-Liang Chang (張溫良)、Hsien-Chang Chang (張憲昌)、Wen-Li Liang (梁文俐)、Wu-Chang Chuang (莊武璋)、Chao-Lin Kuo (郭昭麟)、Yao-Haur Kuo (郭曜豪)、Lih-Geeng Chen (陳立耿)、Ping-Chi Chen (陳聘琪)、Fu-An Chen (陳福安)、Qi-Quan Huang (黃奇全)、Jeng-Jer Yang (楊政哲)、I-Min Liu (劉怡旻)、Shorong-Shii Liou (劉崇喜)、Mei-Kuang Lu (盧美光)、Po-Chow Hsieh (謝伯舟)。

TCM Assay group 中藥檢驗規格小組

Chairperson：Yuan-Shiun Chang (張永勳)

Vice chairman：Chi-Fang Lo (羅吉方)

Members：Shu-Tuan Chiang (江淑端)、Yu-Ling Ho (何玉鈴)、Tian-Shung Wu (吳天賞)、Yang-Chang Wu (吳永昌)、Wei-Chu Li (李威著)、Mei-Hsien Lee (李美賢)、Jer-Huei Lin (林哲輝)、Ya-Tze Lin (林雅姿)、Lie-Chwen Lin (林麗純)、I-Tsai Ma (馬逸才)、Chun-Pin Kao (高駿彬)、Wen-Te Chang (張文德)、Fang-Rong Chang (張芳榮)、Chia-Chuan Chang (張嘉銓)、Shiow-Chyn Huang (黃秀琴)、Yan-Hao Huang (黃彥豪)、Yu-Ling Huang (黃鈺玲)、Ming-Jaw Don (董明兆)、Hsien-Chang Tsai (蔡憲璋)、Shang-Chih Lai (賴尚志)、Tsai-Pei Hsieh (謝采蓓)、Mei-Yin Chien (簡美英)。

TCM Preparation group 中藥製劑小組

Chairperson：Lie-Chwen Lin (林麗純)

Vice chairman：Jer-Huei Lin (林哲輝)

Members：Ching-Chiung Wang (王靜瓊)、Shu-Tuan Chiang (江淑端)、Chien-Chih Yu (余建志)、Yu-Tse Wu (吳育澤)、Chien-Ta Wu (吳建達)、Lung-Yuan Wu (吳龍源)、Liang-Ying Chou (周良穎)、Yu-Chi Hou (侯鈺琪)、Wen-Te Chang (張文德)、Wu-Chang Chuang (莊武璋)、Yao-Haur Kuo (郭曜豪)、Ming-Chu Chen (陳明珠)、Chao-Jung Chen (陳昭蓉)、Wen-Huang Peng (彭文煌)、Rong-Chi Yang (楊榮季)、Jen-Chieh Tsai (蔡仁傑)、Tung-Hu Tsai (蔡東湖)、Hsien-Chang Tsai (蔡憲璋)、Chen-Hung Cheng (鄭振鴻)、Po-Chow Hsieh (謝伯舟)、Mei-Yin Chien (簡美英)、Chi-Fang Lo (羅吉方)。

Clinical Chinese Medicine group 中醫臨床小組

Chairperson：Jaung-Geng Lin (林昭庚)

Vice chairman：Kuo-Tong Liou (劉國同)

Members：Tsung-Hsiu Wu (吳宗修)、Lung-Yuan Wu (吳龍源)、I-Hsin Lin (林宜信)、Jui-Shan Lin (林睿珊)、Chun-Chuan Shih (施純全)、Shih-Liang Chang (張世良)、Tung-Ti Chang (張東廸)、Hen-Hong Chang (張恒鴻)、Ching-Yao Chang (張景堯)、Chung-Hua Hsu (許中華)、Fang-Pey Chen (陳方佩)、Wang-Chuan Chen (陳旺全)、Ming-Chu Chen (陳明珠)、Hui-ling Tseng (曾卉菱)、Wan-Ru You (游婉如)、Sien-Hung Yang (楊賢鴻)、Chin-Chuan Tsai (蔡金川)、Chen-Hung Cheng (鄭振鴻)、Hui-Zhen Lai (賴慧真)、Ming-Chin Ku (顧明津)。

(In stroke order of Chinese last names)

CONTENTS

Preface ..... **(III)**

History of Taiwan Herbal Pharmacopeia ..... **(V)**

List of Editorial Members ..... **(IX)**

General Notices ..... **(XIII)**

General Rules Lists ..... **(i)**

General Rules ..... **(1)**

Official Names Lists ..... **i**

Monographs **1**

Indexes **443**

Reagents and Test Solutions **445**

Official Names **448**

Chinese Names **454**

Names in Tongyong Pinyin Form **458**

Names in Hanyu Pinyin Form **464**

English Names **470**

Latin names **476**

General Notices

General Notices

Name: The full title of this publication is Taiwan Herbal Pharmacopeia THP. After the pharmacopeia is official promulgated, the text of Taiwan Herbal Pharmacopeia refers to this third edition of Taiwan Herbal Pharmacopeia.

Content: Official text in THP includes general rules and monographs. The general rules include physical properties and the determination tests, identification tests, general determinations, general rules for preparations, identifications of crude drugs, determinations of assays (bioassays), reagents and test solutions, appliances and apparatus, a list of poisonous Chinese herbs and 200 standard Traditional Chinese Medicine (TCM) formulas. The monographs list the statutory crude drugs and concentrated preparations of traditional Chinese medicines used for the purpose of prevention and treatment.

Statutory crude drugs:

1. All identification tests, description, Impurities and other requirementss and assays of all crude drugs recorded in the monographs should comply with phamacopeia standards before manufacturing, selling, and dispensing for medical treatment and health care.
2. The Chinese materia medica is derived from natural sources and contained in the Pharmacopoeia, medical classics or other national, pharmacopoeias or their supplements recognized by the Central Health Authority and used as medicine according to the theory of Chinese medicine. It includes minerals or specific species of plants or animals, processed products and decoction pieces.
3. Decoction pieces refers to the crude drugs that have been cleaned and trimmed or processed, and can be dispensed directly in the clinical prescriptions or preparations production. There are many cutting methods for TCM herbs. The traits of the commonly cut method decoction pieces were described in this pharmacopeia. The TCM community can use other traits and specifications according to their clinical or practical needs.
4. The processing of crude drugs refers to the different processing processes of the crude drugs according to Chinese medicine theory, the nature of drugs, and the needs in dispensing and the production of preparations.
5. The crude drugs recorded in the monographs are arranged in alphabetical order of official names. Indexes of Chinese names, names in Tongyong pinyin form, names in Hanyu pinyin form, English names and latin names are arranged in Chinese character strokes or alphabetical orders.
6. The monographs for each crude drug ~~is~~ are arranged in the following order:
   (1) Chinese name
   (2) Official name
   (3) Name in Tongyong pinyin /
   Names in Hanyu pinyin English name
   (4) Source
   (5) Limits of the content
   (6) Description
   (7) Identification
   (8) Impurities and other requirementss
   (9) Assay
   (10) Storage
   (11) Usage
   (12) “Property and Flavor” and “Meridians and Tropism”
   (13) Effects
   (14) Dosage
   (15) Precaution and warning
7. Latin names, family names and the used parts of the botanical or zoological origin of the crude drugs cited in the monographs are recorded. Most of the family names of plants have -aceae as suffix except the following old descriptive family names to be used as synonyms as follows:
   (1) Compositae = Asteraceae
   (2) Umbelliferae = Apiaceae
   (3) Labiatae = Lamiaceae
   (4) Gramineae = Poaceae
   (5) Palmae = Arecaceae
   (6) Cruciferae = Brassicaceae
   (7) Leguminosae = Fabaceae
8. The original botanical names of TCM herbs included in the text of this pharmacopoeia are expressed in accordance with the principles of the latest international code of botanical nomenclature, taxonomic research, and the priority rules. The genus and species names are added and revised, and they are all listed in the monograph. The new scientific name comes first, and the old common latin names come after in parenthesis. A comparison table of the new and old latin names is given in the General Rules.
9. Unless otherwise directed, all crude drugs should be used in dried form. The crude drugs should be dried at the temperature below 60℃. Those crude drugs that contain volatile oils should be dried at the room temperature (as air drying as an example) to avoid volatilization of volatile oils.
10. Crude drugs should not be adulterated and contaminated with pathogenic microorganisms, insects, residues or secretions from other animals, or other analogous crude drug. More, the crude drugs are not adulterated with poisonous crude drugs. The color and odor of crude drugs should be intact. The crude drugs should not be viscous, molded, and spoiled.
11. All crude drugs should be stored with special care. To prevent insect breeding and extend the storage period, except bulky herbs, crude drugs can be preserved in well closed containers and fumigated with fumigants that are harmless to humans, easily volatile at room temperature, not affect the therapeutic effects of crude drugs and the results of tests. Crude drugs should not be sprayed with pesticides.

12. Unless otherwise directed, inorganic substances adhering on the crude drugs, after identified as acid-insoluble ash should not exceed 2% of the weight of crude drug.

Concentrated Traditional Chinese medicine preparations

1. All identification tests, assays, foreign matters and other tests of the concentrated traditional chinese medicine preparations recorded in the monographs should comply with the phamacopeia standards before manufacturing, selling, and dispensing for medical uses.
2. The concentrated traditional chinese medicine preparations recorded in the monographs are arranged in alphabetical order of official names. Indexes of Chinese names, names in Tongyong pinyin, names in Hanyu pinyin are arranged in Chinese character strokes or alphabetical orders.
3. The description of each monograph for traditional Chinese medicine compound concentrated preparations is arranged in the following order:
   (1) Chinese name
   (2) Name in Tongyong pinyin / Names in Hanyu pinyin
   (3) References
   (4) Compositions
   (5) Assay (content of marker component in a Daily dose)
   (6) Identification
   (7) Impurities and other requirementss
   (8) Assay
   (9) Effect
   (10) Indications
4. The description of each monograph for traditional Chinese medicine single herb concentrated preparations is arranged in the following order:
   (1) Chinese name
   (2) English name (Official name, Tongyong pinyin / Hanyu pinyin)
   (3) Sources
   (4) Content (Limits of the content of marker component in a gm sample)
   (5) Identification
   (6) Impurities and other requirementss
   (7) Assay
   (8) Effect
   (9) Precaution and warning

Units of measurement: The units of measurement employed in this pharmacopeia are the metric system which is a legal system of Republic of China. Metric units include meter, kilogram, liter, etc. Micrometer (μm) is one millionth (10^{-6}) of a meter; microgram (μg) is one millionth (10^{-6}) of a gram; microliter (μL) is one millionth of a liter. The symbols of units of measurement are listed as follows:

m: meter dm: decimeter
cm: centimeter mm: millimeter
μm: micrometer (μm = 10^{-6} m; millionth meter)
nm: nanometer (nm = 10^{-9} m; millionth millimeter)
kg: kilogram g: gram mg: milligram
μg: microgram (μg = 10^{-6} g; millionth gram)
L: liter mL: milliliter
μL: microliter (10^{-6} L; millionth liter)

Concentration and characters of solution:

1. The symbol "%" is used for the expression of weight percentage. % (w/w) expresses the grams of a solute in 100 g of solution. % (w/v) expresses the grams of a solute in 100 mL of solution. % (v/v) expresses the milliliters of a solute in 100 mL of solution.
2. The quantity in each clause, unless otherwise specified, solid refers to weight and liquid refers to volume. "ppm" is the abbreviation of part per million, refers to the impurities proportion by weight.
3. All unspecified water in the text are aqueous solution.
4. The expression "(1 in 10)" or "(1 in 20)" stated under the solution refers to dissolve 1.0 g or 1.0 mL of solute or liquid in sufficient amount of solvents to make up to 10 mL or 20 mL. For the liquid mixture, an expression such as "(10:20:30)" means the respective parts of volume ratio.
5. Unless otherwise directed, all acidity or alkalinity tests of solutions refer to the results of litmus paper tests.

Temperature: The unit of specified temperature in this pharmacopoeia is Celsius (℃). Unless otherwise directed, the temperature is 25℃ when measuring the volumes. Normal temperature refers to 15~30℃, slightly warm refers to 30~40℃. If there has no specified on the water bath temperature, the temperature is same as boiled water (about 100℃).

Constant weight: Constant weight refers to the drying or ignition of 1.0 g substance or material in two consecutive weights with a difference not exceeding 0.5 mg. The second and subsequent weighing is made after an additional hour of drying or after another 15 minutes of ignition.

Description: Describe the form of general characters, tissues and powders of crude drugs.

Identifications: Besides all crude drugs identification methods listed in this pharmacopeia, if necessary, other methods not mentioned in this pharmacopeia can also be applied.

Reference drugs and reference standards: Reference drugs and reference standard refers to the standard materials used for identifications and assays. All standard materials should include instruction, batch number, usage, expiry date, storage condition and content.

Assays, Impurities and other requirementss:

1. All assays, Impurities and other requirementss listed in this pharmacopeia are official and can be used to set the standards of the crude drugs. If there have

other methods whose accuracy is same as the methods described in the pharmanopeia, it is available as alternative methods. In case of legal disputes, the methods from pharmacopoeia should be priority.

2. For the limit requirement, a statement "not less than 100.0%" refers to 100.0% and above. A statement "95.0%~105.0%" refers to range between 95.0%~105.0%. In data of test results, the one after the decimal point shall prevail, and the second digit shall be rounded off and the numerical value shall be revised.
3. All assays should be calculated on the dry weight basis.
4. The sample quantities for assays, Impurities and other requirementss must be measured and weighed accurately according to the rules. The measuring quantities can be little different from the specified, but the difference should not exceed ±10%.
5. "Impurities" refers to foreign matter adulterated with herbal drugs during the processing. If the general impurity check methods are employed, only the maximum allowable limit is given, otherwise, both limit and impurity check methods should be specified. All impurities which should not be adulterated can't be contained in the drugs. Impurities of crude drugs, that are not specified in this Pharmacopeia or other international pharmacopeia, should not exceed 5%
6. Please refer to the general notice of the Taiwan Pharmacopeia for further information.

Storage: Storage method in this pharmacopeia refers to the basic conditions for storage and preservation of crude drugs.

1. Containers are the vessels which storage the crude drugs and contact with the crude drugs directly. The containers should not affect the quality of the contents.
2. "Well closed container" refers to containers that protects the contents from loss and adulterating with other solid matters during processing and storage.
3. "Cool place" refers to the storage temperature below 20℃. "Cold place" refers to the storage temperature between 2℃~8℃. Unless otherwise directed, the storage temperature refers to room temperature.

Usage: According to clinical medicine in TCM, the major grouped indications of the crude drugs are given. It is only provided as a reference. The detailed clinical efficacy and multiple usages are not listed.

"Property and flavor" and "Meridians Tropism": Based on the theory of traditional Chinese medicine and the clinical efficacy of traditional Chinese medicine, it is an overview of the efficacy of crude drugs. The crude drugs contained in the list of poisonous Chinese materia medica, toxicity is indicated in the Property and Flavor of crude drugs as a reference for clinical use.

Effects: Refer to the summary of TCM herbs based on the theory of traditional Chinese medicine and clinical experience, which ~~is~~ are regarded as an extension of the classification of uses.~~;~~ Chinese medicine preparations are described in the forms of efficacy and indications. This content is used as a reference for clinical practice.

Administration and Dosage: Unless otherwise noted, usage refers to the oral administration of decoctions. Dosage refers to the usual daily dose for adults, and the dose for specific purposes is not listed.

Precautions: Refer to the major contraindications and adverse reactions (including the eighteenth antinomies recorded in the traditional Chinese medicine books, etc., meaning that should be used with caution in clinical practice), the common contraindications are not listed.

General Rules

General Rules of Taiwan Herbal Pharmacopeia

GENERAL RULES OF TAIWAN HERBAL PHARMACOPEIA I

I. PHYSICAL PROPERTIES AND DETERMINATION TESTS 1

(1001) Congealing Temperature 1
(1003) Distilling Range 1
(1005) Melting Temperature 2
(1177) Fineness Degree of Powders 3
(1197) Spectrophotometry 4
(1202) Thin Layer Chromatographic Identification Test 6
(1621) Chromatography 6
(1733) Loss on Drying 11
(1781) Optical Rotation 11
(1793) pH Value 11
(1831) Refractive Index 14
(1841) Specific Gravity 14
(1921) Water Determination 15

II. IDENTIFICATION TESTS 18

(2191) General Identification Tests 18
(2211) Arsenic (As) 20
(2221) Chlorides and Sulfates 21
(2251) Lead (Pb) 22
(2281) Residue on Ignition 23
(2525) Sulfur Dioxide 23

III. GENERAL DETERMINATIONS 26

(3061) Microbiological Examination of Nonsterile Products 26
(3063) Tests for Specified Microorganisms 31

IV. GENERAL REQUIREMENTS AND RULES FOR PREPARATIONS 37

(4152) Tablet 37
(4161) Concentrated Traditional Chinese Medicine Preparation 39
(4163) Concentrated Traditional Chinese Medicine Tablet 39
(4165) Concentrated Traditional Chinese Medicine Pill 40
(4216) Test for Tablet Friability 41
(4218) Tablet Breaking Force 41
(4701) Disintegration Test 44

V. DETERMINATIONS OF BIOLOGICAL PRODUCTS 45

VI. IDENTIFICATIONS OF CRUDE DRUGS 45

(6001) Sampling 45
(6003) Processing 46
(6005) Determination of Foreign Matter 46
(6007) Determination of Ash 46
(6009) Determination of Water Content 46
(6011) Determination of Extractives 47
(6013) Determination of Volatile Oil 47
(6015) Determination of Loss on Drying 48
(6301) Determination of Heavy Metals 48
(6303) Determination of Residue of Sulfur Dioxide 52
(6305) Determination of Pesticides Residues 53
(6307) Determination of Aflatoxins (Mycotoxins) 54
(6501) Determination of Swelling Capacity 54
(6503) Microscopic Identification 55

VII. REAGENTS AND TEST SOLUTIONS 60

(7001) Reagents 60
(7003) Test Solutions (TS) 91
(7005) Indicators 95
(7007) Test Paper 95
(7009) Colorimetric Solutions (CS) 95
(7013) Volumetric Solutions (VS) 95

VIII OTHERS 98

(8001) Relative Density of Ethanol 98
(8999) Code Number of Chromatographic Column Packings 102

IX. A LIST OF POISONOUS CHINESE MATERIA MEDICA 103

X. 200 STANDARD TCM FORMULAS 104

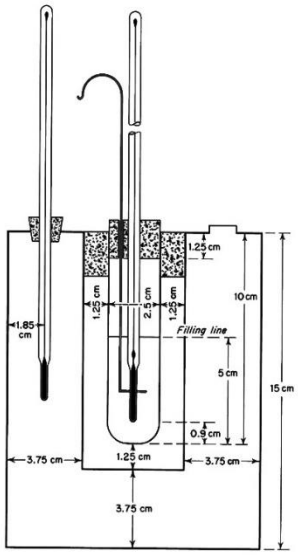
XI. CORRECTION TABLE OF ORIGINAL BOTANICAL NAMES OF CHINESE HERBS 167

I. Physical Properties and Determination Tests

(1001) Congealing Temperature

The temperature at which a substance transfers from the liquid to the solid state upon cooling is called the congealing temperature. All unspecified method in the monographs refers to the method described below.

Apparatus: Set an apparatus similar to illustrated, in which the container for the substance is a 2.5 × 10 cm test tube, with a suitable, short-range thermometer suspended in the center, and a wire stirrer, about 30 cm long, bent at its lower end into a horizontal loop. The specimen container is supported, by means of a cork, in a suitable water-tight cylinder about 5 cm in internal diameter and 11 cm in length. The cylinder, in turn, is supported in a suitable bath sufficient to provide not less than a 3.7 cm layer surrounding the sides and bottom of the cylinder. The outside bath is with a suitable thermometer.



Congealing Temperature Apparatus

Procedure: Melt solid substances at a temperature not exceeding 20℃ above its expected congealing point, and pour into the test tube to a height about 5 cm. Immerse the bulb of the test tube thermometer in the halfway between the top and bottom of the specimen in the test tube. Fill the bath to about 1.2 cm from the top to the surface of the liquid, the temperature is 4~5℃ below the expected congealing point. When the test specimen has cooled to about 5℃ above its expected congealing point, adjust the temperature of bath to 7~8℃ below the expected congealing point. Stir the specimen continuously by moving the loop up and down with the stirrer, at a regular rate of 20 complete cycles per minute, stir continuously till the end of measurement. Record the reading of the test tube thermometer every 30 seconds. Continue stirring only as long as the temperature is gradually falling, stopping when the temperature becomes constant or starts to rise slightly. Continue recording the temperature in the test tube every 30 seconds after the temperature begins to fall again after remaining constant. Supercooling may cause deviation from the normal pattern of temperature changes. If it occurs, repeat the test by introducing small solid particles of the test specimen on the temperature approaches 1℃ intervals as the expected congealing point, induce the test specimen congealing. When the temperature starts to fall from the constant, record the temperature of the test specimen every 30 seconds for 3 minutes, if the difference between four consecutive readings is less than 0.2℃, take the average of the four consecutive readings as congealing temperature.

In case the substance is a liquid at room temperature, carry out the determination using a bath temperature about 10~15℃ below the expected congealing point. Congelation may be induced by rubbing the inner walls of the test tube with the thermometer, or by introducing a small fragment of the previously congealed substance. Stop stirring once the substance starts to congeal and record the temperature in the test tube every 5~10 seconds until it reaches the highest temperature and remain constant for 1 minute. The constant temperature recorded is the congealing temperature of the substance.

(1003) Distilling Range

The boiling point is the certain temperature when the vapor pressure of a liquid is equal to 760 mmHg. To determine the distilling range of temperatures within which an official liquid distills, or the percentage of the material that distills between two specified temperatures. The lower limit of the range is the temperature indicated by the thermometer when the first drop of condensate leaves the tip of the condenser. The upper limit is the dry point, the temperature at which the last drop of liquid evaporates from the lowest point in the distillation flask, without consider to any liquid remaining on the side of the flask. Two ways of distilling range determination described below.

Method I: Unless otherwise directed, this method is applied to the liquid with a boiling range of 5℃ or less.

Apparatus: Take the distilling flask which is 50~60-mL capacity and 100~120 mm total length, and 14~16 mm inside diameter, place in the center hole of an asbestos plate, which is in the form of a square with sides of 120~150 mm, 3~5 mm in thickness, and with a perforation 30 mm in diameter in the center, the side of the bottle must be fitted to the hole tightly, put on the tripod. A side-arm is on the midway of the neck, it is 100~120 mm length and 4~5 mm in internal diameter, which forms an angle about 70~75° by the side-arm and the neck. The thermometer is located in the center of the neck, the bulb should be match the position in the middle of the side tube open, and the side-arm of distilling flask connected with a straight glass condenser, with a water jacket about 400~600 mm in length, the top of the jacket to the neck of the bottle is about 180~250 mm in length. For liquid which distilling range is below 80℃, connect the condenser and the

receiver through a delivery tube, insert another delivery tube into stopper of the receiver, which has a small hole to let the air discharge. The receiver is cooled by cool water during distillation.

Procedure: Pour 25 mL of test specimen into the distillation flask, add several zeolites, insert the thermometer and apply heat, regulate the heat power so that the distillation is at a rate of 3~5 mL of distillate per minute, collecting the distillate in the receiver. Record the temperature when the first drop of distillate falls from the condenser, and the last drop of liquid evaporates from the bottom of the flask or when the specified percentage of the test specimen has distilled over. Correct the observed temperature readings from any variation in the atmospheric pressure, the normal atmospheric pressure is 760 mmHg, by reducing or adding 0.1℃ every 2.7 mmHg increase or decrease of the pressure. If necessary, use auxiliary thermometer, corrected errors by the following formula.

$$0.00015\times N\,(T—t)$$

N: degree of the mercury column above the bottle stopper.
T: temperature of distillation.
t: temperature of auxiliary thermometer.

The mercury ball of auxiliary thermometer should be at the middle part between the highest position of boiling temperature and the bottom of the cork. Add the calibrated value with the measured temperature, and get the calibration temperature.

Method II: The method is applied to the liquid with boiling range above 5℃.

Apparatus: Use apparatus similar to that specified for Method Ⅰ, except that the distilling flask is of 200-mL capacity, and the internal diameter of the neck is 18~24 mm and the side-arm internal diameter is 5~6 mm, an asbestos plate which has a perforation of 50 mm in diameter, a cork stopper of the side-arm which inserts condenser is 25~35 mm in the diameter.

Procedure: Take 100 mL of test specimen by 100-mL cylinder, pour it into the distillation flask and measure the temperature. The cylinder does not need to clean and can be used as receiver. If the distillation temperature of the test specimen is under 80℃, it should be cooled to 20~25℃, and measure the volume. Collect the distillate at specified temperature, adjust the temperature to be the same as test solution, and measure the volume. Read the pressure from barometer and correct the temperature. If necessary, apply the auxiliary thermometer to correct the temperature with the formula.

(1005) Melting Temperature

The melting temperature of a solid is defined as the temperature the solid coalesces and is completely melted. There are different melting temperatures for different pure substances. Three classes of the determination to determine melting range or temperature are given herein, varying in accordance with the nature of the substance.

Class I: For pulverizable solid substances.

Apparatus:

1. One of the hard glass containers described below
   (1) A glass container with one end open and the other end circled to a center ring
   (2) A glass container with a stirring device
   (3) Other suitable containers
2. An accurate thermometer
3. One of the heating bath described below
   (1) Light liquid paraffin
   (2) Water
   (3) Clear silicone oil with low viscosity (50~100 mm^2/s)
   (4) Other suitable heat transfer liquid
4. A hard capillary glass tube with one end sealed is about 10 cm long and 0.8~1.2 mm in internal. The thickness of walls is 0.2~0.3 mm.
5. The heat may be supplied by an open flame or electricity.

Procedure: unless otherwise directed, follow the procedure below. Mill the substance to a very fine powder, render it anhydrous when it contains water of hydration by drying it at the temperature specified in the monographs, when the substance contains no water of hydration, dried it in a suitable desiccator for not less than 16 hours.

Place a sufficient amount of the dry powder to form a column in the bottom of the tube 2.5~3.5 mm high when packed down as closely as possible by moderately tapping on a solid surface. Attach the test tube to the thermometer by wetting both with a drop of the liquid from the bath or fastening by platinum wires, and adjust its height so that the position of the test specimen in the test tube is at the middle of the thermometer bulb. Heat the bath until the temperature is about 10℃ below the expected melting point. Place the thermometer in the bath, and continue the heating, with constant stirring, the temperature rise at a rate about 3℃ per minute. When the temperature is about 3℃ below the expected melting, adjust the temperature rises at a rate of about 1℃ per minute. Continue heating until melting is completed. The temperature at which the test specimen is observed to collapse against the side of the tube at any point is defined as the beginning of melting, and the temperature at which the test substance becomes liquid completely is defined as the end of melting or the "melting point." The two temperatures are within the limits of the melting temperature.

Class II: For substances are not easy to pulverizable such as fats, fatty acids or waxes. Water is selected as the bath fluid.

Procedure: Melt the material to be tested at as low temperature as possible, and draw it into a capillary tube, which is open at both ends, to a depth about 10 mm. Cool

the charged tube at 10℃, or lower, for 24 hours, or in contact with ice for at least 2 hours. Then attach the tube to the thermometer by suitable means, adjust it in a water bath so that the upper edge of the material is 10 mm below the water level, and heat as directed of Class Ⅰ, within 5℃ of the expected melting temperature, to regulate the rate of temperature rise to 0.5~1.0℃ per minute. The temperature at which the material is observed to rise in the capillary tube is the melting temperature.

Class III: For soft paraffin.

Procedure: Melt a quantity of the test substance slowly, while stirring, until it reaches the temperature of 90~92℃. Remove the source of the heat and allow the molten substance to cool to the temperature of 8~10℃ above the expected melting point. Chill the bulb of a suitable thermometer to 5℃, wipe it dry and dip it into the molten substance that approximately the half of the bulb is submerged while it is still cold. Withdraw the thermometer immediately, and hold it vertically away from the heat, until the wax surface dulls, then dip it into a water bath whose temperature is not higher than 16℃ for 5 minutes. Fix the thermometer securely in the test tube by a cork, the lower point is 15 mm above the bottom of the test tube. Suspend the test tube in a water bath adjusted to about 16℃, and raise the temperature of the bath at the rate of 2℃ per minute to 30℃, then change to a rate of 1℃ per minute, and record the temperature at which the first drop of melted substance leaves the thermometer. Repeat the determination twice on a freshly melted portion of the test substance. If the variation of three determinations is less than 1℃, take the average of the three as the melting temperature. If the variation of three determinations is 1℃ or greater than 1℃, make two additional determinations, and take the average of five determinations as the melting temperature.

(1177) Fineness Degree of Powders

The fineness degree of powders in the pharmacopeia is represented as sieve number. For the determination of fineness degree of powders and the specifications of standard test sieve are required in the following: Using standard test sieves in the determination of fineness degree of powders is a practical method, but this method cannot measure the size range of powders. The fineness degree of drug powders is related to the absorption of drug rapid and complete or not in the gastrointestinal tract, which has a direct impact on the efficacy. This method is not suitable to powder marked less than 100 μ, use other method to measure the fineness degree of powders is more convenient.

When separating the powders with sieve, the efficiency and speed of this method are highly related to the amount of retained powder on the sieve. If the thickness of retained powder is more than 6~8 particles, then the efficiency is reduced significantly.

Standard test sieves: Standard test sieves is braided with metal or other wire of appropriate substances. Brass, bronze, stainless steel and other suitable materials may be used as the material for sieve, those metals are not allowed to coat or electroplate with other substances or metals. The sieve number is determined by the number of sieve holes between the parallel sieves lines which distance are 2.54 cm. The following table records the sieve number of each standard test sieve and specification of pore.

Powders of herbal drugs: The requirements of fineness degree of powders in the pharmacopeia, divide into five species, Very coarse (No. 8), Coarse (No.20), Medium (No. 40), Fine (No. 60) and Ultra fine (No. 80). When a crude drug is specified as certain degree powders, unless otherwise directed, no part can be discarded during milling or sieving procedure. Residue remains on a sieve during the process, should not exceed 5% of the original amount. The residue can be added into the next batch of same drugs, but the quantity should not exceed 5%.

The requirement for fineness degree of crude drug powder as follows:

1. Very coarse (No. 8): All particles should pass through No. 8 sieve, but not more than 20% pass through No. 60 sieve.
2. Coarse (No. 20): All particles should pass through No. 20 sieve, but not more than 40% pass through No. 60 sieve.
3. Medium (No. 40): All particles should pass through No. 40 sieve, but not more than 40% pass through No. 80 sieve.
4. Fine (No. 60): All particles should pass through No. 60 sieve, but not more than 40% pass through No. 100 sieve.
5. Ultra fine (No. 80): All particles should pass through No. 80 sieve.

The chemical powder: The requirements for fineness degree of chemical powders in the pharmacopeia divided into four species, requirement as follows:

1. Coarse (No. 20): All particles should pass through No. 20 sieve, but not more than 60% pass through No. 40 sieve.
2. Medium (No. 40): All particles should pass through No. 40 sieve, but not more than 60% pass through No. 60 sieve.
3. Fine (No. 80): All particles should pass through No. 80 sieve
4. Ultra fine (No. 120): All particles should pass through No. 120 sieve.

Determination for the uniformity of powder:

The uniformity of drug powders or chemical powders are measured as follows, use the standard test sieves as described above. Avoid shaking too long for increasing the fineness of the powder during the test.

1. Determination of very coarse, coarse and medium powders: Place 25~100.0 g of test specimen in a suitable standard test sieve, the bottom of sieve tightly connect with a suitable receiver, the top of sieve tightly stoppered. Rotate and shake standard

sieve by the horizontal direction, and often tap the sieve on the hard plane. The sieving requires at least 20 minutes, or no more powders pass through the standard test sieve. Weigh the powder in a receiver and powder remains in the sieve separately.

2. Determination of fine and ultra-fine powders: The method is as above, the maximum amount of test specimen is not more than 25.0 g, rotate the standard test sieve at least 30 minutes, or no powder passes through standard test sieve. If the powder contains oil or other substance which makes obstruction, carefully flick sieve to make it disintegrating. During sieving, no more grinding to avoid further fineness of the powder. It is able to use motorized sifter device in determination for the uniformity of drug powders or chemical powders. The method refers to that place the standard test sieve in a motorized sifter device, shake in a suitable rate. This method gives a greater effectivity than hand- sifter method.

(1197) Spectrophotometry

Spectrophotometry is the determination of the monochromatic radiation absorption by the substance. The monochromatic radiation obtained from the spectrophotometer refers to the electromagnetic radiation in the specified narrow wavelength range. The electromagnetic radiation with different wavelength includes: UV light (185~380 nm), visible light (380~780 nm), the NIR (780~3,000 nm) and the IR (3~40 μm).

When monochromatic radiation passes through a medium, the intensity of the transmitted light is determined by the intensity of the incident light, wavelength, characteristic of light absorbing molecule or ion, concentration, and optical path (the distance of the radiation pass through the medium). The ratio of the intensity of the transmitted radiation (I) and the intensity of the incident radiation (I_0) is called transmittance (T). The logarithm to base 10 of the reciprocal of the transmittance is called absorbance (A).

$$T=\frac{I}{I_0} \qquad A=-\log T$$

For many pharmaceutical substances, determine the absorbance in the wavelength between UV and visible light regions, the solutions are often be observed in 1 cm cells, the concentrations about 10 μg per mL of the specimen can produce the appropriate absorbance (0.2~0.8), in the IR and NIR, the cell lengths is 0.01~3 mm, concentration is 1~10 mg per mL, sometimes up to 100 mg per mL to produce sufficient absorption.

I. Ultraviolet and visible spectrophotometry

For many pharmaceutical substances, measurements made in the UV and visible light regions have greater sensitivity than in the NIR and IR. By Beer's law, if the wavelength of monochromatic radiation and the solute which absorbs the radiation in medium are constant, the absorbance (A) is proportional to the optical path (l) and the concentration (c) of the substance in solution in accordance with the equation:

$$A=klc$$

k is called extinction coefficient, is a constant when the wavelength, the solvent, and the solute is regular, the value is determined by the optical path and the concentration.

1. a is defined as absorbance, a constant when the pathlength expressed in *cm* and the concentration expressed in *g/l*.

$$a=\frac{A}{lc}$$

2. $E_{1cm}^{1\%}$ is a constant when the path expressed in cm and the concentration of the substance expressed in *% (w/v)*.
3. ε is molar absorptivity when the optical path path expressed in cm and the concentration of the substance expressed in mol/L.

Applications:

1. Extinction coefficient is related to solutes chemical structure and wavelength. By Beer's Law, determine the absorbance of a test solution under various wavelengths of lights under the specified optical path and concentration, plot absorption spectrum, i.e. absorbance-wavelength, transmittance-wavelength, transmittance-wave number, the ratio by calculating two specified absorbance wavelength, or calculate the absorbance of test solution at specified wavelength. The data described above can compare with the result of reference standard solution. This method can be applied for identification of drugs and impurities.
2. Extinction coefficient is a constant at specified solute, solvent and wavelength. By Beer's Law, determine the absorbance of the solution with specified wavelength and the tube which has specified optical path. Calculate the concentration of solute in the solution. This method is used for quantitative analysis.
3. If Beer's Law does not apply, determine the absorbance of various concentrations of reference standard solution at specified wavelength, plot a reference standard curve. Determine the absorption of test solution as the method above, and calculate the concentration of test solution by the standard curve. This method can be applied for quantitative analysis.

Apparatus: The basic principle of the instrument is monochromatic light passing through a test specimen in suitable form, and measuring the intensity of the transmitted light. The apparatus contain light source, monochromator, cuvette and photometer or other measuring apparatus. The polychromatic radiation produced from light source passes through the splitter and the selector to obtain monochromatic light. When

monochromatic light passes through the cuvette filled with test specimen, part of the light energy is absorbed by the test solution, the transmittance or the absorbance is determined by photometer.

Before using, adjust the selector to formulate wavelength, turn off the shutter and then adjust the dark current to zero. Fill a cuvette with solvent as blank, place in the optical path, turn on the shutter, and adjust the absorbance to zero or the transmittance is 100%. Replace the blank with a cuvette filled with sample solution, place it in the optical path, and read the absorbance.

Before operating, the graduation of the instrument should be checked, calibrate if necessary. The calibration of the graduations of the spectrophotometer in UV-visible band can use the mercury-quartz lamp (arc tube mercury lamp) (253.7 nm, 302.25 nm, 313.16 nm, 365.48 nm, 404.66 nm, 435.83 nm), the hydrogen lamp (486.13 nm, 656.28 nm), didymium glass filter or holmium glass filter.

To calibrate the absorbance or the graduations of transmittance, use standard inorganic glass filter or a standard solution of known transmittances such as potassium chromate solution, potassium dichromate solution, etc.

Compare the absorbance of the test solution and the standard solution in quantification, and select the maximum absorption wavelength in the absorption spectrum. Recalibrate the instrument if the max absorption is different more than ±1 nm from the wavelength specified in the individual monograph.

Test preparation: Prepare the test solution as specified in the individual monograph. For standard solution and blank solution, use the same batch of solvent which does not contain impurities absorbing light on the test wavelength for test solution. Specified purity of solvent for spectrophotometer is preferred. Many solvents are suitable, including water, alcohols, chloroform, low molecular hydrocarbons, ethers, and dilute solution of strong acids and alkalis.

II. Infrared spectrophotometry

The absorption of the infrared light which passes through the test specimen changes with wavelength (wave-number), recorded in coordinate, which is called infrared absorption spectrum. The ordinate of the absorption spectrum is percentage of transmittance (or absorbance), the abscissa is wave-number (or wavelength).

The infrared absorption spectrum of the test specimen is different from the variety of chemical structures. The IR spectrum is unique to any given chemical compound except the optical isomers, which have identical spectra. Infrared spectrophotometry is applied to the identification of the compound and the determination of the quantity.

Apparatus: First follow the manual to adjust the spectrophotometer before using the double beam IR spectrophotometer. The reproducibility of the transmittance is no more than ±0.5%, the reproducibility of the wave-number near the 3000 cm^{-1} is no more than ±5 cm^{-1}, near the 1000 cm^{-1} is no more than ±1 cm^{-1}. The wave-number scale of an infrared spectrophotometer may be calibrated by using a polystyrene film at the absorption peaks 3060 cm^{-1}, 1601 cm^{-1}, 1029 cm^{-1}, and 907 cm^{-1}.

Procedure: The concentration of the test specimen which has the transmittance at the range 20%~80% is optimum. The usual cuvette substance is sodium chloride, potassium bromide, and thallium bromide/iodide. No solvent is completely transparent in the NIR and IR spectrum. Carbon tetrachloride is practically transparent from the wavelength of NIR to 6 μm. Carbon disulfide is the suitable solvent from the wavelength of NIR to 40 μm with the exception at the 4.2~5.0 μm and the 5.5~7.5 μm. An additional qualification for a suitable solvent is that it must not affect the material, of which the cuvette is made. When no suitable solvent is applicable, use other methods to prepare the test solution. For example, potassium bromide pellet method, solution method, paste method, film method, gas sampling method. When polymorphism compounds of one substance tested in the solid state shows variations in the IR spectra, then choose the suitable solvent, dissolve the test substance and the standard respectively, evaporate to dryness, and produce the residue. Test and get the absorption spectrum of the residues.

1. Potassium bromide pellet method: Powder 1~2 mg of a solid test specimen in an agate mortar, mix well and rapidly with 100~200 mg of potassium bromide which is for infrared spectrophotometry used, careful not to absorb moisture, and compress the mixture with a tablet machine, reduce the atmospheric pressure below 5 mmHg, apply the machine pressure at 5000~10000 kg/cm^2 for 5 to 8 minutes to make the pellet and test.
2. Solution method: Prepare test solution, unless otherwise directed in the monograph, use appropriate solvent to make the solutions with suitable concentrations (usually 5%~10% at 0.1 mm to 0.2 mm optical path). Fill in the cuvette, measure with solvent as blank.
3. Paste method: Powder 2~5 mg of a solid specimen in an agate mortar, triturate and mix the specimen with a small amount of liquid paraffin which is for infrared spectrophotometry used, produce a homogeneous paste. After spreading the paste on the center of an optical plate, place another optical plate on it and test, prevent the intrusion of air to the test specimen.
4. Liquid film method: Examine 1~2 drops of liquid specimen as a thin film held between two optical plates. If the thicker film is required, place aluminum foil between the two optical plates to make a thicker liquid film.
5. Film method: Examine the test specimen as a thin film or a thin film made by the directed in monograph.

Gas sampling method: Under the pressure directed in the monograph, put a test gas in a gas cell evacuated

previously, and examine its absorption spectrum. The path length of the gas cuvette is usually 5~10 cm, if necessary, may use 1 m of gas cuvette.

(1202) Thin Layer Chromatographic Identification Test

This test is an auxiliary test for the identification of thecrude drugs. The procedures are described below:
Prepare a sample solution as indicated in the monograph. Choose a suitable plate coated with a 0.25 mm layer of chromatographic silica gel containing fluorescent agent. Follow the method for Thin-Layer Chromatography (General rule 1621.3). Unless otherwise directed, apply 10 μL of each of the sample solution and the reference standard solution to the plate at about 2 cm from the origin, and use a solution of dichloromethane, methanol, and water (180:15:1) as the developing solvent, add the developing solvent system to one of the troughs of the developing chamber. Once the top of the solvent rise to about three-fourths from the origin, remove the plate from the developing chamber, mark the solvent front, and dry in the air. Unless otherwise directed, examine the plate under ultraviolet light at 254 nm. The spots in the chromatogram obtained from the sample solution correspond in R_f values to the spots in the chromatogram obtained with the reference standard solution.

(1621) Chromatography

Chromatography is the operation when the test specimen passes through a fixed and porous medium, and each component of the test specimen will undergo separation or purification. The chromatography is based on the different affinity of individual components to the stationary phase or on the different distribution coefficient of individual components between two phases, when the mobile phase pass through the stationary phase, different components are separated.

There are four common types of chromatography: column chromatography, paper chromatography, thin-layer chromatography, and gas chromatography. Paper and thin-layer chromatography are ordinarily more useful for purposes of identification, because of their convenience and simplicity, and only use a small amount of test specimen. Column chromatography offers a wider choice of absorbents and is useful for the separation of massive mixtures. Gas chromatography requires more elaborate apparatus, compressed gas, and adsorbents. Column chromatography and gas chromatography apply on quantitative and qualitative analysis.

R_f value of a test compound is the ratio of distance moved by the test specimen from the origin to distance moved by the mobile phase from the origin. Since R_f values may vary considerably due to different experimental condition, the identification of a compound is usually carried out by comparing the behavior of the test specimen with that reference substance under the same conditions. Under the same operation condition, there are three groups: same quantity of test specimen, standard, and mixture of the test specimen and the standard (1:1). If the test specimen is same as the standard, the color and R_f value of the three chromatographic spectrums is identical.

The spots obtained from chromatography can be localized as listed below:

1. If the spots are visible under visible or UV light, localize the spots.
2. After treating with visualization reagents, localize spots under visible or UV light. This method is usually applied in paper and thin-layer chromatography.
3. Localize spots contained radioactive elements with Geiger counter or radiographic technique.
4. Add segments of chromatogram into inoculated culture medium, and observe the effect of stimulation or inhibition on the growth of microorganism to localize the spots.

(1621.1) Column Chromatography

I. Adsorption column chromatography

Absorbent is added into a chromatographic column which has a stopcock under the tube, to form a compact column. Then test specimen is dissolved in a small amount of solvent, or mix solid specimen with a small amount of adsorbent and place on the top of column. First add small amount of solvent until it flow into the adsorbent completely. Continuously add solvent as developing solvent, flow through the column by gravity. The flow rate can be controlled by application of air pressure. Each substance with different characteristics toward absorbents and developing solvents progress down the column to separation and give chromatogram. Continuously add developing solvent with stronger solvency in the column to elute out the compounds separately or take out the column substance from the chromatographic column, separate the column substance as chromatogram directed, each portion is extracted with suitable solvent. The separated compounds in the eluate can be determined by titration, spectrophotometry, colorimetric methods, evaporating the solvent and etc.

II. Partition column chromatography

In partition chromatography, the solutes are partitioned into two immiscible liquids, when the mobile phase passes through the stationary phase, and the separations are based on the differences in partition coefficient of solutes. The apparatus and procedure are identical to adsorption column chromatography. The silica gel or cellulose, which with moisture, is used as stationary phase, and they are equal to the adsorbent of the adsorption column chromatography. For the solvent that is used for mobile phase, it is better to saturate it with the solvent that is used in stationary phase first.

(1621.2) Paper Chromatography

This method applied the principle of the partition column chromatography, the filter paper with suitable texture and thickness is used as an adsorbent. The stationary phase adsorbs on the surface of filter paper fiber, and the mobile phase pass through the filter paper.

I. Descending method

Apparatus: A tight chamber provided with inlets for adding solvent or for releasing internal pressure. The chamber is preferred to be constructed by glass, stainless steel, or porcelain. The design of chamber should be permitted observation of the progress of the chromatographic run without opening of the chamber. A rack of corrosion-resistant material is located about 5 cm beneath the top of the chamber. The rack serves as a support for solvent troughs and chromatographic sheets.

Filter paper: Chromatographic sheets are special filter paper with width not less than 25 mm and can be hanged in the solvent troughs, length approximately equal to the height of the chamber. Draw a fine line horizontally at a suitable distance from one end of the filter paper by pencil, when the sheet is suspended from the upper end of antisiphon rods, the paper resting in the trough and the lower portion hanging free into the chamber, the line is located about 2~3 cm below the rods.

Procedure: Follow as stated below unless otherwise directed:

The substances to be analyzed are dissolved in a suitable solvent. Spot the solution which is contained 1~20 μg of the test specimen on the starting line by micropipette or capillary. The sample spot should have a diameter within 6~10 mm and each spot is at least 3 cm apart from each other. Add small amounts of binary phase solvent in the bottom of the chamber. It is important to ensure that the portion of the sheet hanging below the rods is freely suspended in the chamber without touching the rack or the chamber walls or the fluid in the chamber. The chamber is sealed to allow the chamber reaching saturation with the solvent vapor. Any excess vapor is released if necessary. For large chambers, equilibration overnight may be necessary. The prepared mobile phase solvent is introduced into the trough through the inlet. The inlet is closed and the mobile phase solvent reaches to the desired distance on the paper. Precautions must be taken to prevent the solvent run down the sheet when opening the chamber and removing the chromatogram. The location of the solvent front is quickly marked, dry the sheets. Determine the color and the location of spots as described before, using the equation below to obtain the R_f value:

$$R_f = \frac{distance\ \ of\ starting\ line\ to\ substance\ spot\ center}{distance\ of\ starting\ line\ to\ solvet\ front}$$

II. Ascending method

The apparatus and procedures of this method are similar to the descending method. Put the developing solvent trough on the bottom of the developing chamber. The starting line is located 2~3 cm above the solvent trough and the test specimen does not immerse in solvent.

(1621.3) Thin-Layer Chromatography

The thin-layer chromatography is a separation technique that a uniform thin layer of adsorbent was applied to a glass or other supports. The separations may be achieved based on adsorption, partition, or the combination of both effects. Thin layer chromatography can be used for separation and identification of ingredients in the crude drugs. A visual comparison on the size or intensity of the spots may serve for quantitative estimation. Quantitative determinations are possible by means of densitometry, or the spots may be carefully removed from the plate, followed by extraction with a suitable solvent and use spectrophotometric measurement. For two-dimensional thin-layer chromatography, the developed plate is turned at a 90º angle and again chromatographed in another chamber equilibrated with a different solvent system.

Apparatus: The materials for thin-layer chromatography as following:

Plates: Plastic plates, flat glass plates or aluminum plates with suitable size, typically 5 cm × 20 cm or 20 cm × 20 cm.

Adsorbent: The adsorbent consists of tiny and finely divided adsorbent materials. It can be used alone or with binders such as 5 - 15% calcium sulfate hemihydrate. Fluorescing material may also be added to aid the visualization of spots that absorb UV light. The plates commonly used are silica gel G, silica gel F_{254}, high-performance silica gel F_{254}, silica gel H or silica gel HF_{254}, diatomaceous earth, diatomaceous earth G, aluminum oxide, aluminum oxide G, microcrystalline cellulose, microcrystalline cellulose F_{254}, polyamide film, or sodium carboxymethyl cellulose.

Spreader: It is used to spread adsorbent on glass plate. It can apply a uniform layer of adsorbent with desired thickness over the entire surface of the plate.

Developing chamber: Use a similar chamber as in paper chromatography with glass support.

UV light source: A suitable UV light source for observations with short (254 nm) and long (365 nm) wavelength.

Procedure: Unless otherwise indicated, follow the methods described below:

Clean and dry the glass plate. Specific quantity of the adsorbent and solvent are mixed by grinding or shaking vigorously for 30 seconds to the slurry. Spread a layer of slurry with thickness about 0.2~0.3 mm evenly on glass by a spreader. Dry the plate, heat at a specified temperature in 105~120℃ for 30~60 minutes, place in the

desiccators. At 2 cm below the lower edge of chromatographic plate as the start line, apply sample solution and reference standard solution on the start line by micropipette or capillary tube. The start line is apart at least 1cm from two side of the plate, the interval of the center spots is at least 1~1.5 cm, dry. The plate is placed in the developing chamber with solvent about 1 cm deep, the chamber is seal and the plate is allowed to develop at room temperature.

Remove the plate from the chamber when the solvent reach the predetermined height (8~15 cm from the starting line), mark a line on the solvent front and dry the plate. Developed plates can be observed under short and long UV light, spots can be detected by spraying reagents or exposing in iodine vapor. Measure and record the distance of each spot from the point of origin, and indicate the wavelength for observing at each spot. Calculate the R_f value of the principle spots or zone and compare sample value with reference standard value.

(1621.4) Gas Chromatography

Gas chromatography is a separation technique which is used an inert gas as mobile phase gas, separation is occurred due to the different distribution coefficient between each component in vaporized test specimen. It is the suitable identification test for the gas, liquid, solid test specimen, also test impurities and quantity.

In gas-solid chromatography, the stationary phase is a solid adsorbent with suitable fineness. In gas-liquid chromatography, the stationary phase is the surface of the inert solid support or the capillary wall coated with the non-volatile liquid to form a film.

Apparatus: A gas chromatograph consists of a carrier gas source, a gas flow regulator, an injection port, column, detector, and recording device. Injection port, column and detector are in thermostatic bath.

Procedure: Each thermostatic bath is adjusted to the specified temperature. Suitable carried gas is chosen and the flow rate is adjusted. A specified quantity of the test specimen solution or standard solution is injected by microsyringe which is for gas chromatography. The separated components are determined by detector, and the chromatogram is depicted by recording device. The unit of the abscissa is time, and the unit of the ordinate is millivolt in the chromatogram.

In the qualitative analysis, determine the retention time of the standard solution (the time elapsed between the injection of the test specimen and the appearance of the maximum peak) or the retention volume (the volume of mobile phase required for elution of a component), then determine the test specimen in the same conditions. If the retention time or retention volume of the test specimen is same to the standard, there is a great possibility that the two substances are identical.

For the quantitative analysis, follow the method as described below:

I. Internal standard method: As specified in the monographs, a quantity of internal standard solution is added to the standard solutions with different concentration and chromatogram is recorded under same experimental conditions. Then, a calibration curve is made, the ordinate is the ratio of the peak of the standard to the peak of the internal standard, and the abscissa is the ratio of the content of the standard to the content of the internal standard.

Solutions contained test specimen is prepared as described in the monographs with the same quantity of internal standard, to make the test solution. The solution is injected into the equipment and the chromatogram is recorded under the same conditions. Calculate the ratio of the peak of the objective component to the peak of the internal standard and the quantity of the objective component is calculated by the reference to the calibration curve. Internal standard should have high stability and its peak should be similar to objective component, but totally separate from the peak of the components in test specimen.

II. Absolute calibration curve method: Take a quantity of each standard solution with different concentrations and to record the chromatograms under the same conditions. Calibration curve is depicted with the ordinate is the peak of each standard, and the abscissa is the concentration of the standard.

The sample solution is prepared as specified in the monographs and the chromatograms are recorded under the same conditions. The concentration of sample is calculated by its peak respond with calibration curve.

III. Area normalization Procedure: The total peak area under each component is regarded as 100%, and then the percentage of each component in the test specimen is calculated by the ratio of peak area under each component. For determining the accurate value, calibrate the peak area of each component by the sensitivity of the detector.

Two ways of determining peak response:

1. Peak height method: Draw a vertical line from the maximum of the peak to the horizontal axis, and then draw a line form the start to the end of the peak, the distance of intersecting point of two lines to the horizontal axis is the peak height.
2. Peak area method: Multiply the peak width at the half-height by the peak height to get the area.

(1621.5) Liquid Chromatography

Liquid chromatography (LC) used in the pharmacopoeia is high performance liquid chromatography (HPLC), which uses a suitable filler to fill the chromatography tube and used as stationary phase. The injected mixture is carried into the column by the mobile phase. Each

component is separated by affinity difference with the stationary phase. The method can be applied for identification test, impurities test and quantitative test for liquid or liquid soluble specimen.

Apparatus: Liquid chromatography system consists of injection port for injecting test specimen, a chromatographic column, a detector, and recording device. A pump is the device which forces the mobile phase to pass through the chromatographic column system at high pressure. The temperature of chromatographic column can be maintained in a column oven. Columns are made by inactive metal with internal diameters of 1~10 mm and length of 5~100 cm. The size of packing particles are uniform in size with a range of 1~50 μm. The different properties of the objective compounds in the mobile phase are determined by different detectors. Commonly used detectors are UV/Vis absorption spectrophotometer detector, differential refractometer detectors and fluorometric detectors. Detectors are highly sensitive and the detection limit is in a few μg. The higher concentrations of the target compounds are detected, the stronger signals are presented. The detector gives out signals with different intensity and they are collected by recording device.

Procedure: After adjusting the apparatus, use the detector, chromatographic column and the mobile phase that indicated in the monographs. Equilibrate the column with the prescribed mobile phase, flow rate and at the temperature specified in the monographs, until a stable baseline is achieved. Inject a specified quantity of test solution or the standard solution through sample valve by micro syringe. Separated components are detected by the detector which transfers received signals into the reorder to display chromatogram.

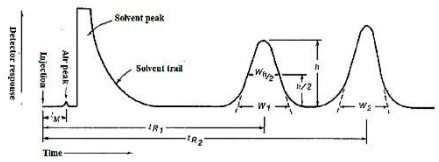


Figure1. Chromatography seperation of two substance

Each component in the mixture injected in the column is often distributed as constant ratio k in the mobile phase and the stationary phase.

$$k = \frac{amount\ of\ substance\ \ in\ \ stationary\ \ phase}{amount\ of\ substance\ \ in\ \ mobile\ \ phase}$$

k: the ratio is also called capacity factor or mass distribution ratio (k').
The relation of the capacity factor (k), time of the mobile phase pass through the column (t_0), and retention time (t_R) is described as below. The retention time of the substance remain constant under the same conditions.
In the same retention time (t_R)
t_0: the retention time of a non-retained (k=0) substance
t_R: the retention time of a test specimen

$$t_R=(1+k')t_0$$

or

$$k'=\frac{t_R}{t_0}-1$$

The relative retention time is applied to identification of the composition. Calculate the relative retention time (α) as described below.

$$\alpha=\frac{t_2-t_0}{t_1-t_0}$$

The t_1, t_2 in the equation is the retention time of the component 1 and component 2 under the same chromatographic factors. The retention volume or the retention distance is usually proportional to the retention time, thus both can be substituted for retention time in the equation. If the value of t_0 is relatively small, relative retention time can be calculated by t_2/t_1
The efficiency of the chromatographic column is described as theoretical plates:

$$n=16\left(\frac{t}{w}\right)^2$$

In the equation, t is the retention time of the component to be determined and w is the width that determined by extending tangent lines on both side of the chromatographic peak through the baseline. The value of theoretical plates (n) is related to the test specimen, flow rate, column temperature, quality and uniformity of packing particles within the column.

Resolution (R) is the extent of the two components' peak separate with each other, calculated by:

$$R=\frac{2(t_2-t_1)}{W_2+W_1}$$

W_1 and W_2 are the width that determined by extending tangent lines on both side of the chromatographic peak through the baseline.
The symmetry factor (T, also known as the tailing factor) of peak is calculated by:

$$T=\frac{W_{0.05}}{2f}$$

$W_{0.05}$: the width at 1/20 height from baseline to peak.
f: distance from peak front to apex point at 5% height.
The tailing factor is limited in the monographs if necessary.

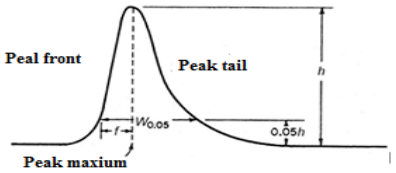


Figure2. Asymmetrical chromatographic peak

System suitability: For ensuring the effectiveness and suitability in the chromatographic factors, all or part of the

chromatographic parameters are usually specified in individual monograph, if necessary, other suitable operating conditions can be used (see procedures under tests and assays in the general notices).

Collecting data from replicate injections of standard or test solutions as specified in the individual monograph, calculate the column efficiency, precision, tailing factor, resolution, retention time, calibration curve, peak area, and recovery, then compare with specified maximum and minimum values in the monographs.

The reproducibility of repeat injection of liquid into chromatographic column is described as relative standard deviation which is one of practical parameter. The equation of Relative Standard Deviation (RSD) is described below:

$$S_R(\%) = \frac{100}{\bar{X}}\left[\frac{\sum_{i=1}^{N}(X_i-\bar{X})^2}{N-1}\right]^{1/2}$$

In the equation, S_R is the relative standard deviation described as %, $\bar{X}$ is an arithmetic mean in a set of N measurements, X_i is an individual measurement in a set. In internal standard, X_i is the ratio of the peak R_S.

$$X_i = R_S = \frac{r_s}{r_i}$$

Where r_s is the peak value of the standard and r_i is the peak value of the internal standard. If external standard is used, Xi is the standard peak value r_s.

As specified in the monographs, replicate injections for standard solution to determine whether the consequence of the analysis suitability meet the requirements. Unless otherwise specified in the individual monograph, if the requirement of relative standard deviation is 2.0% or less, calculate RSD of peak area from five injection bases. If the requirement is more than 2.0%, calculate RSD peak area from six injection bases.

Tailing factor (T) refers to the maximum allowable asymmetry factor. Resolution (R) refers to how well two elution peaks can be separated. It is also called separation efficiency.

Identification and Impurities: When liquid chromatography is used to identify a component in the test specimen, it is performed by confirming identity of the retention time between the component and the standard, or by confirming the peak width and retention time of the component are unchanged after mixing the test specimen with the standard.

Impurities are usually performed by comparison of a reference solution equal to a specified impurities limit with the test specimen. Comparison of peak area percentage by area normalization method can also be used. The isomer ratio of the test specimen is usually calculated by area normalization method.

Area normalization procedure: The total peak area under each component is regarded as 100%, calculate the percentage of each component peak area. For determining the accurate proportion of components, each content peak area must be calibrated by determining sensitivity of each component.

Assay: Internal standard method is commonly applied. If there has no suitable internal standard, the absolute calibration curve method can be applied.

(1) **Method I**: Internal standard method

In the internal standard method, choose a stable compound as an internal standard which retention time closes to the objective compounds, and the peak is well separated from all other peaks in the chromatogram.

As specified in the monographs, prepare several standard solutions with different concentrations, and add a constant amount of the internal standard in each standard solution. Based on the chromatogram obtained from each standard solution which is tested in constant volume, make the calibration curve, the ordinate is the ratio of the peak height or the peak area of the objective compound standard to the internal standard, and the abscissa is the ratio of the content of the objective compound standard to the content of the internal standard. The calibration curve is often a straight line passing through the origin.

Then, according to the method specified in the individual monograph, prepare a test solution by adding the same amount of internal standard as describe above, perform the liquid chromatography under the same operating conditions as for the preparation of the calibration curve, calculate the ratio of the peak area or peak height of the objective compound standard to the internal standard, and get the amount of the compound by the calibration curve.

Generally, in the individual monograph, prepare one of the standard solutions with a concentration within the linear range of the calibration curve and a test solution with a concentration close to the standard solution, take a specified quantity of both solutions, and perform chromatography under constant conditions to determine the amount of the objective compound.

(2) **Method II**: Absolute calibration curve method.

Prepare a serial of standard solutions with different concentration with the objective compound standard solution, and take accurately a fixed volume of these standard solutions for chromatography. Based on the chromatogram obtained, make the calibration curve, the ordinate is the peak areas or peak heights, and the abscissa is the content of the standard. The calibration curve is generally a straight line passing through the origin.

Then, prepare a test specimen solution according to the method specified in the individual monograph, perform the liquid chromatography under the same conditions as the preparation for the calibration curve. Base on the peak area or peak height of the

objective component, determines the amount of the component by the calibration curve.

Generally, in the individual monograph, prepare one of the standard solutions with a concentration within the linear range of the calibration curve and a test solution with a concentration close to the standard solution, take a specified quantity of both solutions, and perform chromatography under constant conditions to determine the amount of the objective compound. In this method, all procedures must be carried out under a strictly constant condition. If necessary, repeating the injection of fixed volume of the standard solution and confirm the peak response of each component on the chromatogram. The relative standard deviation or coefficient of variation is calculated to confirm the reproducibility of the peak response of the objective component.

Peak measuring method: Peak response includes two measuring methods, and both can be automatically recorded as values by recorder.

(1) Peak height method: draw a vertical line from the maximum of the peak to the baseline, and draw another line from the start to the end of the peak, the intersecting point of both lines to the maximum of the peak is the peak height.

(2) Peak area method: Multiply the peak width at the half-height by the peak height.

Although peak height method is simple, due to the temperature and solvent composition may cause the big variation on retention time, thus the peak area method is more accurate.

If the peak area method is indicated in the monographs, follow the rule.

(1733) Determination of Loss on Drying

Dry the weighing bottle at the temperature specified in the monograph for 30 minutes, allow it to cool to room temperature in a desiccator and weigh accurately. Mix the test substance thoroughly. If the test specimen is in the form of large particles, reduce the particle size to about 2.0 mm by grinding. Unless otherwise indicated in the individual monograph, place 1~2 g test specimen in a weighing bottle, weigh accurately. Sidewise shaking gently, distribute the test specimen as evenly as possible to a depth less than 5 mm roughly and not more than 10 mm for bulky materials. Place the loaded bottle in the drying chamber, removing the stopper and leaving it also in the chamber. Dry the test specimen at the temperature and for the time specified in the monographs. Upon opening the chamber, close the bottle promptly, and allow it to come to room temperature in a desiccator before weighing.

If the substance melts at a temperature lower than the specified drying temperature, maintain the bottle with its contents for 1 to 2 hours at a temperature 5~10 below the melting temperature, then dry at the specified temperature.

Where drying in vacuum over a desiccant is directed in the individual monograph, a vacuum desiccator or other suitable vacuum drying apparatus can be used.

Replace the desiccant in the desiccator frequently to assure the efficiency of drying.

(1781) Optical Rotation

When polarized light passes though the pharmaceutical substances or solution of compounds, the plane of polarized light rotate clockwise or counterclockwise, called optical active. The substance which is optically active is called chiral. The strength of optical rotation is expressed in degree, which is called specific rotation. Optical rotation is considered to be positive (+) for dextrorotatory substances and negative (-) for levorotatory substance. The optical rotation of substances remain constant, therefore the measurement of specific optical rotation may be used for an identification test, a purity test or determined the contents.

Procedure: Measure optical rotation with a calibrated polarimeter which is accurately to 0.02° at least, to 0.01° optimal. There are two types of the polarimeter length tube which are 200 mm and 100 mm.

Determine the zero point of the instrument at specified temperature. If the test specimen is liquid, use the reservoir tube to calibrate the zero point. If the test specimen is solid, take the tube which is filled with solvent to calibrate it.

Fill the reservoir tube with test specimen at indicated temperature, use sodium lamp as the light source in the dark and observe the optical rotation. Carry out five measurements at least, take the average and calculate the specific optical rotation from one of the following equations:

$$\text{For liquids} \quad [\alpha]_D^t = \frac{\alpha}{ld}$$

$$\text{For solid} \quad [\alpha]_D^t = \frac{100a}{lpd} \quad \text{or} \quad = \frac{100a}{lc}$$

α: specific rotation.
D: D-line of the sodium lamp.
t: temperature.
a: observed rotation in degrees.
l: reservoir tube in decimeters.
c: concentration of solute in g per 100 mL.
d: specific gravity of the liquid.
p: weight of solute (g) per 100 g.

(1793) pH Value

pH value is the expression of hydrogen ion activity in aqueous solution, which is defined as the negative logarithm of hydrogen ion activity in aqueous solution. By definition, pH is equal to $-\log_{10} a_{H^+}$ where a_{H^+} is the activity of the hydrogen $[H^+]$ or hydronium ion $[H_3O^+]$,

and the hydrogen ion activity very closely approximation hydrogen ion concentration, $[H_3O^+]$ or $[H^+]$
Reference solution of pH by the following equation:

$$pH = pHs + \left[\frac{E-Es}{k}\right]$$

in which *E* is the potential, expressed in volts, of the cell containing the solution to be examined (pH). *Es* is the potential, expressed in volts, of the cell containing the solution of known pH (pHs).
k is the change in potential per unit change in pH expressed in volts.
k = 0.05916 + 0.000198 (T-25) volts at temperature T. Values of *k* from 15~35℃ are provided in Table 1.

Table 1 Values of k for Various Temperatures

Temperature (℃)	*k* (V)
15.00	0.05718
20.00	0.05817
25.00	0.05916
30.00	0.06016
35.00	0.06115

Due to many factors such as the dissociation constant of the test object, the dielectric constant of the medium, and the junction potential, all can affect the accuracy of the pH measurement. The method for measuring the value of the pH only in the solution is called the potentiometric method. If you just want to get an approximate value, you can use a test paper or indicator to determine the colorimetric method.

I. Potentiometric method
This method uses a potentiometer with temperature compensation based on the principle of potential balance, with reference electrode (usually calomel electrode or silver-silver chloride electrode) and indicator electrode (usually glass electrode); unless otherwise specified In addition, immerse it in the test solution under the operating temperature of 25 ± 2℃, and measure the potential difference to determine its pH value.
Instrument requirements:
The measurement system shall be capable of performing a two-point pH calibration. The resolution of the pH measurement system shall be at least 0.01 pH. The instrument shall be capable of temperature compensating the pH sensor measurement to convert the millivolt signal to pH unit at any temperature. The accuracy of the temperature measurement system shall be ± 1℃. The resolution of the temperature measurement system shall be at least 0.1℃. Lab-based pH measurements are typically performed at 25 ± 2℃ unless otherwise specified in the individual monograph or herein.
Buffer solutions for calibration of the pH measurement system:
Buffer solution for calibration are prepared as directed in the following. Buffer solution should be stored in appropriate containers that ensure stability of the pH through the expiry date, and fitted with a tight closure. For buffer solution great than 11, the storage should be in containers that are resistant to or reduce carbon dioxide intrusion which would lower the pH of the buffer. For buffer solution lower than 11, they should typically be prepared at intervals not to exceed 3 months. For buffer solution greater than 11, they should typically be prepared and used fresh unless carbon dioxide ingress is restricted. All buffer solutions should be prepared using purified water which we used in buffer solution.

Table 2 indicate the pH of the buffer solutions as a function of temperature. The original prepared solution was a weight-molality (m), which should be changed to molarity (M). Calibration using buffer solution shall be done in the temperature range of the buffers listed in Table 2.
Calibration:
3 buffers are selected, 2 are used for calibration, and the third is used for checking. The pH value of the checking buffer solution and the test solution must be the middle value of the 2 calibration buffer solutions; if the pH value of the unknown test solution is set to pH, Three-point calibration of 4.0, 7.0 and 10.0. Start with the lowest pH value (pH 4.0).

1. Rinse the pH sensor several times with water, then with the first buffer solution.
2. Immerse the pH sensor in the first buffer solution at a temperature within the range of table 2.
3. The pH meter with automatic temperature compensation function will automatically correct the pH value of the buffer solution at that temperature after measuring the temperature directly [The temperature probe must be calibrated according to the manufacturer's or pharmaceutical manufacturer's regulations, and the error must not be greater than ± 0.5℃ and recorded]. When manual compensation is used, the temperature of the buffer solution is first measured with a calibrated thermometer, and the temperature is manually entered into the instrument. If it is not the temperature listed in table 2, the correlation between pH and temperature is obtained using limit interpolation; the zero-point potential and slope are adjusted to the pH of the buffer at that temperature.
4. Remove the pH sensor from the first buffer and rinse the electrode(s) with water, and then with the second buffer solution.
5. Immerse the pH sensor in the second buffer at a temperature within the range of table 2.

Table 2 pH values of buffer solution for calibration

Temperature (℃)	Potassium Tetraoxalate, 0.05 M	Potassium Hydrogen Tartrate Saturated at 25℃	Potassium Dihydrogen Citrate, 0.05 M	Potassium Biphthalate 0.05 M	Potassium Dihydrogen Phosphate 0.025 M + Disodium Hydrogen Phosphate 0.025 M	Potassium Dihydrogen Phosphate 0.0087 M + Disodium Hydrogen Phosphate, 0.0303 M	Sodium Tetraborate, 0.01 M	Sodium Carbonate 0.025 M + Sodium Bicarbonate, 0.025 M	Calcium Hydroxide, Saturated at 25℃
10	1.67	-	-	4.00	6.92	-	9.33	-	13.00
15	1.67	-	3.80	4.00	6.90	7.45	9.28	10.12	12.81
20	1.68	-	3.79	4.00	6.88	7.43	9.23	10.06	12.63
25	1.68	3.56	3.78	4.01	6.86	7.41	9.18	10.01	12.45
30	1.68	3.55	3.77	4.02	6.85	7.40	9.14	9.97	12.29
35	1.69	3.55	3.76	4.02	6.84	7.39	9.10	9.93	12.13
40	1.69	-	-	4.04	6.84	-	9.07	-	11.98
45	1.70	-	-	4.05	6.83	-	9.04	-	11.84
50	1.71	-	-	4.06	6.83	-	9.01	-	11.71
55	1.72	-	-	4.08	6.83	-	8.99	-	11.57
60	1.72	-	-	4.09	6.84	-	8.96	-	11.45
ΔpH/Δ℃	0.0010	-0.0014	-0.0022	0.0018	-0.0016	-0.0028	-0.0074	-0.0096	-0.0310

Potassium Tetraoxalate, 0.05 M: Dissolve 12.61 g of $KH_3(C_2O_4)_2 \cdot H_2O$, and dilute with water to make 1000.0 mL.

Potassium Hydrogen Tartrate Saturated at 25℃: Add $C_4H_5KO_6$ to water until saturation is exceeded at 25℃. Then filter or decant.

Potassium Dihydrogen Citrate, 0.05 M: Dissolve 11.41 g of $C_6H_7KO_4$, and dilute with water to make 1000.0 mL.

Potassium Biphthalate 0.05 m: Dissolve 10.12 g of $KHC_8H_4O_4$, previously dried a 110℃ for 1 h, and dilute with water to make 1000.0 mL.

Potassium dihydrogen Phosphate 0.025 M + Disodium Hydrogen Phosphate 0.025 M: Dissolve 3.39 g of KH_2PO_4 and 3.53 g of Na_2HPO_4, both previously dried for 2 h at 120℃, and dilute with water to make 1000.0 mL.

Potassium Dihydrogen Phosphate 0.0087 M + Disodium Hydrogen Phosphate, 0.0303 M: Dissolve 1.18 g of KH_2PO_4 and 4.30 g Na_2PO_4, both dried for 2 h at 120℃, and dilute with water to make 1000.0 mL.

Sodium Tetraborate, 0.01 M: Dissolve 3.80 g of $Na_2B_4O_7 \cdot 10H_2O$, and dilute with water to make 1000.0 mL. Protect from absorption of carbon dioxide.

Sodium Carbonate 0.025 M + Sodium Bicarbonate, 0.025 M: Dissolve 2.64 g of sodium carbonate (Na_2CO_3) and 2.09 g of Sodium Bicarbonate ($NaHCO_3$), and dilute with water to make 1000.0 mL.

Calcium Hydroxide, Saturated at 25℃: Add $Ca(OH)_2$ to water until saturation is exceeded at 25℃. Use water that has been recently boiled and protected from the atmosphere to limit carbon dioxide absorption. Then filter or decant.

6. Continue the two-point it calibration sequence with the second buffer according to the manufacturer's instructions.
7. After completion of the two-point calibration process, verify that the pH slope and offset are within acceptable parameter. Typical acceptable parameters are a slope of 90% - 105% and an offset of 0 ± 30 mV (0.5 pH units at 25℃). If these parameters are not within acceptable parameters, the sensor should be properly cleaned, replenished, serviced, or replaced, and the two-point calibration process shall be repeated.
8. Remove the pH sensor from the second buffer, and rinse thoroughly with water, and then the verification buffer.
9. Immerse the pH sensor in the verification buffer at a temperature within the range of table 2. The pH reading shall be within ± 0.05 pH of the value in table 2 at the buffer solution temperature.

Operation:

All test samples should be prepared using purified water, unless otherwise specified in the monograph. All test measurements should use manual or automated Nernst temperature compensation.

1. Prepare the test material according to requirements in the monograph or according to specific procedures. If the pH of the test sample is sensitive to ambient carbon dioxide, then use purified water that has been

recently boiled, and subsequently stored in a container designed to minimize ingress of carbon dioxide.
2. Rinse the pH sensor with water, then with a few portions of the test solution.
3. Immerse the pH sensor into the test material and record the pH value and temperature.
4. Except for special requirements, take 2 samples of each test solution and measure 2 to 3 times each. The difference should be less than 0.05 pH unit and expressed as the average value

If the pH of several test solutions is continuously measured, the instrument should be calibrated with a standard buffer solution to ensure that the readings are correct.

II. Colorimetric method

Unless otherwise stated, the indicator solution in Table 3 was added to 0.1 mL in a 10 mL test solution to observe the color change.

Table 3

Reaction	pH	Test strip or solution	Color
Base	>8	Red litmus test strip	Blue
		Thymol blue (0.05 mL)	Bright or purple blue
Weak base	8.0-10.0	Phenolphthalein (0.05 mL)	Colorless or pink
		Thymol blue (0.05 mL)	Bright blue
Strong base	>10	Phenolphthalein test strip	Red
		Thymol blue (0.05 mL)	Violet
Neutral	6.0-8.0	Methyl red	Yellow
		Phenol red (0.05 mL)	
Neutral – methyl red	4.5-6.0	Methyl red	Orange-red
Neutral – phenolphthalein	<8	Phenolphthalein (0.05 mL)	Colorless; pink or red after adding 0.1 M 0.05 mL
Acid	<6	Methyl red	Orange-red
		Thymol blue	Yellow
Weak acid	4.0-6.0	Methyl red	Orange
		Bromocresol green	Green or blue
Strong acid	<4	Congo red test strip	Green or blue

(1831) Refractive Index

Refraction takes place when a beam of light is transmitted from the first substance into the second one, due to the velocity of light changes in different substance. The refractive index (n) of a substance is the ratio of the velocity of light in air to the velocity of light in the substance. The refractive index may also be defined as the ratio of the sine of the angle of incidence to the sine of the angle of refraction. It is valuable in the identification of substances and the detection of impurities.

Although the standard temperature for Pharmacopeia measurement is 25℃, most of the temperature for refractive index is 20℃, the temperature should be carefully adjusted and maintained, since the refractive index varies significantly with temperature. The wavelength of incident light also affects the results. The values for refractive index given in this Pharmacopeia are for the D line of sodium (doublet at 589.0 nm and 589.6 nm). Most instruments available are designed for use with white light but are calibrated to give the refractive index in terms of the D line of sodium light.

To achieve the theoretical accuracy of ±0.0001, it is necessary to calibrate the instrument against a standard provided by the manufacturer and to check frequently the temperature control and cleanliness of the instrument by determining the refractive index of distilled water, which is 1.3330 at 20℃ and 1.3325 at 25℃. The Abbé refractometer is usually used for the refractive index to those Pharmacopeia materials with such values. Other refractometers with the same or greater accuracy may be employed. Take three readings and use the average value as the refractive index for the specimen.

(1841) Specific Gravity

The specific gravity is the ratio of the weight of a liquid in air at the specified temperature to that of an equal volume of water at the same temperature, unless otherwise directed, the specified temperature is 25℃, expressed as d_{25}^{25}. The specific gravity determination is only applicable to liquids. To solid form from liquids at 25℃, follow the individual monograph to test and contrast with water at 25℃.

Procedure: Select a clean, dry pycnometer that previously has been calibrated by determining its weight, and the weight of recently boiled water contained in it at 25℃. Adjust the temperature of the water to about 20℃, and fill the pycnometer with it, place the pycnometer in a water bath maintained at 25℃ for 30 minutes. Wipe off the excess water and adjust the water surface on the pycnometer scale.

Take the pycnometer from the water bath, wipe the pycnometer and weigh. Pour out the water from the pycnometer and rinse several times with ethanol, then ethyl ether, wait the pycnometer to dryness, and then add the test specimen in it. Determine the weight of test specimen as described. The specific gravity of the test specimen at 25℃ is the weight of the test specimen divided by the weight of water.

(1921) Water Determination

Many pharmacopeial article either are hydrates or contain water in adsorbed form. As result, the determination of the water content is important in demonstrating compliance with the pharmacopeial standards. Generally one of the methods give below is called for in the individual monograph, depending upon the nature of the article .In rare case, a choice is allowed between two methods .When the article contains water of hydration, Method I (titrimetric), Method II (Azeotropic), Method III (Gravimetric) is employed, as directed in the individual monograph and the requirement is given under the heading water.

The heading loss on drying is used in those cases where the loss sustained on heating may be not entirely water.

1. Method I: Titrimetric

Determine the water by Method I, unless otherwise specified in the individual monograph.

(1) Method I: Directed titration

Principle: The titrimetric determination of water is based upon the quantitative reaction of water with an anhydrous solution of sulfur dioxide and iodine in the presence of a buffer that reacts with hydrogen ions.

In the original titrimetric solution, known as Karl Fischer reagent, the sulfur dioxide and iodine are dissolved in pyridine and methanol. The test specimen may be titrated with the reagent directly, or the analysis may be carried out by a residual titration procedure. The stoichiometry of the reaction is not exact, and the reproducibility of a determination depends upon such factors as the relative concentrations of the reagent ingredients, the nature of the inert solvent used to dissolve the test specimen, and the technique used in the particular determination. Therefore, an empirically standardized technique is used in order to achieve the desired accuracy Precision in the method is governed largely by the extent to which atmospheric moisture is excluded from the system.

The titration of water is usually carried out with the use of anhydrous methanol as the solvent for the test specimen; however, other suitable solvents may be used for special or unusual test specimens

Apparatus: Any apparatus may be used that provides for adequate exclusion of atmospheric moisture and determination of the endpoint. In the case of a colorless solution that is titrated directly, the endpoint may be observed visually as a change in color from canary yellow to amber. The reverse is observed in the case of a test specimen that is titrated residually. More commonly, however, the endpoint is determined electrometrically with an apparatus employing a simple electrical circuit that serves to impress about 200 mV of applied potential between a pair of platinum electrodes immersed in the solution to be titrated. At the endpoint of the titration a slight excess of the reagent increases the flow of current to between 50 and 150 microamperes for 30 seconds to 30 minutes, depending upon the solution being titrated. The time is shortest for substances that dissolve in the reagent. With some automatic titrators, the abrupt change in current or potential at the endpoint serves to close a solenoid-operated valve that controls the buret delivering the titrant. Commercially available apparatus generally comprises a closed system consisting of one or two automatic burets and a tightly covered titration vessel fitted with the necessary electrodes and a magnetic stirrer. The air in the system is kept dry with a suitable desiccant, and the titration vessel may be purged by means of a stream of dry nitrogen or current of dry air.

Reagent: Prepare the Karl Fischer reagent as follows. Add 125 g of iodine to a solution containing 670 mL of methanol and 170 mL of pyridine, and cool. Place 100 mL of pyridine in a 250-mL graduated cylinder, and, keeping the pyridine cold in an ice bath, pass in dry sulfur dioxide until the volume reaches 200 mL. Add this solution, with shaking, to the cooled iodine mixture slowly. Shake to dissolve the iodine, transfer the solution to the apparatus, and allow the solution to stand overnight before standardizing. One mL of this solution when freshly prepared is equivalent to approximately 5 mg of water, but it deteriorates gradually; therefore, standardize it within 1 hour before use, or daily if in continuous use. Protect from light while in use. Store any bulk stock of the reagent in a suitably sealed, glass-stoppered container, fully protected from light, and under refrigeration. A commercially available, stabilized solution of Karl Fischer type reagent may be used. Commercially available reagents containing solvents or bases other than pyridine or alcohols other than methanol may be used also. These may be single solutions or reagents formed in situ by combining the components of the reagents present in two discrete solutions. The diluted reagent called for in some monographs should be diluted as directed by the manufacturer. Either methanol or other suitable solvent, such as ethylene glycol monomethyl ether, may be used as the diluent.

Test Preparation: Unless otherwise specified in the individual monograph, use an accurately weighed or measured amount of the specimen under test estimated to contain 2 to 250 mg of water. The amount of water depends on the water equivalency factor of the reagent and on the method of endpoint determination. In most cases, the minimum amount of specimen, in mg, can be estimated using the formula:

$$M=FCV/KF$$

M: the weight of sample, in mg.

F: the water equivalency factor of the reagent, in mg per mL.
C: the used volume, in percent, of the capacity of the buret.
V: the buret volume, in mL.
KF: the limit or reasonable expected water content in the sample, in percent.
C is generally between 30% and 100% for manual titration, and between 10% and 100% for the instrumental method endpoint determination.
[NOTE: It is recommended that the product of FCV be greater than or equal to 200 for the calculation to ensure that the minimum amount of water titrated is greater than or equal to 2 mg.]
Where the specimen under test is an aerosol with propellant, store it in a freezer for not less than 2 hours, open the container, and test 10 mL of the well-mixed specimen. In titrating the specimen, determine the endpoint at a temperature of 10° or higher.
Where the specimen under test is capsules, use a portion of the mixed contents of not fewer than 4 capsules. Where the specimen under test is tablets, use powder from not fewer than 4 tablets ground to a fine powder in an atmosphere of temperature and relative humidity known not to influence the results. Where the monograph specifies that the specimen under test is hygroscopic, use a dry syringe to inject an appropriate volume of methanol, or other suitable solvent, accurately measured, into a tared container, and shake to dissolve the specimen. Using the same syringe, remove the solution from the container and transfer it to a titration vessel prepared as directed for Procedure. Repeat the procedure with a second portion of methanol, or other suitable solvent, accurately measured, add this washing to the titration vessel, and immediately titrate. Determine the water content, in mg, of a portion of solvent of the same total volume as that used to dissolve the specimen and to wash the container and syringe, as directed for Standardization of Water Solution for Residual Titrations, and subtract this value from the water content, in mg, obtained in the titration of reagent is titrated with a standard solution of water in the specimen under test. Dry the container and its closure at 100° for 3 hours, allow to cool in a desiccator, and weigh. Determine the weight of specimen tested from the difference in weight from the initial weight of the container.
Standardization of the reagent: Place enough methanol or other suitable solvent in the titration vessel to cover the electrodes, and add sufficient reagent to give the characteristic endpoint color, or 100±50 microamperes of direct current at about 200 mV of applied potential. For determination of trace amounts of water (less than 1%), it is preferable to use a reagent with a water equivalency factor of not more than 2.0. Purified Water, sodium tartrate dihydrate, or commercial standards with a certificate of analysis traceable to a national standard may be used to standardize the reagent. The reagent equivalency factor, the recommended titration volume, buret size, and amount of standard to measure are factors to consider when deciding which standard and how much to use. For Purified Water or water standards, quickly add the equivalent of between 2.0 and 250.0 mg of water. Calculate the water equivalency factor, F, in mg of water per mL of reagent, by the formula:

$$F = W/V$$

F: the water equivalency factor of the reagent, in mg per mL.
W: the weight, in mg, of the water contained in the aliquot of standard used.
V: the volume, in mL, of the reagent used in the titration.
For sodium tartrate dihydrate, quickly add 20.0 to 125.0 mg of sodium tartrate dihydrate ($Na_2C_4O_6 \cdot 2H_2O$), accurately weighed by difference, and titrate to the endpoint. The water equivalence factor F, in mg of water per mL of reagent, is given by the formula:

$$F = W/V\ (36.04/230.08)$$

F: the water equivalency factor of the reagent, in mg per mL.
36.04: two times the molecular weight of water.
230.08: the molecular weight of sodium tartrate dehydrate.
W: the weight, in mg, of sodium tartrate dehydrate.
V: the volume, in mL, of the reagent consumed in the second titration.
Note that the solubility of sodium tartrate dihydrate in methanol is such that fresh methanol may be needed for additional titrations of the sodium tartrate dihydrate standard.
Procedure: Unless otherwise specified, transfer enough methanol or other suitable solvent to the titration vessel, ensuring that the volume is sufficient to cover the electrodes (approximately 30 to 40 mL), and titrate with the reagent to the electrometric or visual endpoint to consume any moisture that may be present. (Disregard the volume consumed, because it does not enter into the calculations.) Quickly add the Test Preparation, mix, and again titrate with the reagent to the electrometric or visual endpoint. Calculate the water content of the specimen, in mg, taken by the formula:

$$M = SF$$

M: the weight of sample in mg.
S: the volume, in mL, of the reagent consumed in the second titration.

F: the water equivalence factor of the reagent, in mg per mL.

(2) Method II: Residual Titration

Principle—See the information given in the section Principle under Method Ia. In the residual titration, excess reagent is added to the test specimen, sufficient time is allowed for the reaction to reach completion, and the unconsumed reagent is titrated with a standard solution of water in a solvent such as methanol. The residual titration procedure is applicable generally and avoids the difficulties that may be encountered in the direct titration of substances from which the bound water is released slowly.

Apparatus, Reagent, and Test Preparation—Use Method I

Standardization of Water Solution for Residual Titration: Prepare a Water Solution by diluting 2 mL of water with methanol or other suitable solvent to 1000 ml. Standardize this solution by titrating 25.0 mL with the reagent, previously standardized as directed under Standardization of the reagent. Calculate the water content, in mg per mL, of the Water Solution taken by the formula:

$$M=V'F/25$$

M: the weight of sample, in mg

V': the volume of the reagent consumed.

F: the water equivalence factor of the reagent.

Determine the water content of the water solution weekly, and standardize the reagent against it periodically as needed.

Procedue: Where the individual monograph specifies that the water content is to be determined by Method II, transfer enough methanol or other suitable solvent to the transfer enough methanol or other suitable solvent to the titration vessel, ensuring that the volume is sufficient to cover the electrodes (approximately 30 to 40 mL), and titrate with the reagent to the electrometric or visual endpoint. Quickly add the Test Preparation, mix, and add an accurately measured excess of the reagent. Allow sufficient time for the reaction to reach completion, and titrate the unconsumed reagent with standardized Water Solution to the electrometric or visual endpoint. Calculate the water content of the specimen, in mg, taken by the formula:

$$M=F\,(X'-XR)$$

M: the weight of sample, in mg.

F: the water equivalence factor of the reagent

X': the volume, in mL, of the reagent added after introduction of the specimen.

X: the volume, in mL, of standardized Water Solution required to neutralize the unconsumed reagent.

R: is the ratio, $V'/25$ (mL reagent/mL Water Solution), determined from the Standardization of water solution for residual titration.

(3) Method III: Coulometric Titration

Principle—The Karl Fischer reaction is used in the coulometric determination of water. Iodine, however, is not added in the form of a volumetric solution but is produced in an iodide-containing solution by anodic oxidation. The reaction cell usually consists of a large anode compartment and a small cathode compartment that are separated by a diaphragm. Other suitable types of reaction cells (e.g., without diaphragms) may also be used. Each compartment has a platinum electrode that conducts current through the cell. Iodine, which is produced at the anode electrode, immediately reacts with water present in the compartment. When all the water has been consumed, an excess of iodine occurs, which usually is detected electrometrically, thus indicating the endpoint. Moisture is eliminated from the system by pre-electrolysis. Changing the Karl Fischer solution after each determination is not necessary because individual determinations can be carried out in succession in the same reagent solution.

A requirement for this method is that each component of the test specimen is compatible with the other components, and no side reactions take place. Samples are usually transferred into the vessel as solutions by means of injection through a septum. Gases can be introduced into the cell by means of a suitable gas inlet tube.

Precision in the method is predominantly governed by the extent to which atmospheric moisture is excluded from the system; thus, the introduction of solids into the cell may require precautions, such as working in a glove-box in an atmosphere of dry inert gas. Control of the system may be monitored by measuring the amount of baseline drift. This method is particularly suited to chemically inert substances like hydrocarbons, alcohols, and ethers. In comparison with the volumetric Karl Fischer titration, coulometry is a micromethod.

Apparatus: Any commercially available apparatus consisting of an absolutely tight system fitted with the necessary electrodes and a magnetic stirrer is appropriate. The instrument's microprocessor controls the analytical procedure and displays the results. Calibration of the instrument is not necessary, as the current consumed can be measured absolutely.

Reagent—See the manufacturer's recommendations.

Test Preparation: Where the specimen is a soluble solid, an appropriate quantity, accurately weighed, may be dissolved in anhydrous methanol or other suitable solvents. Where the specimen is an insoluble solid, an appropriate quantity, accurately weighed, may be extracted using a suitable anhydrous solvent, and may be injected into the

anolyte solution. Alternatively, an evaporation technique may be used in which water is released and evaporated by heating the specimen in a tube in a stream of dry inert gas. The gas is then passed into the cell. Where the specimen is to be used directly without dissolving in a suitable anhydrous solvent, an appropriate quantity, accurately weighed, may be introduced into the chamber directly. Where the specimen is a liquid, and is miscible with anhydrous methanol or other suitable solvents, an appropriate quantity, accurately weighed, may be added to anhydrous methanol or other suitable solvents.

Procedure: Using a dry device, inject or add directly an accurately measured amount of the sample or sample preparation estimated to contain between 0.5 and 5.0 mg of water, or an amount recommended by the instrument manufacturer into the anolyte, mix, and perform the coulometric titration to the electrometric endpoint. Read the water content of the liquid Test Preparation directly from the instrument's display, and calculate the percentage that is present in the substance. Perform a blank determination, as needed, and make any necessary corrections.

2. Azeotropic—toluene distillation

Apparatus: Use a 500-mL glass flask A connected by means of a trap B to a reflux condenser C by ground glass joints (see Figure.). The critical dimensions of the parts of the apparatus are as follows. The connecting tube D is 9 to 11 mm in internal diameter. The trap is 235 to 240 mm in length. The condenser, if of the straight-tube type, is approximately 400 mm in length and not less than 8 mm in bore diameter. The receiving tube E has a 5-mL capacity, and its cylindrical portion, 146 to 156 mm in length, is graduated in 0.1-mL subdivisions, so that the error of reading is not greater than 0.05 mL for any indicated volume. The source of heat is preferably an electric heater with rheostat control or an oil bath. The upper portion of the flask and the connecting tube may be insulated. Clean the receiving tube and the condenser with chromic acid cleansing mixture, thoroughly rinse with water, and dry in an oven. Prepare the toluene to be used by first shaking with a small quantity of water, separating the excess water, and distilling the toluene.

Procedure: Place in the dry flask a quantity of the substance, weighed accurately to the nearest centigram, which is expected to yield 2 to 4 mL of water. If the substance is of a pasty character, weigh it in a boat of metal foil of a size that will just pass through the neck of the flask. If the substance is likely to cause bumping, add enough dry, washed sand to cover the bottom of the flask, or a number of capillary melting-point tubes, about 100 mm in length, sealed at the upper end. Place about 200 mL of toluene in the flask, connect the apparatus, and fill the receiving tube E with toluene poured through the top of the condenser. Heat the flask gently for 15 minutes and, when the toluene begins to boil, distill at the rate of about 2 drops per second until most of the water has passed over, and then increase the rate of distillation to about 4 drops per second. When the water has apparently all distilled over, rinse the inside of the condenser tube with toluene while brushing down the tube with a tube brush attached to a copper wire and saturated with toluene. Continue the distillation for 5 minutes, then remove the heat, and allow the receiving tube to cool to room temperature. If any droplets of water adhere to the walls of the receiving tube, scrub them down with a brush consisting of a rubber band wrapped around a copper wire and wetted with toluene. When the water and toluene have separated completely, read the volume of water, and calculate the percentage that was present in the substance.

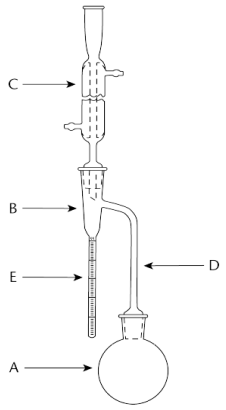


Figure. Toluene Moisture Apparatus

3. Gravimetric

Procedure for Chemicals: Proceed as directed in the individual monograph preparing the chemical as directed under Loss on Drying.

Procedure for Biologics: Proceed as directed in the individual monograph.

Procedure for Articles of Botanical Origin: Place about 10.0 g of the drug, prepared as directed and accurately weighed, in a tared evaporating dish. Dry at 105° for 5 hours, and weigh. Continue the drying and weighing at 1 hour intervals until the difference between two successive weightings corresponds to not more than 0.25%.

II. Identification Tests

(2191) General Identification Tests

Under this heading are placed tests that are frequently referred to in the pharmacopeia for the identification of reagents and crude drugs. The tests are not intended to be applicable to mixtures of substances unless otherwise directed.

Acetate

1. When acetate is warmed with dilute sulfuric acid, its characteristic odor is evolved.
2. When acetic acid or acetate is warmed with sulfuric acid and alcohol, the characteristic odor of ethyl

acetate is evolved.
3. With ferric chloride TS, neutral or weakly acidic solutions of acetates produce a dark red color and a red-brown precipitate when boiled. The precipitate is soluble in hydrochloric acid with the color of the solution changes to yellow.

Borate

1. Turmeric paper is dipped into a borate solution acidified with hydrochloric acid, exhibiting a brown color, the color turning darker after drying and changing to greenish-black with ammonia TS.
2. When a borate is treated with sulfuric acid, methanol is added, and the mixture is ignited, it burns with a green-bordered flame.

Carbonate and bicarbonate

1. Carbonates and bicarbonates effervesce with dilute acids, evolving a colorless gas of carbon dioxide, which produces a white precipitate immediately, when passed into calcium hydroxide TS.
2. A cold solution of carbonates is colored red by phenolphthalein TS, while a cold solution of bicarbonates remains unchanged or exhibits only a slightly red color.

Ferric salt and ferrous salt

1. Neutral solutions of ferric salts or ferrous salts produce a black precipitate immediately with ammonium sulfide TS. This precipitate is soluble in cold and dilute hydrochloric acid with the evolution of hydrogen sulfide.
2. Acidic solutions of ferric salts produce a dark blue precipitate with potassium ferrocyanide TS.
3. Solutions of ferric salts produce a reddish-brown precipitate with an excess of sodium hydroxide TS.
4. With ammonium thiocyanate TS, solutions of ferric salts produce a deep red color that is not destroyed by dilute mineral acids.
5. With potassium ferricyanide TS, solutions of ferrous salts produce a dark blue precipitate that is insoluble in dilute hydrochloric acid but is decomposed by sodium hydroxide TS.
6. With sodium hydroxide TS, solutions of ferrous salts produce a pale green precipitate, the color rapidly changing to green and then to brown when shaken.

Iodide

1. Solutions of iodides, upon the addition of chlorine TS, dropwise, liberate iodine, which is shaken with chloroform, the chloroform layer is colored violet; which gives a blue color with starch TS.
2. With silver nitrate TS, solutions of iodides produce a yellow, curdy precipitate that is insoluble in nitric acid and ammonia TS.
3. When an iodide is warmed with sulfuric acid and manganese dioxide, its violet vapor is evolved.
4. With mercuric chloride TS, solutions of iodides produce a scarlet precipitate that is slightly soluble in an excess of mercuric chloride TS but readily soluble in an excess of potassium iodide TS.

Nitrite

1. Nitrites evolve brownish-red fumes with dilute mineral acids or acetic acid.
2. Solutions of nitrites, upon the addition of potassium iodide TS and dilute sulfuric acid, dropwise, liberate iodine, which gives a blue color with starch TS.

Permanganate

1. Solutions of permanganates acidified with sulfuric acid are decolorized by hydrogen peroxide TS and by sodium bisulfite TS, in the cold, and by oxalic acid TS, in hot solution.

Phosphate

1. With silver nitrate TS, neutral solutions of phosphates produce a pale yellowish precipitate that is soluble in dilute nitric acid and ammonia TS.
2. With dilute nitric acid and ammonium molybdate TS, neutral solutions of phosphates produce a yellow precipitate that is soluble in ammonia TS.
3. With magnesium ammonium chloride TS, neutral solutions of phosphates produce a white crystalline precipitate that is soluble in dilute hydrochloric acid.

Potassium salt

1. Potassium salts are applied to the platinum wire moistened with hydrochloric acid, imparting a violet color to a nonluminous flame by viewing through cobalt glass.
2. With sodium bitartrate TS, neutral, concentrated solutions of potassium salts slowly produce a white crystalline precipitate that is soluble in ammonia TS and solutions of alkali hydroxides and carbonates. The formation of the precipitate, which is usually slow, is accelerated by stirring or rubbing the inside of the test tube with a glass rod. The addition of a small amount of glacial acetic acid or alcohol also promotes the precipitation.
3. With a small amount of hydrochloric acid and platinic chloride TS, concentrated solutions of potassium salts produce a yellow crystalline precipitate. The precipitate is decomposed to potassium chloride and platinum after ignition.

Silver salt

1. With hydrochloric acid, solutions of silver salts produce a white, curdy precipitate that is insoluble in nitric acid but readily soluble in ammonia TS.
2. When the solution of silver salts is warmed with ammonia TS and a small quantity of formaldehyde TS, a mirror of metallic silver upon the sides of the container.
3. With potassium chromate TS, solutions of silver salts produce a red precipitate that is soluble in dilute nitric acid.

Sodium salt

1. With cobalt–uranyl acetate TS, solutions of sodium salts after conversion to chlorides or nitrates produce a yellow precipitate, which forms after agitation for several minutes.
2. Sodium salts are applied to the platinum wire moistened with hydrochloric acid, imparting an intense yellow color to a nonluminous flame.
3. With potassium pyroantimonate TS, neutral or alkaline concentrated solutions of sodium salts produce a white crystalline precipitate. The formation of the precipitate is accelerated by rubbing the inside of the test tube with a glass rod.

Sulfate

1. With barium chloride TS, solutions of sulfates produce a white precipitate that is insoluble in hydrochloric acid and nitric acid.
2. With lead acetate TS, neutral solutions of sulfates produce a white precipitate that is soluble in ammonium acetate TS.
3. With hydrochloric acid, solutions of sulfates produce no precipitate. (Distinction from thiosulfates).

Sulfide

With hydrochloric acid, sulfides evolve the characteristic odor of hydrogen sulfide, which blackens lead acetate paper moistened with water.

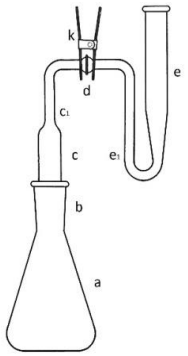
Sulfite and bisulfite

1. With dilute hydrochloric acid, sulfites and bisulfites evolve the characteristic odor of sulfur dioxide, which blackens filter paper moistened with mercurous nitrate TS.
2. With sodium sulfide TS, solutions of sulfites and bisulfites produce a white precipitate, which changing to yellow gradually.
3. Solutions of sulfites and bisulfites decolorize iodine TS.

(2211) Arsenic (As)

This method, based on the color reaction between hydrogen arsenide and silver diethyldithiocarbamate to produce the red complex which can be determined arsenic limits of crude drugs tested by visually or spectrophotometrically. All the reagents applied in this method should be as lower as possible in arsenic content, except arsenic trioxide.

Apparatus: See illustration.



a: arsine generator— a 125 ml conical flask.
b: frosted standard connector (24/40), constituted by a and c.
c: scrubber unit— the inner diameter is 25 mm.
c_1 and e_1: Glass tubes, the inner diameter is 2 mm and bent 90 degrees at the appropriate place.
d: rounded connector, constituted by c_1 and e_1.
e: absorber tube, 15 mL standard centrifuge tube.
k: retaining clip, forked. Insert c_1 and e_1 to stabilize d.

Standard arsenic solution: Take 132.0 mg of arsenic trioxide fine powder which is previously dried at 105℃ for 1 hour and weigh accurately, dissolve in 5 mL of sodium hydroxide solution (1 in 5) in a 1000-mL volumetric flask. Neutralize the solution with 10 mL dilute sulfuric acid, and add recently boiled and cooled water to volume, and mix (the procedure as above is the method to make stock solution). Transfer 10.0 mL of arsenic trioxide stock solution to a 1000-mL volumetric flask, and add 10 mL of 2N dilute sulfuric acid, add recently boiled and cooled water to volume, and mix. Each mL of standard arsenic solution contains 1.0 μg of arsenic (As). Keep this solution in an all-glass container with stopper, and use within 3 days.

Test solution preparation:

NOTE:
1. Some substances may explode violently when digested with hydrogen peroxide. Operate carefully, be cautious at all times.
2. If halogen-containing compounds are present, use a

lower temperature while heating the test specimen with sulfuric acid, avoid boiling the mixture, before charring begins, and add the hydrogen peroxide carefully, to prevent loss of trivalent arsenic.

If non-specified in the monographs, take test specimen contained 10.0 μg of arsenic in a gas generating bottle. Add 5 mL of sulfuric acid and a few glass beads, and digest in a fume hood, until carbonization occurs. If necessary, add small amount of sulfuric acid to keep the test specimen moistened, but the total acid added is not more than 10 mL. Until the reaction complete, cool, carefully add 30 % hydrogen peroxide, after add the first drop and react completely, heat slightly, remove the burner, mix, then add the second drop, and repeat the procedure above. Slowly add the first few drops with sufficient mixing, in order to prevent a rapid reaction. Discontinue heating if foam becomes excessive. During the digestion, rotate the flask occasionally to prevent the specimen from caking on the glass bottom or glass wall. Maintain oxidizing conditions at all times during the digestion by adding small quantities of the hydrogen peroxide solution whenever the mixture turns brown or darken. Continue the digestion until the organic matter is digested completely, gradually raising the temperature of the hot plate until fumes of sulfur trioxide are copiously evolved, and the solution becomes colorless or only light yellow color. Cool, add 10 mL of water carefully, mix, and again evaporate to strong fuming, repeat this procedure to remove any trace of hydrogen peroxide. Cool, add 10 mL of water carefully, wash the sides of the flask with a few mL of water, and dilute with water to 35 mL as the test solution.

Procedure: To test specimen and standard, add 20 mL of dilute sulfuric acid (1 in 5), 2 mL of potassium iodide TS, 0.5 mL of stronger acid stannous chloride TS and 1 mL of isopropanol, mix (Add 1 mL isopropanol to the gas generating bottle to make the gas escape evenly.) and stand at room temperature for 30 minutes. Pack the scrubber tube with two pledgets that have been soaked in saturated lead acetate solution and squeezed to dryness, leaving an interspace between the two pledgets. Dry the tube in vacuum at room temperature. Transfer 3.0 mL of silver diethyldithiocarbamate TS to the absorber tube, add 3.0 g of granular zinc (No. 20 sieve) to the mixture in the flask, immediately connect the assembled scrubber unit, Place the flask in a water boiler at 25 ± 3℃, swirling the flask gently every 10 minutes. After 45 minutes, transfer the absorbing solution to a 1-cm absorption cell, determine the absorbance at the wavelength of maximum absorbance in 525 nm, using silver diethyldithio-carbamate TS as the blank. The absorbance of the test solution is lower than the standard solution under the same monograph.

Interfering chemicals: Metals or salts of metals, such as chromium, cobalt, copper, mercury, molybdenum, nickel, palladium, silver may interfere the production of arsine. Antimony, which forms stibine, reacts with silver diethyldithiocarbamate TS and produces the color, but the absorbance of the color is at the wavelength of 525 nm, since at this wavelength the interference due to stibine is negligible.

(2221) Chlorides and Sulfates

The following tests are provided as general procedures for use where limits for chloride or sulfate are specified in the individual monograph. Use the same quantities of the same reagents for both the sample solution under test and the control solution containing the specified amount of chloride or sulfate. If, after acidification, the solution is not perfectly clear, pass it through a filter paper that gives negative tests for chloride and sulfate. Add the precipitant, silver nitrate or barium chloride as required, to both the test solution and the control solution in immediate sequence. When comparing the turbidity, place the solution in colorimetric tubes which are same in diameter and observe the solution in the specified time.

Where the individual monograph calls for applying the test to a specific volume of a test solution of the substance, if chloride or sulfate content are corresponded to 0.20 mL or less of 0.020 N hydrochloric acid or sulfuric acid, use the solution directly on the test without further dilution. In such cases maintain the same volume relationships for the control solution as specified for the solution under test. In applying the test to the salts of heavy metals, which normally show the acidic reaction in solution, the acidification can be omitted in the procedure, and do not neutralize the solution. For detecting bismuth salt samples, dissolve bismuth salts in a small quantity of water and 2 mL of nitric acid, then determine the solution as above.

Chlorides: Dissolve the specified quantity of sample in 30~40 mL of water. If the sample had been prepared in solution already, make up chloride solution with the sample solution to a total volume of 30~40 mL by adding extra water. If necessary, use litmus paper as an indicator, and neutralize the solution with nitric acid. Add 1 mL of nitric acid, 1 mL of silver nitrate TS and sufficient water to make 50 mL solution. Mix well and allow it to stand for 5 minutes in dark. Unless otherwise directed in the monographs. If any turbidity occurs, compare the turbidity with the solution containing 0.020 N of hydrochloric acid specified in the monographs.

Sulfates: Dissolve the specified quantity of the sample in 30~40 mL of water. If the sample had been prepared in solution already, make up sulfate solution with the sample solution to total volume of 30~40 mL by adding extra water. If necessary, use litmus paper as an indicator, and neutralize the solution with hydrochloric acid. Add 1 mL of 3 N dilute hydrochloric acid, 3 mL of barium chloride, and sufficient water to make 50 mL solution. Mix well, stand for 10 minutes. Unless otherwise directed in the monographs, compare the turbidity with the solution containing 0.020 N sulfuric acid specified in the monographs.

(2251) Lead (Pb)

All reagents used in this method do not contain lead, and should be stored in borosilicate glasses. Rinse all glassware thoroughly with warm dilute nitric acid (1in2), and then rinse by water.

Solution preparation

Ammonia-cyanide solution: Dissolve 2.0 g of potassium cyanide in 15 mL of concentrated ammonium hydroxide, and dilute with appropriate amount of water to 100 mL.

Ammonium citrate solution: Dissolve 40.0 g of citric acid in 90 mL of water. Add 2 or 3 drops of phenol red TS, then cautiously add concentrated ammonium hydroxide until the solution appears a reddish color. Remove any lead that may contain in the solution by extracting with dithizone extraction solution, 20-mL each time, until the dithizone solution retains orange-green color.

Diluted standard lead solution: Dilute 10 mL of standard lead solution containing 10.0 µg of lead per mL (General rule 6301), with dilute nitric acid to 100 mL (1 in 100) and obtain a diluted solution that contains 1.0 µg of lead per mL.

Dithizone extraction solution: Dissolve 30 mg of dithizone in 1000 mL of chloroform, and add 5 mL of alcohol. Store the solution in a refrigerator. Before use, shake a portion of the dithizone extraction solution with half portion of dilute nitric acid (1 in 100), discarding the nitric acid in the water layer.

Hydroxylamine hydrochloride solution: Dissolve 20.0 g of hydroxylamine hydrochloride in sufficient water to make approximately 65 mL. Transfer to a separator, add 5 drops of thymol blue TS, and add ammonium hydroxide until the solution appears a yellow color. Add 10 mL of sodium diethyldithiocarbamate solution (1 in 25), mix, and stand for 5 minutes. Extract this solution with successive 10~15 mL portions of chloroform, until a 5 mL portion of the chloroform extract does not appear a yellow color when shaken with cupric sulfate TS. Add 3N dilute hydrochloric acid until the solution is pink, if necessary, add one to two drops of thymol blue TS, and then dilute with water to 100 mL.

Potassium cyanide solution: Dissolve 50.0 g of potassium cyanide in sufficient water to make 100 mL. Remove the lead from this solution by extraction with successive portions of dithizone extraction solution, follow the method as described under ammonium citrate solution above, then extract any dithizone remaining in the cyanide solution by shaking with chloroform. Finally dilute the cyanide solution with sufficient water so that each 100 mL contains 10.0 g of potassium cyanide.

Standard dithizone solution: Dissolve 10.0 mg of dithizone in 1000 mL of chloroform. Keep the solution in a glass-stopper, lead-free bottle, suitably wrapped to protect it from light, and store in a refrigerator.

NOTE: The special reagents are used for the determination of lead in ferrous sulfate.

Potassium cyanide citrate: Add 50 mL of ammonium citrate and 4 mL of potassium cyanide to 50 mL of water, then well mix. Adjust to pH 9 by concentrated ammonium hydroxide, if necessary.

pH 2.5 buffer solution: Add 37.0 mL of 0.1 N hydrochloric acid to 25.0 mL of 0.2 M potassium hydrogen phthalate solution, add water to 100 mL.

Dithizone-carbon tetrachloride solution: Dissolve 10.0 mg of dithizone in 1000 mL carbon tetrachloride. The solution can only use one day.

pH 2.5 lotion: Take 500 mL of dilute nitric acid(1 in 100), adjust to pH 2.5 by adding ammonia solution, then add 10 mL of pH 2.5 buffer solution, mix.

Ammonia-cyanide lotion: Add 4 mL of ammonia-cyanide solution to 35 mL of pH 2.5 lotion, mix.

Test solution preparation: Unless otherwise directed in the monographs, prepare a test preparation as follows:

Caution— operate in this procedure carefully, as some substances may explosive violently when digested with hydrogen peroxide. Transfer 1.0 g of the test specimen to a suitable flask, add 5 mL of sulfuric acid and a few glass beads, and digest on a hot plate in a hood until charring begins. Other suitable means of heating may be substituted. Add additional sulfuric acid, if necessary, to wet the test specimen completely, but do not add more than a total of 10 mL. After the reaction finished, cool, drop 30% hydrogen peroxide with caution, after first drop reacts completely, heat gently, stop the heat, shake, and then add second drop, repeat the procedure carefully. Add the first few drops very slow, mix carefully to prevent a rapid reaction, and discontinue heating if foaming becomes excessive. Swirl the solution to prevent unreacted substance from caking on the walls or bottom of the flask. Add peroxide whenever the mixture turns brown or darkens. Continue the digestion until the substance is completely decomposed and produced copious fumes of sulfur trioxide, and the solution is colorless or slightly yellow, and cool.

Procedure: Place the test solution in a separator, unless otherwise directed in the monographs, operate as described below: add 6 mL of ammonium citrate solution and 2 mL of hydroxylamine hydrochloride solution. For the determination of lead in iron salts use 10 mL of ammonium citrate solution. Add 2 drops of phenol red TS, and make the solution alkaline in red color by the addition of ammonium hydroxide. Cool the solution if necessary, and add 2 mL of potassium cyanide solution, immediately extract the solution with 5 mL portions of dithizone

extraction solution several times, until the dithizone solution retains in green color, draining off each extract into another separator. Shake the combined dithizone solutions for 30 seconds with 20 mL of dilute nitric acid (1 in 100), and discard the chloroform layer. Add 5.0 mL of standard dithizone solution and 4 mL of ammonia-cyanide solution to the acid solution, and shake for 30 seconds: the color of the chloroform layer is violet which is not darker than the control solution under examination. The control solution is made with a volume of diluted standard lead solution (the lead content is equivalent to the lead limit in the test specimen).

(2281) Residue on Ignition

Ignite a suitable crucible at about 600℃, cool the crucible in a desiccator, and weigh it accurately. Weigh accurately 1~2 g of test sample specified in the individual monograph in the crucible and weigh accurately again. Ignite the crucible gently and slowly, until it is thoroughly charred, cool. Unless otherwise directed, add 1 mL of sulfuric acid, then ignite at 600 ± 25℃ until the residue is completely incinerated. Cool the crucible in a desiccator and weigh accurately, and calculate the percentage of residue. If the amount of the residue obtained exceeds the limit specified in the individual monograph, add 1 mL of sulfuric acid, again and repeat the procedures as described above.

(2525) Sulfur Dioxide

The following methods are provided for the determination of sulfur dioxide in pharmaceutical excipients.

1. Method I

(1) Procedure

Mix 20 g of the test specimen, accurately weighed, with 200 mL of an appropriate solvent as indicated in each individual monograph, and stir until a smooth suspension is obtained. Allow the test specimen mixture to remain undisturbed until most of the test specimen has settled, and filter the aqueous portion through paper (Whatman No. 1 or equivalent). To 100 mL of the clear filtrate add an additional solvent as indicated in each individual monograph, add 3 mL of starch TS, and titrate with 0.01 N iodine solution VS to the first permanent blue or purple color. Each 1.0 mL of 0.01 N iodine solution VS consumed corresponds to 0.003% of sulfur dioxide found.

2. Method II

(1) Procedure

Transfer about 50 ~ 100 g of the substance to be tested, accurately weighed, to a 250-mL conical flask, add 100 ~ 150 mL of water, and mix. Cool to between 5° and 10℃. While stirring with a magnetic stirrer, add 10 mL of cold 1.5 N sodium hydroxide (at a temperature between 5° and 10℃). Stir for an additional 20 seconds, and add 10 mL of starch indicator solution, prepared as follows: mix 10 g of soluble starch with 50 mL of cold water, transfer to 1000 mL of boiling water, stir until completely dissolved, cool, and add 1 g of salicylic acid preservative. (NOTE—Discard the solution after 1 month.). Add 10 mL of 2.0 N sulfuric acid (at a temperature between 5° and 10℃), and titrate immediately with 0.005 N iodine VS until a light blue color persists for 1 minute (see General rule 3062). Perform a blank determination, using 200 mL of water treated similarly to the solution under test, and make any necessary correction. Each mL of 0.005 N iodine is equivalent to 0.16 mg of SO_2.

3. Method III

(1) Procedure

Dissolve 20.0 g of the test specimen in 150 mL of hot water in a flask having a round bottom and a long neck, add 5 mL of phosphoric acid and 1 g of sodium bicarbonate, and at once connect the flask to a condenser. (NOTE—Excessive foaming can be alleviated by the addition of a few drops of a suitable antifoaming agent.) Distill 50 mL, receiving the distillate under the surface of 50 mL of 0.1 N iodine. Acidify the distillate with a few drops of hydrochloric acid, add 2 mL of barium chloride TS, and heat on a steam bath until the liquid is nearly colorless. The precipitate of barium sulfate, if any, when filtered, washed, and ignited, weighs not more than 3 mg, corresponding to not more than 0.004% of sulfur dioxide, correction being made for any sulfate that may be present in 50 mL of the 0.1 N iodine. Acidify the distillate with a few drops of hydrochloric acid, add 2 mL of barium chloride TS, and heat on a steam bath until the liquid is nearly colorless. The precipitate of barium sulfate, if any, when filtered, washed, and ignited, weighs not more than 3 mg, corresponding to not more than 0.004% of sulfur dioxide, correction being made for any sulfate that may be present in 50 mL of the 0.1 N iodine.

4. Method IV

In this test, sulfur dioxide is released from the test specimen in a boiling acid medium and is removed by a stream of carbon dioxide. The separated gas is collected in a dilute hydrogen peroxide solution, in which the sulfur dioxide is oxidized to sulfuric acid and titrated with standard alkali, using a pH meter to control the pH value and titration. This test is performed under conditions such that the requirements specified in the system suitability test are met.

(1) Special Reagents

a. Carbon Dioxide:

Use carbon dioxide with a flow regulator that will maintain a flow of 100 ± 10 mL per minute.

b. Hydrogen Peroxide Solution:

Dilute 30% hydrogen peroxide with water to obtain a 3% solution. Neutralize the 3% hydrogen peroxide solution with 0.01 N sodium hydroxide to a pH of 4.1 determined potentiometrically.

c. Potassium Metabisulfite Solution:
Transfer 0.87 g of potassium metabisulfite ($K_2S_2O_5$) and 0.2 g of edetate disodium to a 1000-mL volumetric flask. Dilute with water to volume before mixing. (NOTE—Edetate disodium is used to protect sulfite ion from oxidation.)

(2) Apparatus
A suitable apparatus for sulfur dioxide determination is shown in the accompanying diagram (Figure 1). The apparatus consists of a 500 mL three-neck, round-bottom boiling flask, A; a separatory funnel, B, having a capacity of 100 mL or greater; a gas inlet tube of sufficient length to permit introduction of the carbon dioxide within 2.5 cm of the bottom of the boiling flask; a reflux condenser, C, having a jacket length of 200 mm; and a delivery tube, E, connecting the upper end of the reflux condenser to the bottom of a receiving test tube, D. Apply a thin film of stopcock grease to the sealing surfaces of all joints except the joint between the separatory funnel and the boiling flask, and clamp the joints to ensure tightness.

(3) System Suitability Test

a. Test A:
Using the Potassium Metabisulfite Solution as the standard, proceed as directed for Procedure, except replace the 25.0 g of test substance with 20 mL of Potassium Metabisulfite Solution. Calculate the content, in mg per mL, of sulfur dioxide in the Potassium Metabisulfite Solution taken by the formula:

$$1000(32.03)\ VN/V_P$$

in which the factor 1000 converts mg to mg; 32.03 is the milliequivalent weight of sulfur dioxide; V is the volume, in mL, of titrant consumed; N is the normality of the titrant; and V_P is the volume, in mL, of the Potassium Metabisulfite Solution taken for the test.

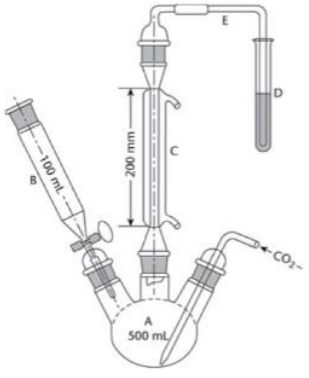


Figure 1. Apparatus for Method IV.

b. Test B:
In a 100-mL conical flask, add 20 mL of 0.02 N iodine solution and 5 mL of 2 N hydrochloric acid. Add 1 mL of starch TS, and titrate with the Potassium Metabisulfite Solution until the first discoloration is observed. Calculate the content, in mg per mL, of sulfur dioxide in the Potassium Metabisulfite Solution by the formula:

$$1000(32.03)\ V_I N_I/V_P$$

in which 1000 and 32.03 are defined above; V_I is the volume, in mL, of the iodine solution used in the test; N_I is the normality of the iodine solution; and V_P is the volume, in mL, of the Potassium Metabisulfite Solution consumed.
The difference between the sulfur dioxide contents obtained from Test A and Test B is not more than 5% of their mean value. Test B shall be performed within 15 minutes after completion of Test A. (NOTE—This avoids a potential variation of the sulfur dioxide content in the Potassium Metabisulfite Solution when stored at room temperature).

(4) Procedure
Add 150 mL of water to the boiling flask (A). Close the stopcock of the separatory funnel, and begin the flow of carbon dioxide at a rate of 100 ± 5 mL per minute through the apparatus. Start the condenser coolant flow. Place 10 mL of Hydrogen Peroxide Solution in the receiving test tube (D). After 15 minutes, without interrupting the flow of carbon dioxide, remove the separatory funnel (B) from the boiling flask, and transfer 25.0 g of the test specimen to the boiling flask with the aid of 100 mL of water. Apply stopcock grease to the outer joint of the separatory funnel, and replace the separatory funnel in the boiling flask. Close the stopcock of the separatory funnel, and add 80 mL of 2 N hydrochloric acid to the separatory funnel. Open the stopcock of the separatory funnel to permit the hydrochloric acid solution to flow into the boiling flask, guarding against escape of sulfur dioxide into the separatory funnel by closing the stopcock before the last few mL of hydrochloric acid drain out. Boil the mixture for 1 hour. Open the stopcock of the funnel, stop the flow of carbon dioxide, discontinue heating the flask, and turn off the cooling water in the condenser. Remove the receiving test tube, and transfer its contents to a 200 mL wide-necked, conical flask. Rinse the receiving test tube with a small portion of water, add the rinsing to the 200 mL conical flask, and mix. Heat on a water bath for 15 minutes, and allow to cool. Add 0.1 mL of bromophenol blue TS, and titrate the contents with 0.1 N sodium hydroxide VS until the color changes from yellow to violet-blue, with the color change lasting for at least 20 seconds. Perform a blank determination and make any necessary correction (see General

rule 3062). Calculate the content, in mg per g, of sulfur dioxide in the test specimen taken by the formula:

$$1000(32.03)\ VN/W$$

in which the factor 1000 converts mg to mg; 32.03 is the milliequivalent weight of sulfur dioxide; *V* is the volume, in mL, of titrant consumed; *N* is the normality of the titrant; and *W* is the weight, in g, of the test specimen taken.

5. Method V

In this method, similar to Method IV, sulfur dioxide is released from the test specimen in a boiling acid medium and is removed by a stream of nitrogen. The separated gas is collected in a dilute hydrogen peroxide solution, in which the sulfur dioxide is oxidized to sulfuric acid and titrated with standard alkali, using methyl red as an indicator. This test is performed under conditions such that the requirements specified in the system suitability test are met.

(1) Special Reagents

a. Hydrogen Peroxide Solution:
Dilute a portion of 30 percent hydrogen peroxide with water to obtain a 3% solution. Just before use, add 3 drops of methyl red TS, and neutralize to a yellow endpoint with 0.01 N sodium hydroxide. Do not exceed the endpoint.

b. Nitrogen:
Use high-purity nitrogen with a flow regulator that will maintain a flow of 200 ± 10 mL per minute. Guard against the presence of oxygen by passing the nitrogen through a scrubber, such as alkaline pyrogallol, prepared as follows: add 4.5 g of pyrogallol to a gas-washing bottle, purge the bottle with nitrogen for 3 minutes, and add a solution containing 85 mL of water and 65 g of potassium hydroxide while maintaining an atmosphere of nitrogen in the bottle.

c. Potassium Metabisulfite Solution:
Transfer 0.87 g of potassium metabisulfite ($K_2S_2O_5$) and 0.2 g of edetate disodium to a 1000-mL volumetric flask. Dilute with water to volume before mixing. (NOTE—Edetate disodium is used to protect sulfite ion from oxidation.)

(2) Apparatus

The apparatus (see Figure 2) is designed to effect the selective transfer of sulfur dioxide from the specimen in boiling aqueous hydrochloric acid to the Hydrogen Peroxide Solution in vessel G. The backpressure is limited to the unavoidable pressure due to the height of the Hydrogen Peroxide solution above the tip of the bubbler, F. Keeping the backpressure as low as possible reduces the likelihood that sulfur dioxide will be lost through leaks. Preboil vinyl and silicone tubing. Apply a thin film of stopcock grease to the sealing surfaces of all joints, except the joint between the separatory funnel and the flask, and clamp the joints to ensure tightness. The separatory funnel, B, has a capacity of 100 mL or greater. The inlet adapter, A, with a hose connector provides a means of applying headpressure over the solution. (NOTE— A pressure-equalizing dropping funnel is not recommended because condensate, which may contain sulfur dioxide, is deposited in the funnel and the side arm).

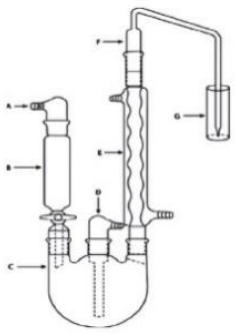


Figure 2. Apparatus for Method V

The round-bottom flask, C, is a 1000-mL flask with three 24/40 tapered joints. The gas inlet tube, D, is long enough to permit introduction of the nitrogen to within 2.5 cm of the bottom of the flask. The Allihn condenser, E, has a jacket length of 300 mm. The bubbler, F (see Figure 3), is fabricated from glass according to the dimensions given in Figure 3. The Hydrogen Peroxide Solution is contained in the vessel, G, having an inside diameter of about 2.5 cm and a depth of about 18 cm. Circulate coolant, such as a mixture of water and methanol (4:1) maintained at 5℃, to chill the condenser.

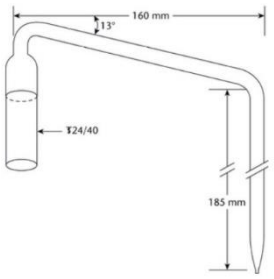


Figure 3. Bubbler (F) for apparatus in Method V.

(3) System Suitability Test

a. Test A:
Using the Potassium Metabisulfite Solution as the standard, proceed as directed for Procedure, except replace the 50.0 g of test substance with 20 mL of Potassium Meta bisulfite Solution. Calculate the content, in mg per mL, of sulfur dioxide in the Potassium Metabisulfite Solution taken by the formula:

$$1000(32.03)\ VN/V_P$$

in which the factor 1000 converts mg to mg; 32.03 is the milliequivalent weight of sulfur dioxide; V is the volume, in mL, of titrant consumed; N is the normality of the titrant; and V_P is the volume, in mL, of Potassium Metabisulfite Solution taken for the test.

b. Test B:

In a 100-mL conical flask, add 20 mL of 0.02 N iodine solution and 5 mL of 2 N hydrochloric acid. Add 1 mL of starch TS, and titrate with the Potassium Metabisulfite *Solution* until the first discoloration is observed. Calculate the content, in mg per mL, of sulfur dioxide in the Potassium Metabisulfite Solution by the formula:

$$1000(32.03)\ V_I N_I / V_P$$

in which 1000 and 32.03 are defined above; V_I is the volume, in mL, of iodine solution used in the test; N_I is the normality of the iodine solution; and V_P is the volume, in mL, of Potassium Metabisulfite Solution consumed.

The difference between the sulfur dioxide contents obtained from Test A and Test B is not more than 5% of their mean value. Test B shall be performed within 15 minutes after completion of Test A. (NOTE—This avoids a potential variation of the sulfur dioxide content in the Potassium Metabisulfite Solution when stored at room temperature.)

(4) Procedure

Position the apparatus in a heating mantle controlled by a power regulating device. Add 400 mL of water to the flask. Close the stopcock of the separatory funnel, and add 90 mL of 4 N hydrochloric acid to the separatory funnel. Begin the flow of nitrogen at a rate of 200 ± 10 mL per minute. Start the condenser coolant flow. Add 30 mL of Hydrogen Peroxude Solution to the vessel (G). After 15 minutes, remove the separatory funnel, and transfer a mixture of 50.0 g of the test specimen, accurately weighed, and 100 mL of alcohol solution (5 in 100) to the flask. Apply stopcock grease to the outer joint of the separatory funnel, return the separatory funnel to the tapered joint flask, and concomitantly resume the nitrogen flow. Apply headpressure above the hydrochloric acid solution in the separatory funnel with a rubber bulb equipped with a valve. Open the stopcock of the separatory funnel to permit the hydrochloric acid solution to flow into the flask. Continue to maintain sufficient pressure above the hydrochloric acid solution to force it into the flask. (NOTE— The stopcock may be temporarily closed, if necessary, to increase the pressure.) To guard against escape of sulfur dioxide into the separatory funnel, close the stopcock before the last few mL of hydrochloric acid drain out. Apply power to the heating mantle sufficient to cause about 85 drops of reflux per minute. After refluxing for 1.75 hours, remove the vessel (G), add 3 drops of methyl red TS, and titrate the contents with 0.01 N sodium hydroxide VS, using a 10-mL buret with an overflow tube and a hose connection to a carbon dioxide-absorbing tube, to a yellow endpoint that persists for at least 20 seconds. Perform a blank determination, and make any necessary correction (see General rule 3062). Calculate the quantity, in mg, of SO_2 in each g of the test specimen taken by the formula:

$$1000(32.03)\ VN/W$$

in which the factor 1000 converts mg to mg; 32.03 is the milliequivalent weight of sulfur dioxide; V is the volume, in mL, of titrant consumed; N is the normality of the titrant; and W is the weight, in g, of the test specimen taken.

III. General Determinations

(3061) Microbiological Examination of Nonsterile Products

(3061) Microbial enumeration tests

The tests described hereafter will allow quantitative enumeration of mesophilic bacteria and fungi that may grow under aerobic conditions. The tests are designed primarily to determine whether a substance or preparation complies with an established specification for microbiological quality. When used for such purposes, follow the instructions given below, including the number of samples to be taken, and interpret the results as stated below.

The methods are not applicable to products containing viable microorganisms as active ingredients. Alternative microbiological procedures, including automated methods, may be used, provided that their equivalence to the pharmacopeial method has been demonstrated.

Carry out the determination under conditions designed to avoid extrinsic microbial contamination of the product to be examined. The precautions taken to avoid contamination must be such that they do not affect any microorganisms that are to be revealed in the test. If the product to be examined has antimicrobial activity, this is, insofar as possible, removed or neutralized. If inactivators are used for this purpose, their efficacy and their absence of toxicity for microorganisms must be demonstrated.

If surface-active substances are used for sample preparation, their absence of toxicity for microorganisms and their compatibility with any inactivators used must be demonstrated.

The choice of a method is based on factors such as the nature of the product and the required limit of microorganisms. The method chosen must allow testing of a sufficient sample size to judge compliance with the specification. The suitability of the chosen method must be established.

Use the membrane filtration method or one of the plate count methods, as directed. The most-probable-number (MPN) method is generally the least accurate method for microbial counts; however, for certain product groups with very low bioburden, it may be the most appropriate method.

I. Applicability of medium potency test, counting method and negative control

(1) General considerations
The ability of the test to detect microorganisms in the presence of product to be tested must be established. Suitability must be confirmed if a change in testing performance or a change in the product that may affect the outcome of the test, is introduced.

(2) Preparation of test strains
Use standardized stable suspensions of test strains or prepare as stated below. Seed-lot culture maintenance techniques (seed-lot systems) are used so that the viable microorganisms used for inoculation are not more than five passages removed from the original master seed-lot. Grow each of the bacterial and fungal test strains separately as described in Table 1.
Use buffered sodium chloride–peptone solution pH 7.0 or phosphate buffer solution pH 7.2 to make test suspensions; to suspend *A. brasiliensis* spores, 0.05% of polysorbate 80 may be added to the buffer. Use the suspensions within 2 hours, or within 24 hours if stored between 2℃~8℃. As an alternative to preparing and then diluting a fresh suspension of vegetative cells of *A. brasiliensis* or *B. subtilis*, a stable spore suspension is prepared and then an appropriate volume of the spore suspension is used for test inoculation. The stable spore suspension may be maintained at 2℃~8℃for a validated period of time.

(3) Negative control
To verify testing conditions, a negative control is performed using the chosen diluent in place of the test preparation. There must be no growth of microorganisms. A negative control is also performed when testing the products as described under Testing of Products. A failed negative control requires an investigation.

(4) Growth promotion of the media
Test each batch of ready-prepared medium and each batch of medium prepared either from dehydrated medium or from the ingredients described.
Inoculate portions/plates of Soybean–Casein Digest Broth and Soybean–Casein Digest Agar with a small number (not more than 100 CFU) of the microorganisms indicated in Table 1, using a separate portion/plate of medium for each.
For solid media, growth obtained must not differ by a factor greater than 2 from the calculated value for a standardized inoculum. For a freshly prepared inoculum, growth of the microorganisms comparable to that previously obtained with a previously tested and approved batch of medium occurs. Liquid media are suitable if clearly visible growth of the microorganisms comparable to that previously obtained with a previously tested and approved batch of medium occurs.

(5) Suitability of the counting method in the presence of product
1. Preparation of the sample
The method for sample preparation depends on the physical characteristics of the product to be tested. If none of the procedures described below can be demonstrated to be satisfactory, a suitable alternative procedure must be developed.
   a. Water-soluble products—dissolve or dilute (usually a 1 in 10 dilution is prepared) the product to be examined in buffered sodium chloride–peptone solution pH 7.0, phosphate buffer solution pH 7.2, or Soybean–Casein Digest Broth. If necessary, adjust to a pH of 6~8. Further dilutions, where necessary, are prepared with the same diluent.
   b. Non-fatty products insoluble in water suspend the product to be examined (usually a 1 in 10 dilution is prepared) in buffered sodium chloride–peptone solution pH 7.0, phosphate buffer solution pH 7.2, or soybeancasein digest broth. A surface-active agent such as 1 g per L of polysorbate 80 may be added to assist the suspension of poorly wet table substances. If necessary, adjust to a pH of 6~8. Further dilutions, where necessary, are prepared with the same diluent.
   c. Fatty products—Dissolve in isopropyl myristate sterilized by filtration, or mix the product to be examined with the minimum necessary quantity of sterile polysorbate 80 or another non-inhibitory sterile surface-active reagent heated, if necessary, to not more than 40℃ or, in exceptional cases, to not more than 45℃. Mix carefully and if necessary maintain the temperature in a water bath.
   Add a sufficient quantity of the prewarmed chosen diluent to make a 1 in 10 dilution of the original product. Mix carefully, while maintaining the temperature for the shortest time necessary for the formation of an emulsion. Further serial 10-fold dilutions may be prepared using the chosen diluent containing a suitable concentration of sterile polysorbate 80 or another non-inhibitory sterile surface-active reagent.
   d. Fluids or solids in aerosol form— Aseptically transfer the product into a membrane filter apparatus or a sterile container for further sampling. Use either the total contents or a defined number of metered doses from each of the containers tested.
   e. Transdermal patches— Remove the protective cover sheets (“release liners”) of the transdermal patches and place them,

adhesive side upwards, on sterile glass or plastic trays. Cover the adhesive surface with a suitable sterile porous material (e.g., sterile gauze) to prevent the patches from sticking together, and transfer the patches to a suitable volume of the chosen diluent containing inactivators such as polysorbate 80 and/or lecithin. Shake the prepartion vigorously for at least 30 minutes.

Table 1. Preparation and Use of Test Microorganisms

Microorganism	Preparation of Test Strain [2]	Growth Promotion		Suitability of Counting Method in the Presence of Product	
		Total Aerobic Microbial Count	Total Yeasts and Molds Count	Total Aerobic Microbial Count	Total Yeasts and Molds Count
Staphylococcus aureus (such as ATCC 6538[1], BCRC 12154)	Soybean–Casein Digest Agar or Soybean–Casein Digest Broth 30~35℃ 18–24 hours	Soybean–Casein Digest Agar and Soybean–Casein Digest Broth ≤100 CFU 30~35℃ ≤3 days		Soybean–Casein Digest Agar/MPN Soybean–Casein Digest Brot ≤100 CFU 30~35℃ ≤3 days	
Pseudomonas aeruginosa (such as ATCC 9027, BCRC 11633)	Soybean–Casein Digest Agar or Soybean–Casein Digest Broth 30~35℃ 18–24 hours	Soybean–Casein Digest Agar and Soybean–Casein Digest Broth ≤100 CFU 30~35℃ ≤3 days		Soybean–Casein Digest Agar/MPN Soybean–Casein Digest Broth ≤100 CFU 30~35℃ ≤3 days	
Bacillus subtilis (such as ATCC 6633, BCRC 10447)	Soybean–Casein Digest Agar or Soybean–Casein Digest Broth 30~35℃ 18–24 hours	Soybean–Casein Digest Agar and Soybean–Casein Digest Broth ≤100 CFU 30~35℃ ≤3 days		Soybean–Casein Digest Agar/MPN Soybean–Casein Digest Broth ≤100 CFU 30~35℃ ≤3 days	
Candida albicans (such as ATCC 10231, BCRC 21538)	Sabouraud Dextrose Agar or Sabouraud Dextrose Broth 20~25℃ 2–3 days	Soybean–Casein Digest Agar and Soybean–Casein Digest Broth ≤100 CFU 30~35℃ ≤3 days	Sabouraud Dextrose Agar ≤100 CFU 20~25℃ ≤5 days	Soybean–Casein Digest Agar ≤100 CFU ≤5 days MPN: not applicable	Sabouraud Dextrose Agar ≤100 CFU 20~25℃ ≤5 days
Aspergillus brasiliensis (such as ATCC 16404, BCRC 30506)	Sabouraud Dextrose Agar or Potato–Dextrose Agar 20~25℃ 5–7 days, or until good sporulation is achieved	Soybean–Casein Digest Agar and Soybean–Casein Digest Broth ≤100 CFU 30~35℃ ≤3 days	Sabouraud Dextrose Agar ≤100 CFU 20~25℃ ≤5 days	Soybean–Casein Digest Agar ≤100 CFU ≤5 days MPN: not applicable	Sabouraud Dextrose Agar ≤100 CFU 20~25℃ ≤5 days

Note 1: ATCC 6538 is a number which included in American Type Culture Collection (ATCC) and so on；BCRC 12154 is a number which included in Bioresource Collection and Research Center, FIRDI, ROC and so on.
Note 2: The volume of the test strain suspension should not exceed the volume of test solution 1%

【See I. (1) General considerations】

2. Inoculation and dilution add to the sample prepared as directed above and to a control (with no test material included) a sufficient volume of the microbial suspension to obtain an inoculum of not more than 100 CFU. The volume of the suspension of the inoculum should not exceed 1% of the volume of diluted product.

   To demonstrate acceptable microbial recovery from the product, the lowest possible dilution factor of the prepared sample must be used for the test. Where this is not possible due to antimicrobial activity or poor solubility, further appropriate protocols must be developed. If inhibition of growth by the sample cannot otherwise be avoided, the aliquot of the microbial suspension may be added after neutralization.

3. Neutralization/removal of antimicrobial activity: The number of microorganisms recovered from the prepared sample diluted as described in inoculation and dilution and incubated following the procedure described in recovery of microorganisms in the Presence of Product, is compared to the number of microorganisms recovered from the control preparation. If growth is inhibited (reduction by a factor greater than 2), then modify the procedure for the particular enumeration test to ensure the validity of the results. Modification of the procedure may include, for example, (i) An increase in the

volume of the diluent or culture medium; (ii) Incorporation of a specific or general neutralizing agents into the diluent (iii) Membrane filtration; or (iv) A combination of the above measures.

Neutralizing agents—Neutralizing agents may be used to neutralize the activity of antimicrobial agents (see Table 2). They may be added to the chosen diluent or the medium preferably before sterilization. If used, their efficacy and their absence of toxicity for microorganisms must be demonstrated by carrying out a blank with neutralizer and without product.

If no suitable neutralizing method can be found, it can be assumed that the failure to isolate the inoculated organism is attributable to the microbicidal activity of the product. This information serves to indicate that the article is not likely to be contaminated with the given species of the microorganism. However, it is possible that the product inhibits only some of the microorganisms specified herein, but does not inhibit others not included among the test strains or those for which the latter are not representative. Then, perform the test with the highest dilution factor compatible with microbial growth and the specific acceptance criterion.

4. Recovery of microorganisms in the presence of product

For each of the strain listed on table 1, counted and separate tests are performed.

a. Membrane filtration—Use membrane filters having a nominal pore size not greater than 0.45 μm. The type of filter material is chosen in such a way that the bacteria retaining efficiency is not affected by the components of the sample to be investigated. For each of the micro-organisms listed, one membrane filter is used. Transfer a suitable quantity of the sample prepared as described under preparation of the sample, inoculation and dilution, and neutralization/removal of antimicrobial activity (preferably representing 1 g of the product, or less if large numbers of CFU are expected) to the membrane filter, filter immediately, and rinse the membrane filter with an appropriate volume of diluent.

For the determination of total aerobic microbial count (TAMC), transfer the membrane filter to the surface of the soybean–casein digest agar. For the determination of total combined yeasts and molds count (TYMC), transfer the membrane to the surface of the sabouraud dextrose agar. Incubate the plates as indicated in Table 1 perform the counting.

b. Plate-count methods — Perform plate-count methods at least in duplicate for each medium, and use the mean count.

i. Pour-plate method—For petri dishes 9 cm in diameter add to the dish 1 mL of the sample prepared as described under Preparation of the Sample, inoculation and dilution, and neutralization/ removal of antimicrobial activity and 15 to 20 mL of soybean–casein digest agar or sabouraud dextrose agar, both media maintained at not more than 45 ℃. If larger petri dishes are used, the amount of agar medium is increased accordingly. For each of the microorganisms listed in Table 1, at least two petri dishes are used. Incubate the plates as indicated in Table 1. Take the arithmetic mean of the counts per medium, and calculate the number of CFU in the original inoculum.

ii. Surface-spread method—For petri dishes 9 cm in diameter, add 15 to 20 mL of soybean–casein digest agar or sabouraud dextrose agar at about 45℃ to each petri dish and allow to solidify. If larger petri dishes are used, the volume of the agar is increased accordingly. Dry the plates, for example, in a laminar-airflow cabinet or in an incubator. For each of the microorganisms listed in Table 1, at least two petri dishes are used. Spread a measured volume of not less than 0.1 mL of the sample, prepared as directed under preparation of the sample, inoculation and dilution, and neutralization/removal of antimicrobial activity over the surface of the medium. Incubate and count as directed for pour- plate method.

Table 2. Common Neutralizing Agents/Methods for Interfering Substances

Interfering Substance	Potential Neutralizing Agents/Method
Glutaraldehyde, mercurials	Sodium hydrogen sulfite (Sodium bisulfite)
Phenolics, alcohol, aldehydes, sorbate	Dilution
Aldehydes	Glycine
Quaternary ammonium com- pounds (QACs), parahydroxybenzoates parabens, bis-iguanides	Lecithin
QACs, iodine, parabens	Polysorbate
Mercurials	Thioglycollate
Mercurials, halogens, aldehydes	Thiosulfate

c. Most-probable-number (MPN) method—The precision and accuracy of the MPN method is less than that of the membrane

filtration method or the plate-count method. Unreliable results are obtained particularly for the enumeration of molds. For these reasons, the MPN method is reserved for the enumeration of TAMC in situations where no other method is available. If the use of the method is justified method is available. If the use of the method is justified

Prepare a series of at least three serial 10-fold dilutions of the product as described for preparation of the sample, inoculation and dilution, and neutralization/removal of antimicrobial activity. From each level of dilution, three aliquots of 1.0 g or 1 mL are used to inoculate three tubes with 9 to 10 mL of Soybean–casein Digest Broth. If necessary a surfactant such as polysorbate 80, or an inactivator of antimicrobial agents may be added to the medium. Thus, if three levels of dilution are prepared, nine tubes are inoculated.

Incubate all tubes at 30℃~35℃ for not more than 3 days. If reading of the results is difficult or uncertain owing to the nature of the product to be examined, subculture in the same broth or in Soybean-Casein Digest Agar for 1 to 2 days at the same temperature, and use these results. From table 3, determine the most probable number of microorganisms per g or mL of the product to be examined.

Table 3. Most-Probable-Number Values of Microorganisms

Observed Combinations of Numbers of Tubes Showing Growth in Each Set			MPN per g or per mL of Product	95% Confidence Interval
Number of g or mL of Product per Tube				
0.1	0.01	0.001		
0	0	0	<3	0-9.4
0	0	1	3	0.1-9.5
0	1	0	3	0.1-10
0	1	1	6.1	1.2-17
0	2	0	6.2	1.2-17
0	3	0	9.4	3.5-35
1	0	0	3.6	0.2-17
1	0	1	7.2	4-35
1	0	2	11	1.3-20
1	1	0	7.4	4-35
1	1	1	11	4-35
1	2	0	11	5-38
1	2	1	15	5-38
1	3	0	16	1.5-35
2	0	0	9.2	4-35
2	0	1	14	5-38
2	0	2	20	4-38
2	1	0	15	5-38
2	1	1	20	9-94
2	1	2	27	5-40
2	2	0	21	9-94
2	2	1	28	9-94
2	2	2	35	9-94
2	3	0	29	9-94
2	3	1	36	9-94
3	0	0	23	5-94
3	0	1	38	9-104
3	0	2	64	16-181
3	1	0	43	9-181
3	1	1	75	17-199
3	1	2	120	30-360
3	1	3	160	30-380
3	2	0	93	18-360
3	2	1	150	30-380
3	2	2	210	30-400
3	2	3	290	90-990
3	3	0	240	40-990
3	3	1	460	90-1980
3	3	2	1100	200-4000
3	3	3	>1100	

5. Results and interpretation

When verifying the suitability of the membrane filtration method or the plate-count method, a mean count of any of the test organisms not differing by a factor greater than 2 from the value of the control defined in inoculation and dilution in the absence of product must be obtained. When verifying the suitability of the MPN method, the calculated value from the inoculum must be within 95% confidence interval of the results obtained with the control. If the above criteria cannot be met for one of more of the organisms tested with any of the described methods, the method and test conditions that come closest to the criteria are used to test the product.

II. Testing of products

(1) Amount used for the test.

Unless otherwise directed, use 10 g or 10 mL of the product to be examined taken with the precautions referred to above. For fluids or solids in aerosol form, sample 10 containers. For transdermal patches, sample 10 patches.

The amount to be tested may be reduced for active substances that will be formulated in the following conditions: the amount per dosage unit (e.g., tablet, capsule, injection) is less than or equal to 1 mg, or the amount per g or mL (for preparations not presented in dose units) is less than 1 mg. In these cases, the amount of sample to be tested is not less than the amount counted in 10 dosage units or 10 g or 10 mL of the product.

For materials used as active substances where the sample quantity is limited or batch size is extremely small (i.e., less than 1000 mL or 1000 g), the amount tested shall be 1% of the batch unless a lesser amount is prescribed or justified and authorized.

For products where the total number of entities in a batch is less than 200 (e.g., samples used in clinical

trials), the sample size may be reduced to two units, or one unit if the size is less than 100.

Select the sample(s) at random from the bulk material or from the available containers of the preparation. To obtain the required quantity, mix the contents of a sufficient number of containers to provide the sample.

(2) Examination of the product

1. Membrane Filtration

Use a filtration apparatus designed to allow the transfer of the filter to the medium. Prepare the sample using a method that has been shown to be suitable as described in growth promotion test and suitability of the counting method, transfer the appropriate amount to each of two membrane filters, and filter immediately. Wash each filter following the procedure shown to be suitable.

For the determination of TAMC, transfer one of the membrane filters to the surface of Soybean–Casein Digest Agar. For the determination of TYMC, transfer the other membrane to the surface of Sabouraud Dextrose Agar. Incubate the plate of Soybean–Casein Digest Agar at 30℃ ~35℃ for 3 to 5 days and the plate of Sabouraud Dextrose Agar at 20℃~25℃ for 5 to 7 days. Calculate the number of CFU per g or per mL of product.

When examining transdermal patches, separately filter 10% of the volume of the preparation described for preparation of the sample through each of two sterile filter membranes. Transfer one membrane to soybean–casein digest agar for TAMC and the other membrane to Sabouraud Dextrose Agar for TYMC.

2. Plate-count methods

a. Pour-plate method:

Prepare the sample using a method that has been shown to be suitable as described in growth promotion test and suitability of the counting method. Prepare for each medium at least two petri dishes for each level of dilution. Incubate the plates of Soybean–Casein Digest Agar at 30℃ to 35℃for 3 to 5 days and the plates of Sabouraud Dextrose Agar at 20℃~25℃ for 5 to 7 days. Select the plates corresponding to a given dilution and showing the highest number of colonies less than 250 for TAMC and 50 for TYMC. Take the arithmetic mean per culture medium of the counts, and calculate the number of CFU per g or per mL of product.

b. Surface-spread method:

Prepare the sample using a method that has been shown to be suitable as described in growth promotion test and suitability of the counting method. Prepare at least two petri dishes for each medium and each level of dilution. For incubation and calculation of the number of CFU, proceed as directed for the pour-plate method. Most-problem-number method.

【See II. (3) Interpretation of the results】

3. Prepare and dilute the sample using a method that has been shown to be suitable as described in growth promotion test and suitability of the counting method. Incubate all tubes for 3 to 5 days at 30℃ to 35℃. Subculture if necessary, using the procedure shown to be suitable. Record for each level of dilution the number of tubes showing microbial of dilution the number of tubes showing microbial growth. Determine the most probable number of microorganisms per g or mL of the product to be examined from Table 3.

(3) Interpretation of the results

The total aerobic microbial count (TAMC) is considered to be equal to the number of CFU found using soybean–casein digest agar; if colonies of fungi are detected on this medium, they are counted as part of TAMC. The total combined yeasts and molds count (TYMC) is considered to be equal to the number of CFU found using Sabouraud Dextrose Agar; if colonies of bacteria are detected on this medium, they are counted as part of TYMC. When the TYMC is expected to exceed the acceptance criterion due to the bacterial growth, Sabouraud Dextrose Agar containing antibiotics may be used. If the count is carried out by the MPN Method, the calculated value is TAMC. When an acceptance criterion for microbiological quality is prescribed, it is interpreted as follows:

10^1 CFU: maximum acceptable count = 20 CFU;

10^2 CFU: maximum acceptable count = 200 CFU;

10^3 CFU: maximum acceptable count = 2000 CFU; and so forth.

The recommended solutions and media are described in tests for Specified Microorganisms (3063).

(3063) Tests for Specified Microorganisms

The tests described hereafter will allow determination of the absence of, or limited occurrence of, specified microorganisms that may be detected under the conditions described.

The tests are designed primarily to determine whether a substance or preparation complies with an established specification for microbiological quality. When used for such purposes, follow the instructions given below, including the number of samples to be taken, and interpret the results as stated below.

Alternative microbiological procedures, including automated methods, may be used, provided that their equivalence to the pharmacopeial method has been demonstrated.

The preparation of samples is carried out as described in microbiological examination of nonsterile products: Microbial enumeration tests (3061).

If the product to be examined has antimicrobial activity, this is insofar as possible removed or neutralized as described in Microbiological Examination of Nonsterile Products: Microbial enumeration tests (3061).

If surface-active substances are used for sample preparation, their absence of toxicity for microorganisms and their compatibility with any inactivators used must be demonstrated as described in Microbiological Examination of None sterile Products: Microbial enumeration tests (3061).

I. The ability of the test to detect microorganisms in the presence of the product to be tested must be established. Suitability must be confirmed if a change in testing performance or a change in the product that may affect the outcome of the test is introduced.

(1) Preparation of test strains

Use standardized stable suspensions of test strains as stated below. Seed-lot culture maintenance techniques (seed-lot systems) are used so that the viable microorganisms used for inoculation are not more than five passages removed from the original master seed-lot.

a. Aerobic microorganisms

Grow each of the bacterial test strains separately in containers containing Soybean-Casein Digest Broth or on Soybean-Casein Digest Agar at 30~35℃ for 18 to 24 hours. Grow the test strain for *Candida albicans* separately on Sabouraud Dextrose Agar or in Sabouraud Dextrose Broth at 20~25℃ for 2 to 3 days.

Use buffered sodium chloride-peptone solution pH7.0 or phosphate buffer pH 7.2 to make test suspensions. Use the suspensions within 2h or within 24 h if stored at 2~8℃.

Staphylococcus aureus	such as ATCC 6538, BCRC 12154
Pseudomonas aeruginosa	such as ATCC 9027, BCRC 11633
Escherichia coli	such as ATCC 8739, BCRC 11634
Salmonella enterica ssp. *enterica* serovar. Typhimurium or, as an alternative	such as ATCC 14028, BCRC 10747
Salmonella enterica ssp. *enterica* serovar. Abony	such as ATCC BAA-2162
Candia albicans	such as ATCC 10231, BCRC 21538

b. Clostridia

Use *clostridium sporogenes* such as ATCC 11437 (BCRC 13856) or ATCC 19404 (BCRC 11258). Grow the clostridia test strain under anaerobic conditions in Reinforced Medium for Clostridia at 30~35℃ for 24 to 48 hours. As an alternative to preparing and then diluting down a fresh suspension of vegetative cells of *cl. sporogenes*, a stable spore suspension is used for test inoculation. The stable spore suspension may be maintained at 2~ 8℃ for a validated period.

(2) Negative control

To verify testing conditions, a negative control is performed using the chosen diluent in place of the test preparation. There must be no growth of microorganisms. A negative control is also performed when testing the products as described under testing of products. A failed negative control requires an investigation.

(3) Growth promotion and inhibitory properties of the media

Test each batch of ready-prepared medium and each batch of medium prepared either from dehydrated medium or from ingredients. Verify suitable properties of relevant media as described in table 1.

a. Test for growth-promoting properties, Liquid Media:

Inoculate a portion of the appropriate medium with a small number (not more than 100 CFU) of the appropriate microorganism. Incubate at the specified temperature for not more than the shortest period of time specified in the test. Clearly visible growth of the microorganism comparable to that previously obtained with a previously tested and approved batch of medium occurs.

b. Test for growth-promoting properties, solid media:

Perform surface-spread Method (see plate-count methods under microbiological examination of nonsterile products: Microbial enumeration tests (3061), inoculating each plate with a small number (not more than 100 CFU) of the appropriate microorganism. Incubate at the specified temperature for not more than the shortest period of time specified in the test. Growth of the microorganism comparable to that previously obtained with a previously tested and approved batch of medium occurs.

c. Test for inhibitory properties, liquid or solid media:

Inoculate the appropriate medium with at least 100 CFU of the appropriate microorganism. Incubate at the specified temperature for not less than the longest period of time specified in the test. No growth of the test microorganism occurs.

d. Test for indicative properties:

Perform surface-spread method (see plate-count methods under microbiological examination of nonsterile products: Microbial enumeration tests (3061), inoculating each plate with a small number (not more than 100 CFU) of the appropriate microorganism. Incubate at the specified temperature for a period of time within the range specified in the test. Colonies are comparable in appearance and indication reactions to those previously obtained with a previously tested and approved batch of medium.

(4) Suitability of the test method

For each new product to be tested perform sample preparation as described in the relevant paragraph under testing products. At the time of mixing, add each test strain in the prescribed growth medium. Inoculate the test strains individually. Use a number of microorganism equivalent to not more than 100 CFU in the inoculated test preparation.

Perform the test as described in the relevant paragraph under testing of products using the shortest incubation period prescribed. The specified microorganisms must be detected with the indication reactions as described under testing of products. Any antimicrobial activity of the product necessitates a modification of the test procedure (see neutralization/removal of antimicrobial activity under microbiological examination of nonsterile products: microbial enumeration tests (3061).

For a given product, if the antimicrobial activity with respect to a microorganism for which testing is prescribed cannot be neutralized, then it is to be assumed that the inhibited microorganism will not be present in the product.

Table 1. Growth promoting, inhibitory and indicative properties of media

Test/Medium	Property	Test Strains
Test for *bile-tolerant Gram-negative bacteria*		
Enterobacteria enrichment broth mossel	Growth promoting	*E. coli*
		P. aeruginosa
	Inhibitory	*S. aureus*
Violet red bile glucose agar	Growth promoting + indicative	*E. coli*
		P. aeruginosa
Test for *Eschreichia coli*		
MacConkey Broth	Growth promoting	*E. coli*
	Inhibitory	*S. aureus*
MacConkey Agar	Growth promoting + indicative	*E. coli*
Test for *salmonella*		
Rappaport vassiliadis enrichment broth	Growth promoting	*Salmonella enterica* ssp. *enterica* serovar *Typhiumurium* or *Salmonella enterica* ssp. *enterica* serovar. Abony
	Inhibitory	*S. aureus*
Xylose lysine deoxycholate enrichment broth	Growth promoting + indicative	*Salmonella enterica* ssp. *enterica* serovar *Typhiumurium* or *Salmonella enterica* ssp. *enterica* serovar Abony
	Identification test	*E. coli*
Test for *Pseudomonas aeruginosa*		
Cetrimide agar	Growth promoting	*P. aeruginosa*
	Inhibitory	*E. coli*
Test for *Pseudomonas aureus*		
Manntiol salt agar	Growth promoting + indicative	*S. aureus*
	Inhibitory	*E. coli*
Test for *Clostridia*		
Reinforcrd medium for clostridia	Growth promoting	*Cl. Sporogenes*
Columbia agar	Growth promoting	*Cl. Sporogenes*
Test for *Candida albicans*		
Sabouraud dextrose broth	Growth promoting	*C. albicans*
Sabouraud dextrose aguar	Growth promoting + indicative	*C. albicans*

II. Testing of products

【See I. (2) Negative control】

(1) Bile-Tolerant Gram-Negative Bacteria

a. Sample preparation and pre-incubation:

Prepare a sample using a 1 in 10 dilution of not less than 1 g of the product to be examined as described in microbiological examination of nonsterile products: microbial enumeration tests (3061), but using Soybean–Casein Digest Broth as the chosen diluent, mix, and incubate at 20~25 ℃ for a time sufficient to resuscitate the bacteria but not sufficient to encourage multiplication of the organisms (usually 2 hours but not more than 5 hours).

b. Test for absence

Unless otherwise prescribed, use the volume corresponding to 1 g of the product, as prepared in sample preparation and pre-incubation, to inoculate *enterobacteria enrichment broth mossel*. Incubate at 30~35℃ for 24 to 48 hours. Subculture on plates of violet red bile glucose agar. Incubate at 30~35℃ for 18 to 24 hours. The product complies with the test if there is no growth of colonies.

c. Quantitative Test:

i. Selection and subculture: Inoculate suitable quantities of *enterobacteria enrichment broth mossel* with the preparation as directed under sample preparation and pre-incubation and/or dilutions of it containing respectively 0.1 g, 0.01 g, and 0.001 g (or 0.1 mL, 0.01 mL, and 0.001 mL) of the product to be examined. Incubate at 30~35℃ for 24 to 48 hours. Subculture each of the cultures on a plate of violet red bile glucose agar. Incubate at 30~35 ℃for 18 to 24 hours.

ii. Interpretation—Growth of colonies constitutes a positive result. Note the smallest quantity of the product that gives a positive result and the largest quantity that gives a negative result. Determine from table 2 the probable number of bacteria.

Table 2. Interpretation of results

Results for each quantity of product			Probable number of bacteria per g or mL of product
0.1 g or 0.1 mL	0.01 g or 0.01 mL	0.001 g or 0.001 mL	
+	+	+	$>10^3$
+	+	-	$10^2<N<10^3$
+	-	-	$10<N<10^2$
-	-	-	<10

(2) *Escherichia coli*

a. Sample preparation and pre-incubation:
Prepare a sample using a 1 in 10 dilution of not less than 1 g of the product or 1 mL of test solution to be examined as described in microbiological examination of nonsterile products: Microbial enumeration tests (3061), and use 10 mL or the quantity corresponding to 1 g or 1 mL, to inoculate a suitable amount (determined as described under suitability of the test method) of Soybean-Casein Digest Broth, mix, and incubate at 30~35℃ for 18 to 24 hours.

b. Selection and subculture:
Shake the container, transfer 1 mL of Soybean–Casein Digest Broth to 100 mL of *MacConkey Broth*, and incubate at 42~44℃ for 24 to 48 hours. Subculture on a plate of *MacConkey Agar* at 30~35℃ for 18 to 72 hours.

c. Interpretation:
Growth of colonies indicates the possible presence of *E. coli.* is confirmed by identification tests. The product complies with the test if no colonies are present or if the identification tests are negative.

(3) *Salmonella*

a. Sample preparation and pre-Incubation:
Prepare the product to be examined as described in microbiological examination of nonsterile products: microbial enumeration tests (3061), and use the quantity corresponding to not less than 10 g or 10 mL to inoculate a suitable amount (determined as described under suitability of the test method) of soybean-casein digest broth, mix, and incubate 30~35℃ for 18 to 24 hours.

b. Selection and subculture:
Transfer 0.1 mL of Soybean-Casein Digest Broth to 10 mL of *rappaport vassiliadis salmonella enrichment broth*, and incubate at 30~35℃ for 18 to 24 hours. Subculture on plates of xylose lysine deoxycholate agar. Incubate at 30~35℃ for 18 to 48 hours.

c. Interpretation:
The possible presence of *salmonella* is indicated by the growth of well-developed, red colonies, with or without black centers. This is confirmed by identification tests. The product complies with the test if colonies of the types described are not present or if the confirmatory identification tests are negative.

(4) *Pseudomonas aeruginosa*

a. Sample preparation and pre-Incubation Prepare a sample using a 1 in 10 dilution of not less than 1 g of the product to be examined as described in microbiological examination of nonsterile products: Microbial enumeration tests (3061), and use 10 mL or the quantity corresponding to 1 g or 1 mL to inoculate a suitable amount (determined as described under suitability of the test method) of soybean–casein digest broth, and mix. When testing transdermal patches, filter the volume of sample corresponding to one patch of the preparation (see transdermal patches under preparation of the sample in microbiological examination of nonsterile products: Microbial enumeration tests (3061) through a sterile filter membrane, and place in 100 mL of soybean–casein digest broth. Incubate at 30~35℃ for 18 to 24 hours.

b. Selection and Subculture:
Subculture on a plate of cetrimide agar, and incubate at 30~35℃ for 18 to 72 hours.

c. Interpretation
Growth of colonies indicates the possible presence of *P. aeruginosa*. This is confirmed by identification tests.
The product complies with the test if colonies are not present or if the confirmatory identification tests are negative.

(5) *Staphylococcus aureus*

a. Sample preparation and pre-incubation:
Prepare a sample using a 1 in 10 dilution of not less than 1 g of the product to be examined as

described in microbiological examination of nonsterile products: microbial enumeration tests. (3061), and use 10 mL or the quantity corresponding to 1 g or 1 mL to inoculate a suitable amount (determined as described under suitability of the test method) of Soybean–Casein Digest Broth, and homogenize. When testing transdermal patches, filter the volume of sample corresponding to one patch of the preparation (see transdermal patches under preparation of the sample in microbiological examination of nonsterile products: Microbial enumeration tests (3061) through a sterile filter membrane, and place in 100 mL of soybean–casein digest broth. Incubate at 30~35℃ for 18 to 24 hours.

b. Selection and subculture:
Subculture on a plate of mannitol salt agar, and incubate at 30~35℃ for 18 to 72 hours.

c. Interpretation:
The possible presence of *S. aureus* is indicated by the growth of yellow or white colonies surrounded by a yellow zone. This is confirmed by identification tests. The product complies with the test if colonies of the types described are not present or if the confirmatory identification tests are negative.

(6) *Clostridia*

a. Sample preparation and heat treatment:
Prepare a sample using a 1 in 10 dilution (with a minimum total volume of 20 mL) of not less than 2 g or 2 mL of the product to be examined as described in microbiological examination of nonsterile products: Microbial enumeration tests (3061). Divide the sample into two portions of at least 10 mL. Heat one portion at 80℃ for 10 minutes, and cool rapidly. Do not heat the other portion.

b. Selection and Subculture:
Use 10 mL or the quantity corresponding to 1 g or 1 mL of the product to be examined of both portions to inoculate suitable amounts (determined as described under suitability of the test method) of reinforced medium for clostridia. Incubate under anaerobic conditions at 30~35℃ for 48 hours. After incubation, make subcultures from each container on *Columbia Agar*, and incubate under anaerobic conditions at 30~35℃ for 48 to 72 hours.

c. Interpretation:
If there are colonies on the surface of Columbia agar medium, and the anaerobic growth of the bacilli (whether or not the endospores are produced), as long as the catalase reaction is negative, it means that the specimen contains clostridia. If a sterile colony is produced, or if the catalase reaction is positive, it means that the test product meets the requirements of *Clostridium*.

(7) *Candida albicans*

a. Sample preparation and pre-incubation:
Prepare the product to be examined as described in microbiological examination of nonsterile products: microbial enumeration tests (3061), and use 10 mL or the quantity corresponding to not less than 1 g or 1 mL, to inoculate 100 mL of *Sabouraud Dextrose Broth*, and mix. Incubate at 30~35℃ for 3 to 5 days.

b. Selection and Subculture:
Subculture on a plate of *Sabouraud Dextrose Agar*, and incubate at 30~35℃ for 24 to 48 hours.

c. Interpretation:
Growth of white colonies may indicate the presence of *C. albicans*. This is confirmed by identification tests.
The product complies with the test if such colonies are not present or if the confirmatory identification tests are negative.

III. Recommended solutions and culture media

The following solutions and culture media have been found satisfactory for the purposes for which they are prescribed in the test for microbial contamination in the pharmacopeia. Other media may be used provided that their suitability can be demonstrated.

(1) Phosphate buffer solution pH 7.2:
Transfer 34 g of potassium dihydrogen phosphate to a 1000-mL volumetric flask, dissolve in 500 mL of purified water, adjust with sodium hydroxide to a pH of 7.2 ± 0.2, add purified water to volume, and mix. Dispense in containers, and sterilize. Store at a temperature of 2~8℃. Prepare a mixture of purified water and stock buffer solution (800:1 v/v), and sterilize.

(2) Buffer sodium chloride-peptone solution pH 7.0

Potassium dihydrogen phosphate	3.6 g
Disodium hydrogen phosphate dehydrate (equivalent to 0.067 M phosphate)	7.2 g
Sodium chloride	4.3 g
Peptone (meat or casein)	1.0 g
Purified Water	1000 mL

Sterilize in an autoclave using a validated cycle.

(3) Soybean-Casein Digest Broth

Pancreatic digest of casein	17.0 g
Papaic digest of soybean	3.0 g
Sodium chloride	5.0 g
Dibasic hydrogen phosphate	2.5 g
Glucose monohydrate	2.5 g
Purified water	1000 mL

Adjust the pH so that after sterilization it is 7.3 ± 0.2 at 25℃. Sterilize in an autoclave using a validated cycle.

(4) Soybean-Casein Digest Agar

Pancreatic digest of casein	15.0 g
Papaic digest of soybean	5.0 g
Sodium chloride	5.0 g
Agar	15.0 g
Purified water	1000 mL

Adjust the pH so that after sterilization it is 7.3 ± 0.2 at 25 ℃. Sterilize in an autoclave using a validated cycle.

(5) Sabouraud Dextrose Agar

Dextrose	40.0 g
Mixture of peptic digest of animal tissue and pancreatic digest of casein (1:1)	10.0 g
Aguar	15.0 g
Purified water	1000 mL

Adjust the pH so that after sterilization it is 5.6 ± 0.2 at 25 ℃. Sterilize in an autoclave using a validated cycle.

(6) Potato Dextrose Agar

Infusion from potatoes	200 g
Dextrose	20.0 g
Agar	15.0 g
Purified water	1000 mL

Adjust the pH so that after sterilization it is 5.6 ± 0.2 at 25 ℃. Sterilize in an autoclave using a validated cycle.

(7) Potato Dextrose Broth

Dextrose	20.0 g
Mixture peptic digest of animal tissue and pancreatic digest of casein (1:1)	10.0 g
Purified water	1000 mL

Adjust the pH so that after sterilization it is 5.6 ± 0.2 at 25 ℃. Sterilize in an autoclave using a validated cycle

(8) Enterobacteria Enrihment Broth Mossel

Pancreatic digest of gelatin	10.0 g
Glucose monohydrate	5.0 g
Dehydrated ox bile	20.0 g
Potassium dihydrogen phosphate	2.0 g
Disodium hydrogen phosphate dihydrate	8.0 g
Brilliant green	15 mg
Purified water	1000 mL

Adjust the pH so that after heating it is 7.2 ± 0.2 at 25℃. Heat at 100℃ for 30 minutes, and cool immediately.

(9) Violet Red Bile Glucose Agar

Yeast extract	3.0 g
Pancreatic digest of gelatin	7.0 g
Bile Salts	1.5 g
Sodium chloride	5.0 g
Glucose monohydrate	10.0 g
Agar	15.0 g
Neutral red	30.0 mg
Crystal Violet	2.0 mg
Purified water	1000 mL

Adjust the pH so that after heating it is 7.4 ± 0.2 at 25℃. Heat to boiling; do not heat in an autoclave.

(10) MacConkey Broth

Pancreatic digest of gelatin	20.0 g
Lactose monohydrate	10.0 g
Dehydrated ox bile	5.0 g
Bromocresol purple	10 mg
Purified water	1000 mL

Adjust the pH so that after sterilization it is 7.3 ± 0.2 at 25 ℃. Sterilize in an autoclave using a validated cycle.

(11) MacConkey Agar

Pancreatic digest of gelatin	17.0 g
Peptones (meat and casein)	3.0 g
Lactose monohydrate	10.0 g
Sodium chloride	5.0 g
Bile salts	1.5 g
Agar	13.5 g
Neutral red	30.0 mg
Crystal violet	1.0 mg
Purified water	1000 mL

Adjust the pH so that after sterilization it is 7.1 ± 0.2 at 25 ℃. Boil for 1 minute with constant shaking, then sterilize in an autoclave using a validated cycle.

(12) Rappaport Vassiliadis Salmonella Enrichment Broth

Soya peptone	4.5 g
Magnesium chloride exahydrate	29.0 g
Sodium chloride	8.0 g
Dipotassium phoshate	0.4 g
Potassium dihydrgen phosphate	0.6 g
Magnesium chloride green	0.036 g
Purified water	1000 mL

Dissolve, warming slightly. Sterilize in an autoclave using a validated cycle, at a temperature not exceeding 115℃. The pH is to be 5.2 ± 0.2 at 25℃ after heating and autoclaving.

(13) Xylose Lysine Deoxycholate Agar

Xylose	3.5 g
L-Lysine	5.0 g
Lactose monohydrate	7.5 g
Sucrose	7.5 g
Sodium chloride	5.0 g
Yeast extract	3.0 g
Phenol red	80 mg

Agar	13.5 g
Sodium deoxycholate	2.5 g
Sodium thiosulfate	6.8 g
Ferric ammonium citrate	0.8 g
Purified water	1000 mL

Adjust the pH so that after heating it is 7.4 ± 0.2 at 25℃. Heat to boiling, cool to 50℃, and pour into petri dishes. Do not heat in an autoclave.

(14) Cetrimide Agar

Pancreatic digest of gelatin	20.0 g
Magnesium chloride	1.4 g
Dipotassium sulfate	10.0 g
Cetrimide	0.3 g
Agar	13.6 g
Purified water	1000 mL
Glycerol	10.0 mL

Heat to boiling for 1 minute with shaking. Adjust the pH so that after sterilization it is 7.2 ± 0.2 at 25℃. Sterilize in an autoclave using a validated cycle.

(15) Mannitol Salt Agar

Pancreatic digest of casein	5.0 g
Peptic digest of animal tissue	5.0 g
Beef extract	1.0 g
D-Mannitol	10.0 g
Sodium chioride	75.0 g
Agar	15.0 g
Phenol red	0.025 g
Purified water	1000 mL

Heat to boiling for 1 minute with shaking. Adjust the pH so that after sterilization it is 7.4 ± 0.2 at 25℃. Sterilize in an autoclave using a validated cycle.

(16) Reinforced medium for clostridia

Beef extract	10.0 g
Peptone	10.0 g
Yeast extract	3.0 g
Soluble starch	1.0 g
Glucose monohydrate	5.0 g
Cysteine hydrochloride	0.5 g
Sodium chloride	5.0 g
Sodium acetate	3.0 g
Agar	0.5 g
Purified water	1000 mL

Hydrate the agar, and dissolve by heating to boiling with continuous stirring.
If necessary, adjust the pH so that after sterilization it is about 6.8 ± 0.2 at 25℃.
Sterilize in an autoclave using a validated cycle.

(17) Columbia Agar

Pancreatic digest of casein	10.0 g
Meat peptic digest	5.0 g
Heart pancreatic digest	3.0 g
Yeast extract	5.0 g
Maize starch	1.0 g
Sodium chloride	5.0 g
Agar, according to gelling power	10.0-15.0 g
Purified water	1000 mL

Hydrate the agar, and dissolve by heating to boiling with continuous stirring. If necessary, adjust the pH so that after sterilization it is 7.3 ± 0.2 at 25℃.
Sterilize in an autoclave using a validated cycle. Allow to cool to 45~50 ℃; Add where necessary, gentamicin sulfate corresponding to 20 mg of gentamicin base, and pour into petri dishes.

IV. General Requirements and Rules for Preparations

(4152) Tablet

A tablet is a solid preparation which is prepared from medicament with or without excipients, and can be classified into molded tablet and compressed tablet according to the production methods.
Most of the tablets are made by pressing and are one of the most widely used dosage forms. The pressed tablets are pressed into the steel mold from above and below, and the powder or granules are pressed into tablets at high pressure. Large tablets of various sizes, shapes, and surfaces with graphic symbols are available for veterinarians to administer to large animals.
Molded tablets are filled with a moistened powder into a suitable mold recess, lightly formed, and cured by drying due to a combination of crystallization, rather than pressure.
The dispensing tablet is small, often rounded, and molded or pressed. The potent drugs are often made into tablets to provide a suitable amount of the medication. The dispensing tablet is now less used.

1. Preparation of mold tablet:

The mold tablet can be prepared by mixing the medicine with different proportions of excipients lactose or such as sucrose powder, and the mixed powder is wetted by the high concentration ethanol solution (the concentration of ethanol depends on the solubility of the medicine and the excipients in the ethanol and the hardness of the final tablet product. The wetted powder is filled into the model, taken out after light press molding, and placed in a dry state. Since the finished product is fragile, attention should be paid to its packaging and blending.

2. Preparation of pressed tablets:

(1) **Prescription:**

Most of the pressed tablets contain composition such as main ingredients, diluents, binders, disintegrants and lubricants. Legal pigments and tartrazine aluminum lake, flavors and sweeteners can also be added. When the main ingredients is small or difficult to press, a suitable diluent such as lactose, starch, calcium phosphate, and crystalline cellulose may be added.

Binders:

For the manufacture of the primary granules, as well as the compression of the tablets, the adhesion is provided, and the original cohesive force of the granules can be strengthened. The dry adhesive can be added directly. It is not formulated into a solution, the dry powder is added, directly and the adhesive effect is better. Commonly used binders include gum Arabic, sucrose, povidone, methyl cellulose, sodiumhydroxymethyl cellulose and hydrolyzed starch paste. The most effective dry binder is microcrystalline cellulose, which is commonly used in the manufacture of direct pressed tablets.

Disintegration agent:

It is used to promote the disintegration of tablets after they are administered. Starch is chemically treated starch and cellulose, alginic acid, microcrystalline cellulose and cross-linked polyvinylpyrrolidone are the commonly used integrants. The concentration of the disintegrating agent, the method of addition, the degree of consolidation of the tablet, etc. all have an influence on the disintegration effect.

Lubricant:

It is used to reduce the friction and the adhesion of the powder to the die when the tablet is pressed and shot. Commonly used lubricants are metal stearates, stearic acid, hardened vegetable oil and talc. Since the lubricating function is mostly hydrophobic, it also causes the tablet disintegration degree and the degree of dissolution to be low, so excessive use should be avoided. Polyethylene glycol and lauryl sulfate have been used as soluble lubricants, but because of their poor lubricity, higher concentrations are required.

Glidants agent:

It is used to improve the fluidity of powder. It is often added to the straight pressed tablet without making granules. The most effective one is gelatinous pyrolytic vermiculite.

Legal color:

It is used in the manufacture of tablets to increase the appearance or for product identification. The legal food coloring and tartrazine aluminum lake can be used. However most of the pigments are light sensitive, and the color is often faded as exposed to light. It should be used carefully.

(2) **Manufacturing:**

The production of pressed tablets usually has three methods: wet granule method, dry granule method and direct pressed method. The granule method is used to promote the fluidity of the powder during the pressing process, improve the compressibility and increase the uniformity of the weight. Wet granule method: Usually, the main ingredients are added with excipients such as diluents or disintegrating agents. The mixture is uniformly mixed, and an appropriate amount of the binder is added. After mixing and pressure-control treatment, it is made into granules in an appropriate manner, and dried graded and then compressed into tablet.

Dry granule method:

That is, the heavy pressing method. It is a method in which the prescription ingredients are uniformly mixed and then pressed into a large and not very solid ingot, which is pressed into an appropriate size of the granules and then pressed into a tablet. This manufacturing process can avoid the heating implant of or humidity on the prescription ingredients. The prescription ingredients may also be pressed into a thin piece by a pressure roller, and then appropriately sieved or broken to prepare appropriate granules.

Direct pressure method:

It is a method without granulation process. The prescription ingredients are directly pressed into tablets, which are suitable for high-speed production. The excipients used in this method include various materials with special physical properties and ideal fluidity and compressibility, such as lactose and sucrose, glucose or cellulose, etc., while microcrystalline cellulose, anhydrous lactose, spray-dried lactose, compressible sucrose, and modified starch are also widely used in the direct-pressing methods. The direct pressure method can avoid the difficulties encounter in wet granules and dry pressure methods. Special attention should be paid to the individual physical properties of many fillers. A minor difference may affect its flow and compression properties, and may even not suitable for the direct pressure method.

3. Tablet quality:

The quality of the tablet, besides physical factors, intergradient of tablet is particularly important in the stability and its bio-availability. When the active ingredient is the main component of the tablet, and the weight control can properly control the content uniformity, the tablet must meet the unit weight difference requirement as specified (General Rule 3016). When the effective ingredient is only a small part of the tablet (or sugar-coated tablet), the difference in weight does not indicate a uniformity of the content, that is, the tablet has a main component of 50 mg or less, and the weight of main component is less than 50% of tablet, which is

subject to the determination of the individual actual content by the unit dose uniformity measurement method as specified (General rule 3016).

The degree of disintegration, the Pharmacopoeia stipulates a test for disintegration (General rule 4701), and there are time limits in each of the monographs.

Solubility is more meaningful for the quality of low-water-soluble drug tablets. Although this quality characteristic is only the initial screening quality and routine quality control steps, it is related to the bioavailability of the active ingredient and the dissolution rate of the tablet (General rule 3015). The test method has been specified, and its allowable range is listed in the text specifications of each monographs.

4. Tablet coating:

There are many reasons why tablets need coating: to protect the active ingredients against light, moisture and air stability, to mask bad odors, to improve the appearance and to control the release of gastrointestinal drugs.

(1) **General coating tablet:** Traditionally with the aids of gun Arabic or gelatin, the sugar solution can make. Insoluble powder such as starch, calcium carbonate, talc, or titanium dioxide to be uniformly dispersed and coated on the surface of the tablet. The outer layer can be colored for product identification and increase the appearance. The coated tablet can be polished with a dilute solution of wax (such as Chloroform) or mixed dry powder. Waterproof tablets can be prepared by coating a solution containing shellac or non-aqueous solution of cellulose phthalate before sugar coating. Excessive use should be avoided. The shortcomings of sugar coating include that the long processing time. The waterproof processing also hinders the release of the active ingredients and increase of the finished sugar-coated tablets.

(2) **Film tablets:** The film-coated tablet may be made with water-soluble or dispersible, such as hydroxy-propyl-methyl cellulose, methylcellulose, hydroxyl-propyl-cellulose, sodium carboxyl-methylcellulose, and a mixture of cellulose acetate and polyethylene glycol, etc. They can be dissolved in either hydrophilic or hydrophobic solution. When the solvent is evaporated, a film is directly adhered to the appearance of the tablet, while maintaining the appearance of the original tablet, the groove line or other symbols.

(4161) Concentrated Traditional Chinese Medicine Preparation

The concentrated preparation of traditional Chinese medicine is prepared by decocting or extracting, concentrating, drying and processing the Chinese herbal medicine into various dosage forms. According to the composition of the medicine, it can be divided into a single extract preparation and a compound extract preparation. According to the dosage form, it can be divided into concentrated powder, concentrated granules, concentrated fine granules, concentrated pills, concentrated troches, concentrated sugar-coated tablets, concentrated film-coated concentrate tablet concentrated made principally from capsules or other derivatized dosage forms.

The compound concentrate preparation is combined decoction. The extract extracted by decoction can be prepared by using the lactose, starch, recorded in the Chinese Pharmacopoeia or approved by this central health authority adjuvants, excipients or powder of the ingredient herbs. The limits of microorganisms, heavy metals and pesticide residues in concentrated preparations shall be in accordance with the regulations stimulated by the central health authority.

The quality of traditional Chinese medicine concentrate preparations should meet the general inspection (weight difference test, disintegration test), identification, impurity inspection (dry weight loss, heavy metal test, total ash, acid-insoluble ash powder) and content determination (index ingredient, water extract and ethanol extract). The provisions of the allowable range or time limit for the relevant provisions are listed in the text specifications of each monographs.

The concentrated preparation of traditional Chinese medicine should meet the following requirements during production and storage.

(1) Traditional Chinese medicine concentrate extract should be evenly mixed with the excipient or powders of traditional Chinese medicine.

(2) In order to prevent moisture and mask the bad odor of the raw material, the concentrated preparation of the traditional Chinese medicine can be coated with a film.

(3) The concentrated preparation of traditional Chinese medicine should be dry, with uniform particle size and color, no moisture absorption, softening, agglomeration and deliquescence.

(4) Unless otherwise specified, concentrated preparations of traditional Chinese medicines should be sealed and stored in a dry place to prevent moisture.

Chinese medicine concentrated granules

The concentrated granules of traditional Chinese medicine can be divided into concentrated granules, concentrated fine granules and the like according to the particle size.

(4163) Concentrated Traditional Chinese Medicine Tablet

The concentrated tablet of traditional Chinese medicine is a solid preparation of traditional chinese medicine, which is prepared by decoction or extraction, concentration,

drying, adding appropriate adjuvants and excipient to form solid preparations with different shapes. According to the clothes material, it can be divided into concentrated tablets, concentrated sugar-coated tablets and concentrated film-coated tablets. Most traditional chinese medicine tablets are made by pressing and can be made into various products of different sizes, shapes and surfaces with graphic symbols.

Production of compressed traditional Chinese medicine concentrated tablets

(1) Prescription:
The pressed tablet prescription contains a concentrated extract of traditional Chinese medicine, a diluent, a binder, a disintegrating agent, a lubricant, and can also be colored with a legal pigment, and seasoned with aromatic flavors and sweeteners. When the concentration of the concentrated extract of the medicament is small or it is difficult to suppress, a suitable diluent such as lactose, starch, calcium phosphate and crystalline cellulose can be added.

(2) Manufacturing:
There are three kinds of pressed tablet methods, such as wet granule method, dry granule method and direct pressed method can be used according to the characteristics of traditional Chinese medicine. The preparation methods can be referred to the principle described under the tablet (General rule 4152) and can be adjusted as appropriate.

Quality of traditional Chinese medicine concentrated tablets

Besides the specification stimulated in the General rules, the quality of traditional Chinese medicine concentrate tablets shall comply with the relevant provisions of the average weight, the tablet brittleness test method (General rule 4216), the tablet crushing force measurement method (General rule 4218), etc., and the allowable range or time limit shall also be in accordance with the regulations specified in the monographs.

The degree of disintegration is one of the main quality characteristics of oral Chinese medicine concentrate tablets. It should be tested according to the disintegration test method stipulated by the Pharmacopoeia (General rule 4701) and should meet the time limit specifications in each monograph.

Coating of Chinese medicine concentrated tablet

Traditional Chinese medicine concentrated tablets need coating for various reasons: to protect the active ingredients from light, humidity and air stability, to mask bad odor and improve the appearance, etc. Traditionally, traditional Chinese medicine concentrated tablets are mostly coated with sugar liquid, with the aid of gum arabic or gelatin, and the insoluble powder such as starch, calcium carbonate, talcum powder or titanium dioxide is evenly dispersed and coated on the surface of the traditional Chinese medicine concentrate tablet. For the identification and appearance, the outer layer can be colored. The finished Chinese medicine concentrated tablet can be polished with a thin solution of wax or mixed dry powder; the waterproof tablet can be prepared by coating the solution with a non-aqueous solvent containing shellac or cellulose phthalate before the sugar coating. Disadvantages of sugar coatings include long processing time. The waterproof, material also hinder the release of active ingredients and increase the volume of finished sugar-coated tablets.

Chinese medicine concentrated tablets should meet the following relevant regulations during production and storage.

(1) Chinese medicine concentrated tablets should be smooth, without shrinkage, cracks, deformation and hollows.

(2) Unless otherwise specified, traditional Chinese medicine concentrated tablets should be sealed and stored in a cool dry place.

(4165) Concentrated Traditional Chinese Medicine Pill

Concentrated traditional Chinese medicine pills are made by decocting or extracting, concentrating and drying TCM herbs, adding appropriate diluents, binders and other excipients and mixing them uniformly, first forming a plastic mass, then cutting, rolling, forming and drying. It is spherical. According to the different adhesives used, it is divided into concentrated water pill, concentrated honey pill and concentrated water honey pill.

Manufacturing of concentrated traditional Chinese medicine pills

(1) Prescription:
The prescription of concentrated traditional Chinese medicine pills contains concentrated traditional Chinese medicine extract, excipients and binders. If necessary, sucrose or other suitable substances can be used as the pill coating, but these substances must be harmless to the human body, and the pill coating must be able to dissolve or disintegrate in the digestive tract.

(2) Manufacturing:
The manufacturing method can refer to the principles described under the Chinese Pharmacopoeia Pills, and can be adjusted as appropriate.

(3) Unless otherwise specified, concentrated water honey pill and concentrated water pill should be dried below 80°C; pills with volatile ingredients or more starch should be dried below 60°C; those not suitable for heat drying should be dried by other suitable methods.

Except as otherwise specified in the text, the concentrated traditional Chinese medicine pills should be inspected according to the following methods:

(1) Average weight: Take 20 pills, weigh them separately, and calculate their average weight. The

average weight must be within ± 10% of the marked weight.

(2) Weight difference test: Take 20 pills and weigh them separately. The difference between the weight of each pill and the average weight shall be calculated. The number of pills that exceed 10% between the weight of each pill and the average weight should not more than 2. The difference between the weight of each pill and the average weight shall not exceed 2 pills, and none of the pill shall exceed ± 20% of the average weight.

(3) Disintegration test: Follow the disintegration test method (General Rule 4701). Concentrated traditional Chinese medicine pills should be immersed in artificial gastric juice at a temperature of 37 ± 2℃. Take 6 pills for testing. After 60 minutes, rlift the basket and observe the pills. If it is not disintegrated completely, then 37 ± 2℃ artificial intestinal juice is used as the immersion solution. After 60 minutes, all the pills should be disintegrated completely. If 1~2 pills are not completely disintegrated, another 12 pills should be tested. and in all 18 pills, at least 16 pills should be completely disintegrated.

(4) Limit of microorganisms: Total plate count of microorganism not more than 10^5 CFU/g.

Concentrated traditional Chinese medicine pills should meet the following relevant regulations during production and storage.

(1) The appearance of concentrated traditional Chinese medicine pills should be complete without adhesion.

(2) Unless otherwise specified, concentrated traditional Chinese medicine pills should be sealed and stored in a cool and dry place.

(4216) Test for Tablet Friability

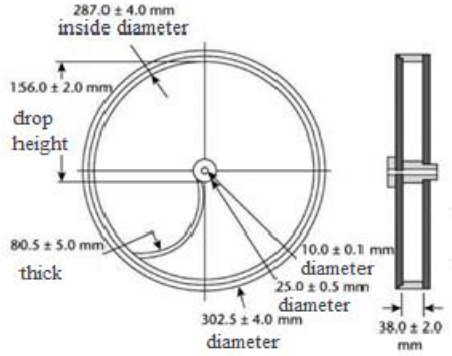
This chapter provides guidelines for the friability determination of compressed, uncoated tablets. The test procedure presented in this chapter is generally applicable to most compressed tablets and supplements other physical strength measurements, such as tablet crushing strength.

Use a drum, with an internal diameter of about 283-291nm and a depth of 36-40nm, made of a transparent synthetic build-up (as Fig.). One side of the drum is removable. The tablets are tumbled at each turn of the drum by a curved projection with an inside radius of 75.5-85.5mm that extends from the middle of the drum to the drum to the outer wall. The drum is attached to the horizontal axis of a device that rotates at 24.5-25.5nm rpms. Thus, at each turn the tablets roll or slide and fall onto the drum wall or onto each other, rotate at 25 ± 1 rpm.

For tablets weighting up to 650 mg each, take a 6.5 g of sample; for tablets weighting over 650 mg each, a 10 tablets sample is sufficient. Before the test, remove any loose dust with the aid of air pressure or soft brush. Accurately weigh the tablet sample, and place the tablets in the drum. Rotate the drum 100 times, and remove the tablets. Remove any loose dust from the tablet as before and weigh.

Generally, the test is run once. If the results are doubtful or if the weight. Loss is greater than 1%, the test should be repeated twice and determine the mean of the three tests. A maximum weight of the tablets being tested is considered acceptable and any tablets broken, chipped and smashed are not pick up.

Test for Tablet Friability installation drawing



If tablet size or shape causes irregular tumbling, adjust the drum base so that the base form a 10° angle with the horizontal and the tablets no longer bind together when lying next to each other, which prevent them from falling freely.

The brittleness test of foamed tablets and chewable tablets can have different specifications. For easily absorbable tablets, the ambient humidity should be controlled during the test.

If the cylinder is equipped with double spacers, or the instrument is equipped with more than one cylinder, multiple inspection tests can be allowed at the same time.

(4218) Tablet Breaking Force

There are a variety of presentations for tablets as delivery systems for pharmaceutical agents, such as rapidly disintegrating, slowly disintegrating, eroding, chewable, and lozenge. Each of these presentations places a certain demand on the bonding, structure, and integrity of the compressed matrix. Tablets must be able to withstand the rigors of handling and transportation experienced in the manufacturing plant, in the drug distribution system, and in the field at the hands of the end users (patients/consumers). Manufacturing processes such as coating, packaging, and printing can involve considerable stresses, which the tablets must be able to withstand. For these reasons, the mechanical strength of tablets is of considerable importance and is routinely measured. Tablet strength serves both as a criterion by which to guide product development and as a quality control specification.

One commonly employed test of the ability of tablets to withstand mechanical stresses determines their resistance to chipping and surface abrasion by tumbling them in a

rotating cylinder. The percentage weight loss after tumbling is referred to as the friability of the tablets. Standardized methods and equipment for testing friability have been provided in general (rule 4216).

Another measure of the mechanical integrity of tablets is their breaking force, which is the force required to cause them to fail (i.e., break) in a specific plane. The tablets are generally placed between two platens, one of which moves to apply sufficient force to the tablet to cause fracture. For conventional, round (circular cross-section) tablets, loading occurs across their diameter (sometimes referred to as diametral loading), and fracture occurs in that plane.

The breaking force of tablets is commonly called hardness in the pharmaceutical literature; however, the use of this term is misleading. In material science, the term hardness refers to the resistance of a surface to penetration or indentation by a small probe. The term crushing strength is also frequently used to describe the resistance of tablets to the application of a compressive load. Although this term describes the true nature of the test more accurately than does hardness, it implies that tablets are actually crushed during the test, which often is not the case. Moreover, the term strength in this application can be questioned, because in the physical sciences that term is often used to describe a stress (e.g., tensile strength). Thus, the term breaking force is preferred and will be used in the present discussion.

1. Tablet breaking force determinations

Early measuring devices were typically hand operated. For example, the Monsanto (or Stokes) hardness tester was based on compressing tablets between two jaws via a spring gauge and screw. In the Pfizer hardness tester, the vertically mounted tablet was squeezed in a device that resembled a pair of pliers. In the Strong Cobb hardness tester, the breaking load was applied through the action of a small hydraulic pump that was first operated manually but was later motorized. Problems associated with these devices were related to operator variability in rates of loading and difficulties in proper setup and calibration. Modern testers employ mechanical drives, strain gauge–based load cells for force measurements, and electronic signal processing, and therefore are preferred. However, several important issues must be considered when using them for the analytical determination of breaking force; these are discussed below.

(1) **Platens:**

The platens should be parallel. Their faces should be polished smooth and precision-ground perpendicularly to the direction of movement. Perpendicularity must be preserved during platen movement, and the mechanism should be free of any bending or torsion displacements as the load is applied. The contact faces must be larger than the area of contact with the tablet.

(2) **Pressurization rate and uniformity:**

Either the rate of platen movement or the rate at which the compressive force is applied (i.e., the loading rate) should be constant. Maintaining a constant loading rate avoids the rapid buildup of compressive loads, which may lead to uncontrolled crushing or shear failure and greater variability in the measured breaking force. However, constant loading rate measurements may be too slow for real time monitoring of tablet production.

The rate at which the compressive load is applied can significantly affect results, because time-dependent processes may be involved in tablet failure. How a tablet matrix responds to differences in the loading rate depends on the mechanism of failure. At low strain rates, some materials may fail in a ductile manner, but brittle failure is more likely at faster strain rates. The transition from ductile to brittle failure is accompanied by an increase in the breaking force. Devices that simply crush tablets may produce deceptively reproducible data because they lack sensitivity.

The test must be run consistently with equipment which has been routinely calibrated. Changing from testing units of different designs or from different manufacturers will require comparison of data to ensure that the two units are subjecting the dosage form to similar stress in a similar manner. Currently available equipment provides a constant loading rate of 20 newtons (N) or less per second or a constant platen movement of 3.5 mm or less per second. Controlled and consistent breaking is an important test procedure attribute. To ensure comparability of results, testing must occur under identical conditions of loading rate or platen movement rate. Since there are certain advantages to each system of load application, both are found in practice. Because the particular testing situation and the type of tablet matrix being evaluated will pose different constraints, there is also no basis to declare an absolute preference for one system over the other. This general chapter proposes consideration of both approaches.

The different methods may lead to numerically different results for a particular tablet sample, requiring that the rate of load application or displacement must be specified along with the determined breaking force.

(3) **Dependence of Breaking Force on Tablet Geometry and Mass:**

Measurements of breaking force do not take into account the dimensions or shape of the tablet. Thicker tablets of the same material compressed under conditions identical to those of thinner tablets, with the same tooling shape and to the same peak force, will require greater breaking forces.

Tablet orientation and failure should occur in a manner consistent with those used during the development of the dosage form. For direct comparisons (i.e., without any normalizations of

the data), breaking force measurements should be performed on tablets having the same dimensions, geometry, and consistent orientation in test equipment.

(4) **Tablet Orientation:**
Tablet orientation in diametral compression of round tablets without any scoring is unequivocal. That is, the tablet is placed between the platens so that compression occurs across a diameter. However, tablets with a unique or complex shape may have no obvious orientation for breaking force determination. Because the breaking force may depend on the tablet's orientation in the tester, to ensure comparability of results, it is best to settle on a standard orientation, preferably one that is most readily and easily reproduced by operators. In general, tablets are tested either across the diameter or parallel to the longest axis. Scored tablets have two orientation possibilities. When they are oriented with their scores perpendicular to the platen faces, the likelihood that tensile failure will occur along the scored line increases. This provides information about the strength of the matrix at the weakest point in the structure. When scored tablets are oriented with their scores parallel to the platen faces, more general information about the strength of the matrix is derived.
Capsule-shaped tablets or scored tablets may best be broken in a three-point flexure test. A fitting, which is either installed on the platens or substituted for the platens, time ports the tablet at its ends and permits the breaking load to be applied to the opposite face at the unsupported midpoint of the tablet. The fittings are often available from the same source that supplies the hardness tester.

(5) **Units, Resolution, and Calibration:**
Modern breaking force testers are usually calibrated in kiloponds or newtons. The relationship between these units of force is 1 kilopond (kp) = 1 kilogram-force (kgf) = 9.80 N. The test results should be expressed in standard units of force which facilitate communication. Some breaking force testers also will provide a scale in Strong Cobb units (SCU), a carryover from the days when Strong Cobb hardness testers were in common usage. The conversion between SCU and N or kp must be viewed with caution, between SCU and N or kp must be viewed with caution, because the SCU is derived from a hydraulic device and is a pressure.
Generally, contemporary breaking force testers use modern electronic designs with digital readouts. Some units also have an integral printer or may be interfaced with a printer. Breaking forces should be readable to within 1 N.
Breaking force testers should be calibrated periodically. The force sensor as well as the mechanics of the apparatus needs to be considered. For the force sensor, the complete measuring range (or, at a minimum, the range used for measuring the test sample) should be calibrated to a precision of 1 N, using either the static or dynamic method. Static calibration generally employs traceable counterweights; at least three different points are checked to assess linearity. Dynamic calibration makes use of a traceable reference-load cell that is compressed between the platens. The functional calibration of a breaking force test apparatus should also confirm that the velocity and the constancy of velocity for load application or displacement are within prescribed tolerances throughout the range of platen movement.

(6) **Sample Size:**
In order to achieve sufficient statistical precision for the determination of average breaking force, a minimum of 6 tablet samples should be tested. The average breaking force alone may be adequate to fulfill the purpose of process or product quality control. In cases where breaking force may be particularly critical, the average plus individual breaking force values should be accessible.

2. Tensile Strength
The measurement of tensile strengths provides a more fundamental measure of the mechanical strength of the compacted material and takes into account the geometry of the tablet. If tablets fail in tension, the breaking force can be used to calculate the tensile strength. Unfortunately, this is practical only for simple shapes. If flat-faced round tablets (right circular cylinders) fail in tension, as indicated by a clean split into halves under diametral compression, the breaking force may be used to compute the tensile strength from the following equation, which applies only to cylindrical tablets:

$$\Sigma_X = 2F/\pi DH$$

Where Σ_X is the tensile strength, F is the breaking force, D is the tablet diameter, and H is the tablet thickness. Because only tablets that fail in tension are counted, the data are based on tablets that fail in a consistent way. Thus, reproducibility of data should be enhanced when compared to conventional breaking-strength testing. Moreover, the data will be normalized with respect to tablet dimensions, because both diameter and thickness are included in the equation. The derivation of this equation may be found in standard texts; it is based on elastic theory and the following assumptions:

(1) The tablet is an isotropic body
(2) Hooke's law is obeyed
(3) The modulus of elasticity in compression and in tension is the same
(4) Ideal point loading occurs

The derivation has been extended to convex-faced tablets:

$$\Sigma_X = (10\ F/\pi D^2) \times [\ (2.84\ H/D) - (0.126\ H/W) + (3.15\ W/D) + 0.01]^{-1}$$

Where Σ_X is the tensile strength, F is the breaking force, D is the tablet diameter, H is the tablet thickness, and W is the central cylinder thickness (tablet wall height).

The slow and constant loading rate of modern motorized break force testers encourages tensile failure. However, ideal point loading may not occur, because of crushing and the induction of shear failure at the interface with the surface of the platens. The addition of padding to the platens helps prevent shear at contact points and promotes true tensile failure. On that basis, padding is strongly recommended when highly precise measurements are needed. Padding should be relatively thin so that any deviation from the assumption of true point-source force application will not be large. The padding should also collapse very easily so that its deformation does not become part of the force measured by the test apparatus. In more routine settings involving measurements on a large number of samples, the addition of padding could contribute to inaccuracies in measurement as powder from previously tested samples becomes embedded in the collapsible matrix and thereby alters its properties. Unless provisions for frequent and routine replacement of the padding are made, it can be considered acceptable to ignore the use of padding material to maintain constancy of the test conditions.

Bending or flexure of tablets is another option for mining the tensile strength of tablets. Under ideal loading conditions, a breaking load applied to the unsupported midpoint of one face will result in the generation of pure tensile stress in the opposite face. If the tablets are right circular cylinders and are subjected to three-point flexure, the tensile strength may be estimated using the following equation:

$$\Sigma_X = 3FL/2H^2D$$

Where L is the distance between supports, and the other terms are as defined above. The assumptions are the same as those for calculating tensile strength from diametral compression. However, tensile strengths determined by flexure and diametral compression may not agree, because of likely non-ideal loading and the induction of shear failure during testing.

(4701) Disintegration Test

The disintegration test is to determine whether various tablets or capsules can collapse within a specified time limit. Lozenges, ingots or chewable ingots of more than 15 mm in diameter and lozenges or capsules which are released in divided doses at specified intervals are not applicable to the provisions of this test. Six tablets of the tablet for the test were taken, and the degree of disintegration was measured based on the type of the dosage form according to the following method.

The test article was placed in a disintegration measuring device as described below, and the degree of disintegration was measured by the indicated method. If the residual tablet stored in the sieve in the measuring device has become a soft mass, and there is no observable hard part, and the capsule contains only the capsule fragment, it can be regarded as completely disintegrated. A tablet containing an insoluble tablet and a tablet fragment formed upon collapse does not apply to the above-mentioned methods. Disintegration of the test product in water and subsequent disintegration does not refer to the complete dissolution of the entire dosage form or the active ingredient contained therein.

Disintegration device:

The device shall have the following parts: measuring grid, suitable container for immersion solution (usually 1 L beaker, height 142~148 mm, outer diameter about 103~108 mm), constant temperature heating device (for maintenance 35~39 ℃), grid lifting device (lifting frequency is 29~32 cycles per minute, lifting height is 5.3~5.7 cm). When the grid is lowered to the lowest point, the screen should be 2.5 cm away from the bottom of the container; when the grid is raised to the highest point, the screen should also be 2.5 cm below the level of the immersion solution; the capacity of the immersion solution contained in the container should be appliable to the above provisions.

Measuring grid: The grid is composed of the following materials

(1) Six glass tubes with two ends open: the length is 7.75 ±0.25 cm, the inner diameter is about 21.5 mm, and the wall thickness is about 2 mm.
(2) Two pieces of graphic plastic plate: Each piece is about 9 cm in diameter and about 6 mm thick. There are six holes with the same size and equidistant from the center of the plastic plate, and evenly distributed. The diameter of each hole is about 24 mm.
(3) Round No. 10 stainless steel screen, the same size as the plastic plate.
(4) Round stainless steel piece with a diameter of about 9 cm and a thickness of about 1 mm. There are six holes with a diameter of about 20 mm. The positions of the round holes are consistent with the positions of the round holes on the plastic plate; the erect handle is about 8 cm long and has a small hole at the upper end of the handle for stringing.

The glass tubes are erected and sandwiched between the two plastic plates, and the positions of the glass tubes are matched with the positions of the round holes on the plastic plate; Screen is fixed under the bottom plastic plate with screws, and the steel sheet is attached to the top. The top of the plastic plate is placed with the handle facing up, and the steel plate and the top plastic plate are strung together by three long screws, so that the entire set of the grid is fixed together with the glass tube sandwiched there between. The above combinations may be slightly modified, but the specifications of the glass tube and the mesh screen shall not be varied.

Round plastic sheet:

When the above-mentioned grid is used to measure the degree of disintegration, a transparent round plastic sheet with a specific gravity of 1.18~1.20 should be placed in each glass tube. The thickness is 9.5 ± 0.15 mm and the diameter is 20.7 ± 0.15 mm; There are five small holes running through the upper and lower sides of the plastic sheet, one of which is located at the center of the plastic sheet, and the other four holes are evenly distributed at the center of the plastic sheet. On the circumference of a radius of 6 mm, each hole has a diameter of 2 mm. There are four V-shaped indentations on the side of the plastic sheet; the depth and width of the bottom surface of the dimple are 1.60 mm; the width of the top surface of the dimple is 9.50 mm and the depth is 2.55 mm, and each surface should be smooth.

Procedure:

Uncoated Tablets: Place 6 tablets in each of the six tubes of the basket, add a plastic disk to each tube. Operate the apparatus, the grids run up and down at the specified speed. Unless otherwise mentioned, used water as the immersion fluid and maintained at 37 ± 2℃. At the end of the specified time, lift the basket from the fluid, and observe the tablets: all of the 6 tablets should disintegrate completely. If 1 or 2 tablets fail to disintegrate completely, repeat the test on 12 additional tablets. The requirement is met if not fewer than 16 of the total of 18 tablets tested disintegrate completely.

Plain Coated Tablets:

Measured according to the method of tablets without coating and the operation and the disintegration time limit are specified in the text.

Delayed-Release (Enteric-Coated) Tablets:

Place 6 tablets in each of the six tubes of the basket, and if the tablet has a soluble external sugar coating, immerse the basket in water at room temperature for 5 minutes. Then operate the apparatus using simulated gastric fluid TS maintained at 37 ± 2℃ as the immersion fluid. After 1 hour of operation in simulated gastric fluid TS, lift the basket from the fluid, and observe the tablets: the tablets should not show any disintegration, cracking, or softening. Then operate the apparatus, using simulated intestinal fluid TS, maintained at 37 ± 2℃, as the immersion fluid for the time specified in the monographs. Lift the basket from the fluid, and observe the tablets: all of the tablets should disintegrate completely. If 1 or 2 tablets fail to disintegrate completely, repeat the test on 12 additional tablets: among 18 tablets tested, at least 16 tablets should be disintegrated completely.

Buccal Tablets:

Apply the test for Uncoated Tablets with no plastic disk in each tube. After 4 hours, lift the basket from the fluid, and observe the tablets: all of the tablets should disintegrate completely. If 1 or 2 tablets fail to disintegrate completely, repeat the test on 12 additional tablets: not fewer than 16 of a total of 18 tablets tested disintegrate completely.

Sublingual Tablets:

Apply the test for Uncoated Tablets with no plastic disk added in each tube. At the end of the time limit specified in the individual monograph, all the tablets should disintegrate completely. If 1 or 2 tablets fail to disintegrate completely, repeat the test on 12 additional tablets not fewer than 16 of a total of 18 tablets tested disintegrate completely.

Hard Shell Capsules:

The test was carried out according to the test for the uncoated tablets, and the plastic disk is replaced by a suitable No. 10 screen. At the end of the specified time limit, besides the capsule fragments, all tablets should be completely disintegrated. If 1 to 2 tablets fail to disintegrate completely, another 12 tablets shall be tested, and in all 18 tablets, at least 16 tablets should completely disintegrate.

Soft capsule:

According to the hard capsule test method, it should correspond the requirements.

Pill:

Follow the disintegration test method of the coating tablet. The artificial gastric juice with the temperature of 37 ± 2 ℃ is used as the immersion solution. After 60 minutes, lift the basket and observe the pills. If it is not disintegrated completely, then 37 ± 2 ℃ artificial intestinal juice is used as the immersion solution. After 60 minutes, all the pills should be disintegrated completely. If 1 to 2 pills are not completely disintegrated, another 12 pills shall be tested, and in all 18 pills, at least 16 pills completely disintegrated.

※Note: "The artificial gastric juice and artificial intestinal juice used in this test do not contain enzymes."

V. Determinations of Biological Products

Please refer to the general rules of the Taiwan Pharmacopeia.

VI. Identifications of Crude Drugs

(6001) Sampling

Use a sampling tool to collect the crude drug at least 2 batches on the different parts of the opposite sides from original packing, this method is only suitable to drug that size less than 1cm, crushed or powdered. If the total quantity of crude drugs is less than 100 kg, the minimum weight of sample is 250.0 g. If the total quantity is more than 100 kg, in accordance with the table as follows, choose several packages, sampling from several packages as above described, mix the sample well on the paper, pave the sample and divide into four equal portions, take the samples in opposite positions, mix and flatten these two parts, divide it into four equal portions, and take the two parts samples in opposite positions, repeat the procedure until the weight of final two parts are at least 250.0 g.

For crude drugs more than 1 cm in size, directly use hand for sampling. If the total quantity is less than 100 kg, randomly collect different parts from the original package with quantity not less than 500.0 g. If the total quantity is

more than 100 kg, choose several packages in accordance with the table as follows, take several packages as described above, quarter the samples repeatedly until the weight of final two parts are at least 500.0 g.

If the total weight of crude drugs is less than 10 kg, sample in accordance with the portions of the package by the method above, the minimum weight of sample is 125.0 g.

Total packages	Sampling packages
1~10	1~3
10~25	3~4
25~50	4~6
50~75	6~8
75~100	8~10
100 above	10 above

(6003) Processing

Test specimens should be processed before testing, unless otherwise directed, process the test specimens as follows: Depending on the required quantity for determination, divide sample herbs into four small portions by the quartering, be aware of that the sample from package needs to represent the original sample in operating. Grind sample into powder and sieve by NO. 20 sieve. Try to grind the sample which is hard to grind into small fragments. Place on a paper after grinding, mix it well, pave into a thin layer, collect the required quantity by quartering, and then prepare for test determination.

(6005) Determination of Foreign Matter

Foreign matters in the crude drugs are two kinds as following:

1. The portions of animal or botanical crude drugs do not meet the monographs for medicine use.
2. Other animal or botanical foreign matters and the crude drugs secretion, differ from the crude drugs specified in the monographs.
   For determination, weigh 25~500 g of crude drugs accurately and pave in a thin layer. Remove the foreign matter by using a suitable pair of forceps. Weigh the foreign matter and calculate the content in percentage. If the crude drugs are bulky or large particle, weigh 500.0 g of the test specimen for determination.

(6007) Determination of Ash

I. Total Ash: Ignite a crucible at 550℃ for 1 hour, cool in a desiccator and weigh accurately. Unless otherwise directed, put 2~4 g of the air-dried test specimen in the crucible and weigh accurately. Heat at a low temperature until it completely charred (do not combustion), then gradually increase the temperature below 550 ℃. Incinerate the residue for more than 4 hours until no carbon substance remains in the ash, cool and weigh the ash accurately. Calculate the percentage of total ash. If the carbon substance remains, dip the charred mass with hot water, collect the insoluble residue by filter paper without ash, and incinerate the residue and filter paper until no carbon substance remains in the ash. Then add the filtrate, evaporate it to dryness, and incinerate at the temperature not more than 550℃. Cool, weigh accurately, and calculate the percentage of total ash. If a carbon-free ash cannot be obtained in this way, cool the crucible, moisten the ash with 15 mL of ethanol and grind the ash with a glass rod. Carefully evaporate the ethanol to dryness and ignite at the temperature not more than 550℃ to constant mass, calculate the percentage of total ash.

II. Acid-Insoluble Ash: Place the ash obtained in the determination of total ash in a crucible, carefully add 25 mL of dilute hydrochloric acid, boil gently for 5 minutes, filter with tared Gooch crucible or filter paper without ash, and wash the residue with hot water. Transfer the filter paper with the residue together to the original crucible, dry and ignite to constant weight. Calculate the percentage of acid-insoluble ash.

(6009) Determination of Water Content

The process of test specimen: Take 10.0 g of test specimen, if the test specimen is not finely grinded, grinded it into about 3 mm of scrap. If the test specimen is seed or fruit which size is less than 3 mm, crush them. During the process, prevent the water losing from the specimen, thus avoid using a high speed milling machine. The picking sample should represent the population.

I. Determination of crude drug water contained no volatile components:

Dried the weighing bottle at 105℃ for 1 hour, weigh accurately. Take 10.0 g of test specimen prepared as above, place it in a weighing bottle, and weigh accurately. Dry it at 105℃ for 5 hours, place it in a desiccator and cool, then weigh. Continue drying, weigh every hour until the difference between two weighing is less than 0.25 %, calculate the percentage of water by the losing weights of test specimen.

II. Determination of crude drug water contained ether-soluble volatile components:

Determine the percentage of the volatile ether extractive in test specimen by determination of extractive method IV (General rule 6011). The percentage of loss on drying minuses the percentage of volatile ether extractives equal to the percentage of the water in the test specimen.
Determination of water in crude drugs is also determined by toluene distillation method (General rule 1921).

(6011) Determination of Extractives

I. Ethanol extractives: Place the prepared test specimen in a glass-stopper weighing bottle, weigh 2 g accurately, transfer to a tared Soxhlet extractor, extract for 5 hours by ethanol in continuous extractor, and place 0.2 g of sodium hydroxide in a receiving flask. Dry the residue at 100℃ for 30 minutes in an annular tuber and weigh. Determine the content of water by toluene distillation method (General rule 1921), and calculate the content of water in this test specimen. The weight of test specimen minus the content of water and weight of the residue equal to the weight of ethanol extractives.

II. Dilute ethanol extractives: Weigh accurately 2 g of prepared tests specimen, place in a glass-stopper conical flask, add about 70 mL of dilute ethanol, immerse 8 hours, constant shaking, and then stand for 16 hours, filter. Rinse the conical flask and the residue with dilute ethanol, washed liquid pass through the filter and add in the filtrate until the total volume reach 100 mL. Dry an evaporating dish at 105℃ for 1 hour, place and cool in a desiccator, then weigh accurately. Place 50 mL of filtrate in an evaporating dish, evaporate to dryness in a boiler, and dry at 105℃ for 4 hours. Calculate the percentage of the dilute ethanol extractives in the test specimen, and calculate the percentage of dilute ethanol extractives on the dried basis with the value of loss on drying.

III. Petroleum benzine extractives: Weigh accurately 2 g of prepared test specimen, use Soxhlet extractor to extract for 20 hours by petroleum benzine until the soluble substance are totally extracted. Transfer the extracted liquid to a tared porcelain evaporating dish, volatilize naturally, then place in a sulfuric acid desiccator and dry for 18 hours, weigh and calculate the percentage of the petroleum benzine extractives in the test specimen.

IV. Volatile ether extractives: Place the prepared test specimen in a sulfuric acid desiccator and dry for 12~48 hours, weigh accurately 2.0 g of test specimen, use Soxhlet extractor to extract for 20 hours by ether. After extraction, transfer the extracted liquid to a tared porcelain evaporating dish, volatilize naturally, place the residue in a sulfuric acid desiccator and dry for 18 hours and weigh, gradually heat to 105℃ until the weight remains constant. According to the difference between two weights, calculate the percentage of the volatile ether extractives in the test specimen.

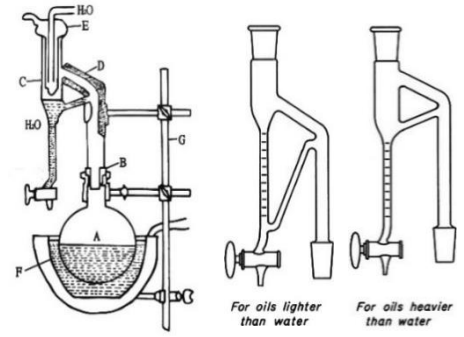
V. Non-volatile ether extractives: Dry the ether extractives which are obtained above at 105°C until the weight remain constant, then weigh. The obtained weight is the weight of the non-volatile ether extractives in the test specimen, calculate the percentage.

VI. Water extractives: As described on method II dilute ethanol extractives, use water substitute the dilute ethanol in the experiment.

VII. Hot extraction method: Weigh accurately 2~4 g of test specimen, place in a 100~250-mL conical flask, accurately add 50~100 mL of ethanol, stopper and weigh, stand for 1 hour, connect a reflux condenser then boil for 1 hour. Cool, take the conical flask, stopper and weigh, add ethanol to its original weight, shake well and filter through a dry filter. Place 25 mL of the filtrate in an evaporating dish dried previously to constant weight. Evaporate the filtrate to dryness on a boiler. Dry at 105°C for 3 hours and cool for 30 minutes in a desiccator. Weigh rapidly and accurately, unless otherwise directed in the monographs, calculate the percentage of water soluble extractives on the dry basis (%).

(6013) Determination of Volatile Oil

Apparatus: A is a 1000 mL round-bottom flask made of hard glass, B is a cork wrapped with aluminum foil, C is an oil collector which has two types: light oil and heavy oil, the scale is 0.1 mL, devices shown in Figure. D is a connect tube of oil collector, wrapped with asbestos yarn to keep the temperature, avoid the oil condense, E is a condenser, F is an oil boiler, G is an iron framework. Check apparatus before determination, each parts should be connected tightly, avoid the volatile oil escape.



Volatile Oil Apparatus

Assay: Weigh accurately a quantity of the test specimen which can evaporate at least 2 mL of volatile oil, place in a flask A, add 3~6 times quantity of water, mix well, connect the flask with the connecting tube. Heat to boiling and keep boiling slightly for 4~8 hours, or until the volatile oil in the test specimen totally distillated.

In the case of light oil, discard liquid on the lower end of the oil collector to allow the oil layer converges at the scale position, adjust the temperature to 25°C, measure the volume.

In the case of heavy oil, after distillation, open the stopcock of oil collector, transfer the oil to a small cylinder, and transfer the water which mixes with oil drops to a small liquid separator, rinse the oil collector with 10 mL of ether, add the ether liquid to the liquid separator, shake and stand for separation, discard the water layer, evaporate the ether solution under slight heat until odor of ether disappear, the remain oil liquid incorporates in the cylinder, adjust the temperature to 25°C and measure the

volume. For measuring the weight of volatile oil, add a small quantity of anhydrous sodium sulfate in obtained oil, shake slowly, and stand until the liquid becomes clear. Pour out the clear oil, measure the specific gravity at 25 ℃, calculate the mass-volume percentage of volatile oil.

(6015) Determination of Loss on Drying

Take 5.0 g of test specimen, place it in a weighing bottle, and weigh accurately. Dry the weighing bottle with test specimen at 105℃ for 5 hours, place it in a silica gel desiccator and cool, and then weigh again. Continue to dry, weigh every hour until the difference between two weights is less than 0.25 %, calculated the percentage of loss on drying by the losing weights. For ensuring desiccator is fully effective, frequently change the desiccant is necessary.

(6301) Determination of Heavy Metals

This test is provided to demonstrate the content of metallic impurities that are colored by sulfide ion, under the specified test conditions. Total heavy metals limit is specified in the individual monograph (represent in parts per million (by weight) of lead in the test specimen), as determined by visual comparison with a control, a standard lead solution. Substances that typically respond to this test are lead, mercury, bismuth, arsenic, antimony, tin, cadmium, silver, copper, and molybdenum.

Determine the amount of total heavy metals by method I, unless otherwise directed in the individual monograph. Method I is used for preparation that yield clear, colorless substances under the specified test conditions. Method II is used for preparation that do not yield clear, colorless substances under the test conditions specified for method I, or for substances have complex nature, which yield interfering sulfide ion metals precipitate, or for fixed and volatile oils. Method III, wet-digestion method, is used only in those cases which neither method I nor method II can be used.

Reagents:

1. **Lead nitrate stock solution**: Add1 mL of nitric acid in 100 mL of water, and dissolve 159.8 mg of lead nitrate in the solution, and then dilute with water to 1000 mL. Prepare and store this solution in glass containers free from soluble lead salts.

2. **Standard lead solution**: Dilute 10 mL of lead nitrate stock solution with water to 100 mL. Each mL of standard lead solution contains 0.01 mg of lead. This solution should be prepared on the day of use. A comparison solution prepared on the basis of 0.1 mL of standard lead solution and 1.0 g of test specimen. If both have the same color, the test specimen contains 1 portion of lead per million which is 1ppm.
3. **pH 3.5 acetate buffer**: Dissolve 25.0 g of ammonium acetate in 25 mL of water, and add 38 mL of 6 N hydrochloric acid. If necessary, adjust with 6 N ammonium hydroxide or 6 N hydrochloric acid to pH 3.5, dilute with water to 100 mL, and mix.

Method I

Standard solution: Measure accurately, a set amount of standard lead solution (lead content meets with the limits of heavy metals contents in test specimen), Pipet the solution in a 50-mL colorimetric tube, and dilute with water to 25 mL. Use a pH meter or a short range pH indicator paper as an external indicator, adjust with 1 N acetic acid or 6N ammonium hydroxide to a pH between 3.0~4.0, dilute with water to 40 mL and mix.

Test solution: Place 25 mL of test solution which prepared as indicated in the monographs in a 50-mL colorimetric tube, adjust the pH value between 3.0~4.0 by 1 N of acetic acid or 6N ammonium hydroxide Using pH meter or pH indicator paper as indicator, dilute with water to 40 mL and mix.

Reference solution: Place 25 mL of solution which is prepared as directed for test preparation in a third 50-mL colorimetric tube and add 2.0 mL of standard lead solution. Use a pH meter or short-range pH indicator paper as an external indicator, adjust with 1 N acetic acid or 6N ammonium hydroxide to a pH between 3.0~4.0, dilute with water to 40 mL, and mix.

Procedure: To each of the three tubes as described above, add 2 mL of pH 3.5 acetate buffer, then add 1.2 mL of thioacetamide-glycerin base TS, dilute with water to 50 mL, mix, allow to stand for 2 minutes, and view downward over a white paper. The color of the solution from test solution is not darker than that of the solution from the standard solution. If the color of the reference solution is lighter than the standard solution, use method II instead of method I.

Method II

Standard solution: Prepare as directed under method I.

Test solution: Place 1.0 g (take 500 mg if total heavy metals limit of test specimen over 30 ppm) of the test specimen in a crucible, moisten test specimen with sufficient sulfuric acid, and carefully ignite at a low temperature until thoroughly carbonized. (The crucible may be loosely covered with a suitable lid during the charring) Add 2 mL of nitric acid and 5 drops of sulfuric acid to the carbonized mass, and heat cautiously until no longer producing white fumes. Ignite, preferably in a muffle furnace, at 500~600 ℃, until the carbon is completely burned off. Cool, add 4 mL of 6N hydrochloric acid, cover it, digest on a steam bath for 15 minutes, uncover, and slowly evaporate on a steam bath to dryness. Moisten the residue with 1 drop of hydrochloric acid, add 10 mL of hot water, and digest for 2 minutes. Add 6 N ammonium hydroxide dropwise until the solution is

alkaline to litmus paper, dilute with water to 25 mL, and adjust with 1 N acetic acid to pH 3.0~4.0, using short-range pH indicator paper as an external indicator. Filter if necessary, rinse the crucible and the filter with 10 mL of water, combine the filtrate and rinsing in a 50-mL colorimetric tube, dilute with water to 40 mL, and mix.

Procedure: To each of the tubes as described above add 2 mL of pH 3.5 acetate buffer, then add 1.2 mL of thioacetamide-glycerin base TS, dilute with water to 50 mL, mix, allow to stand for 2 minutes, and view downward over a white paper. The solution color of the test preparation should be lighter than that the solution of standard preparation.
NOTE: Method does not use for the sample contained mercury.

Method III

Standard solution: Transfer a mixture of 8 mL of sulfuric acid and 10 mL of nitric acid to a 100-mL Kjeldahl flask which is dry and clean, and add a suitable volume of nitric acid which is equal to the volume of nitric acid added to the test preparation. Heat the solution to produce the white fumes, cool, add 10 mL of water and, if hydrogen peroxide was used in the test preparation, add a volume of 30% hydrogen peroxide equal to that used for the test specimen. Boil gently to produce the white fumes, cool again, cautiously add 5 mL of water, mix, boil gently to produce the white fumes until solution volume reduce to 2~3 mL. Cool, dilute with few mL of water, add 2.0 mL of standard lead solution (equal to 0.02 mg of Pb), and mix. Transfer to a 50 mL colorimetric tube, rinse the flask with water, adding the rinsed liquid to the tube until the volume is 25 mL, and mix.

Test solution:

1. **Solid specimen**: Transfer 1.0 g of the test substance to a 100-mL Kjeldahl flask which is clean and dry. (NOTE**:** A 300-mL flask may be used if the reaction foams excessively.) Clamp the flask at an angle of 45°, and add sufficient quantity of a solution mixing with 8 mL of sulfuric acid and 10 mL of nitric acid to the thoroughly rinsed substance. Heat gently until starts the reaction and then stop heating. Add the all remaining acidic solution to the digested residue, part by part, and followed by heating per addition, until the solution is used up. Heat to gently boil and maintain the boiling until the digested solution turning dark. Add 2 mL of nitric acid after cooling down followed by heating it until the digestive solution turning dark again, repeating the stap of addition of 2 mL of nitric acid until no darken and no white fume appearing. Cool down and then add 5 mL of water. Observe the digestive solution color, if appears yellow, add more 3 mL of 30% hydrogen peroxide. Heat again until appearing white fume and the volume of the digestive solution remaining about 2~3 mL. Repeat the treatment of water and hydrogen peroxide until the yellow disappearing. Cool down and then dilute the digested solution with adequate amount of water, wash up and transfer it to a 50-mL colorimetric tube, the final volume of the combined test solution with washing solution should not exceed 25 mL.
2. **Liquid specimen**: Transfer 25 mL of the test substance to a 100-mL Kjeldahl flask which is clean and dry. (NOTE**:** A 300-mL flask may be used if the reaction foams excessively.) Clamp the flask at an angle of 45°, and cautiously add a few mL of a mixture of 8 mL of sulfuric acid and 10 mL of nitric acid. Warm gently until the reaction occurs, until the reaction subsides, and proceed as directed in the solid substance, beginning with "Add the all remaining acidic solution…".

Reference solution: Process the digestion procedure with the test solution, using the same amount of test specimen and the same procedure as directed above. In the section of test solution preparation, if the substance is a solid, only process to the step "Cool, dilute cautiously with a few mL of water.", and then add 2.0 mL of lead standard solution (equal to 0.02 mg of lead), and mix. Transfer to a 50-mL colorimetric tube, rinse the flask with water, adding the rinsing liquid to the tube until the volume is 25 mL, and mix.

Procedure: Treat each of the three tubes as described above. Using a pH meter or short-range pH indicator paper as external indicator, adjust the solution to a pH between 3.0 and 4.0 with ammonium hydroxide (a dilute ammonia solution may be used), dilute with water to 40 mL, and mix. Add 2 mL of pH 3.5 acetate buffer to each tube, then add 1.2 mL of thioacetamide-glycerin base TS, dilute with water to 50 mL, mix, stand for 2 minutes, and view the tubes downward over a white paper: the test solution should appear a lighter color than the standard solution, and the color of reference solution is equal to or darker than that of the standard solution.

I. Inductively coupled plasma-optical emission spectrometry

Inductively coupled plasma-atomic emission spectrometry is used for the measurement of the content of cadmium, lead, mercury, arsenic, or other total heavy metals which may possible exist in Chinese herbs.
The high temperature argon plasma is produced by the high-frequency electromagnetic induction, heat the imported test specimen, apply a series of reactions, like desolvation, decomposition, and atomization/ionization, excited the elements in the plasma, emitted specific emission spectral lines, measure the content by the photo detector.

Apparatus:

1. Inductively coupled plasma optical emission spectrometer
2. Microwave digestion system

Preparation of gold standard solution:
Measure accurately 5 mL of gold standard solution (1000 μg/mL), dilute with 1% nitric acid to 50 mL constant volume, and transfer to a graduated bottle, as an gold standard stock solution. Before use, dilute 5 mL of gold standard stock solution with 1% nitric acid to 50 mL, transfer it to a graduated bottle use as an gold standard solution (containing gold 10μg/mL).

Preparation of standard solution: Measure accurately 1 mL of lead, cadmium, arsenic, and mercury in a 100 mL volumetric flask, dilute with 1% nitric acid to constant volume, transfer to a graduated bottle, as a standard stock solution. Before use, take a quantity of standard stock solution, add the gold standard solution, dilute with 1 % nitric acid to 10~500 ng/mL (containing gold 100 ng/mL) transfer it to a graduated bottle, use as a standard solution.

Test solution preparation: Weigh accurately 0.2~0.5 g of test specimen, place it in a high pressure microwave digestion bottle, add 6 mL of nitric acid and 1.5 mL of hydrogen peroxide, digest it in a microwave digestion bottle, after digest complete, add 0.2 mL of gold standard solution, dilute with deionized water to 20 mL constant volume, use as a test solution.

Procedure:
1. Calibration curve: Introduce a series of standard solution with different concentration in an inductively coupled plasma-atomic emission spectrometer, and make the calibration curve.
2. Quantitation of the test solution: Introduce the test specimen in inductively coupled plasma optical emission spectrometer to test, apply the calibration carve and determine the content of lead, cadmium, arsenic and mercury (ppm) by using the equation below.

The content of lead, cadmium, arsenic and mercury in the test solution =

$$\frac{C \times V}{M \times 1000}$$

C: concentration of lead, cadmium, arsenic, and mercury in the test solution by calibration curve. (ng/mL)
V: final volume of the test (mL)
M: weight of the test (g)

II. Inductively coupled plasma-mass spectrometry

Coupled plasma-mass spectrometry is used for the measurement of the content of lead, cadmium, arsenic, copper, mercury, or other total heavy metals.
The high temperature argon plasma is produced by the high frequency electromagnetic induction, heat the imported test specimen, apply a series of reactions, like desolvation, decomposition, and atomization/ionization, the elements in a plasma change into monovalent cation, measure the content by passing through the vacuum interface and transferring it into mass spectrometer.

Apparatus:
1. Inductively coupled plasma-mass spectrometer
2. Microwave digestion System

Preparation of internal standard solution: Measure accurately 0.5 mL of rhodium standard (1000 μg/mL) and 5 mL of gold standard solution (1000 μg/mL), dilute it with 1% nitric acid to 50 mL, and transfer it to a graduated bottle, as an internal standard stock solution. Before use, dilute 5 mL of internal standard solution with 1 % nitric acid to 50 mL, transfer it to a graduated bottle, use as an internal standard solution (content rhodium 1 μg/mL and gold 10 μg/mL).

Preparation of standard solution: Measure accurately 1 mL of lead, cadmium, arsenic, copper and mercury in a 100-mL volumetric flask, dilute it with 1 % nitric acid to constant volume, move it to a graduated bottle, as a standard stock solution. Before use, take appropriate quantity of standard stock solution, add the internal standard solution, dilute it with 1% nitric acid to 1~10 ng/mL (content rhodium 10 μg/mL and gold 100 μg/mL), transfer it to a graduated bottle, use as a standard solution.

Test solution preparation: Weigh accurately 0.2~0.5 g of test specimen, place it in a high pressure microwave digestion bottle, add 6 mL of nitric acid and 1.5 mL of hydrogen peroxide, digest it in a microwave digestion bottle, after digestion, add 0.2 mL of internal standard solution, dilute with deionized water to 20 mL, use it as a test solution.

Procedure:
1. Calibration curve: Introduce a set of standard solution with different concentrations series in an inductively coupled plasma-mass spectrometer, and make the calibration curve.
2. Quantitation of the test solution: Introduce and determine test specimen in inductively coupled plasma-mass emission spectrometer, apply the calibration carve and determine the content of lead, cadmium, arsenic, copper and mercury (ppm) by using the equation below.

The content of lead, cadmium, arsenic, copper and mercury in the test solution =

$$\frac{C \times V}{M \times 1000}$$

C: concentration of lead, cadmium, arsenic, copper and mercury (ng/ml) in the test solution by calibration curve.
V: final volume of the test specimen (mL)
M: weight of the test specimen (g)

III. Graphite furnace atomic absorption spectrometry

Measure the herbal medicines content of cadmium, lead, mercury, arsenic or other total heavy metals by graphite furnace atomic absorption spectrometry.

Heat the test specimen liquid by electrothermal process in a graphite furnace, through the processes of desolvation, ashing and atomization. The element which is waited to analyze atomized in the graphite furnace atomic. The radiation beam from specified elements which is in excited state pass through the graphite furnace, the beam produced by a hollow cathode lamp or an electrodeless discharge lamp. The concentration of test element is calculated by the change amount of incident light specified intensity.

Apparatus:
1. Graphite furnace atomizer
2. Ashing furnace
3. Electric heating plate
4. Microwave digestion apparatus

Matrix modifier:
1. Matrix modifier I: Mix 1000 μg/mL of palladium solution with 600 μg/mL of magnesium nitrate.

2. Matrix modifier II: A mixed solution with 10000 μg/mL of ammonium dihydrogen orthophosphate and 500 μg/mL of magnesium nitrate.

Preparation of standard solution: Weigh accurately 1 mL of lead, cadmium and arsenic, place in a 100 mL volumetric flask, add 1 % nitric acid to constant volume, transfer to a graduated bottle, as a stock standard solution, dilute cadmium to 0.5~2.0 ng/mL, lead and arsenic to 10~50 ng/mL with 1 % nitric acid, serve those as a standard solution.

Test solution preparation:
1. Dry digestion method: Apply for testing the lead and cadmium. Place 1.0~5.0 g of test specimen in a crucible, weigh accurately, heat to carbonized at a electric hot plate, transfer to an ashing furnace and ash at 450℃ for 3~5 hours. If ashing incompletely, allow it to cool, add 0.5~3 mL of nitric acid, dry on an electric hot plate, transfer to an ashing furnace and ash at 450℃ for 3~5 hours, repeat the operation until the color of ash change to white. Allow to cool and dissolve in 5 mL of 1 N nitric acid with heat, add deionized water to constant volume 20 mL, serve as a the test solution.
2. Acid digestion method: Apply for testing the lead, cadmium and arsenic. Weigh accurately 0.5~1 g of the test specimen, place it in digestion bottle, add 10 mL of nitric acid, heat and digest at 60℃ for 30 minutes on an electric hot plate, and elevate the temperature to 95℃, digest the solution until it is clear, allow it to cool, add deionized water to constant volume 20 mL, serve as a test solution.
3. Acid digestion method by microwave: Suitable for testing lead, cadmium and arsenic. Weigh accurately 0.2~0.5 g of specimen in a high pressure microwave digestion bottle, add 6 mL of nitric acid and 1.5 mL of hydrogen peroxide, digest in a microwave digestion equipment, after the digestion complete, add deionized water to constant volume 20 mL, serve as the test solution.

Procedure:
1. Calibration curve: Weigh accurately 20 μL of a series of standard solution with different concentration, add 2 μl of matrix modifier respectively (If the test sepcimen is arsenic, use matrix modifier I. If the test specimen is lead or cadmium, use matrix modifier II), inject in the graphite furnace atomizer respectively and make a calibration curve.
2. Quantitation of test solution: Weigh accurately 20 μl of test solution, add 2 μl of matrix modifier (If the test specimen is arsenic, use matrix modifier I. If the test specimen is lead or cadmium, use matrix modifier II), inject in the graphite furnace atomizer, substituted into calibration curve, and calculate the content of lead, cadmium and arsenic (ppm) in the test specimen as follow.

The content of lead, cadmium and arsenic in the test specimen (ppm) =

$$\frac{C \times V}{M \times 1000}$$

C: concentration of lead, cadmium and arsenic in the test specimen by the calibration curve (ng/mL).
V: final constant volume of the test solution (mL).
M: weight of the test sample (g).

IV. Hydride generation atomic absorption spectroscopy

Measure the content of arsenic or other total heavy metals in the herbal medicines by hydride generation atomic absorption spectrometry.
Use the selective chemical reduction, arsenic in the test solution is reduced to hydride and separated, then import the sample into the quartz tube, measured by an atomic absorption spectrometer.

Apparatus:
1. Atomic absorption spectrometer
2. Hydrogenation equipment
3. Electric hot plate
4. Microwave digestion system

Preparation of reactant:
1. Sodium borohydride solution: Dissolve 5.0 g of sodium hydroxide and 5.0 g of sodium borohydride in deionized water to 500 mL constant volume.
2. 30% (v/v) Hydrochloric acid: Take 300 mL of hydrochloric acid, dilute with deionized water to 1000 mL constant volume.
3. 40% potassium iodide solution: Dissolve 20.0 g of potassium iodide in deionized water to 50 mL constant volume.

Preparation of standard solution: Weigh accurately 1 mL of standard substance, place in a 100-mL volumetric flask, make it to the constant volume with 1 % nitric acid,

transfer to a graduated bottle as a stock standard solution. Before use, take a quantity of stock standard solution, dilute it with 1 % nitric acid to 1~10 ng/mL, serve as a standard solution.

Test solution preparation:

1. Acid digestion method: Weigh accurately 0.5~1.0 g of the test specimen, place it in digestion bottle, add 10 mL of nitric acid, heat on an electric hot plate at 60℃ for 30 minutes then elevate the temperature to 95℃. Heat and digest the solution until it is clear, heat until remained acid to approximately 1 mL, allow it to cool, add deionized water to 20 mL constant volume, serve as a test solution.
2. Acid digestion method by microwave: Weigh accurately 0.2~0.5 g of specimen, put it in a high pressure microwave digestion bottle, add 6 mL of nitric acid and 1.5 mL of hydrogen peroxide, digest in a microwave digestion system. After the digestion, heat until the remained acid to approximately 1 mL, allow it to cool, add 10 % hydrochloric acid to 20 mL constant volume, serve as the test solution.

Procedure:

1. Calibration curve: Take a series of standard solutions with different concentration 10 mL, add 10 mL of 30% (v/v) hydrochloric acid and 1 mL of 40% potassium iodide, react in the dark for 1 hour. Respectively inject in the hydrogenation equipment, which reacts with sodium borohydride gives production of hydride. Hydride is measured by atomic absorption spectrometer to obtain a calibration curve.
2. Quantitation of test solution: Take 10 mL of test solution, add 10 mL of 30% (v/v) hydrochloric acid and 1 mL of 40% potassium iodide, react in dark for 1 hour. Respectively inject in the hydrogenation equipment, which reacts with sodium borohydride gives production of hydride. Hydride is measured by atomic absorption spectrometer, substituted into calibration curve and calculated the content of arsenic in the test specimen (ppm) as follow.

The content of arsenic in the test specimen (ppm) =

$$\frac{C \times V}{M \times 1000}$$

C: concentration of arsenic in the test solution by the calibration curve (ng/mL).
V: final constant volume of the test specimen (mL).
M: weight of the test specimen (g).

V. Cold-Vapor atomic absorption spectroscopy

Cold-vapor atomic absorption spectrometry is used for the measurement of the content of mercury or other total heavy metals in the herbal medicines.
Use the selective chemical reduction, the mercury in digestion liquid of the test specimen is reduced to mercury vapor, then import the sample into quartz tube, measured by an atomic absorption spectrometer.

Apparatus:

1. Atomic absorption spectrometer
2. Cold vapor generation device
3. Microwave digestion system

Preparation of reactants:

1. 10% (v/v) hydrochloric acid: Take 100 mL of hydrochloric acid, add deionized water to 1000 mL constant volume.
2. Stannous chloride solution: Dissolve 10 g of stannous chloride in 10% (v/v) hydrochloric acid to 500 mL constant volume.

Preparation of standard solution: Weigh accurately 1 mL of standard specimen, place in a 100-mL volumetric flask, add 1 % nitric acid to constant volume, transfer to graduated bottle as a stock standard solution. Before use, take a quantity of stock standard solution, dilute it with 1 % nitric acid to 1~10 ng/mL constant volume, serve as a standard solution.

Test solution preparation: Weigh accurately 0.2~0.5 g of test specimen, put it in a high pressure microwave digestion bottle, add 6 mL of nitric acid and 1.5 mL of hydrogen peroxide, digest in a microwave digestion system. After the digestion, add deionized water to 50 mL constant volume, serve as the test solution.

Procedure:

1. Calibration curve: Take a series of standard solutions with different concentration, respectively inject in the cold vapor generation device, which reacts with stannous chloride and gives production of mercury vapor. Measure the mercury vapor by atomic absorption spectrometer and make a calibration curve.
2. Quantitation of test solution: Inject the test solution in the cold vapor generation device respectively, which reacts with stannous chloride and gives production of mercury vapor. Measure the mercury vapor by atomic absorption spectrometer, substituted into calibration curve, and calculate the content of mercury in the test specimen (ppm) as follow.

The content of mercury in the test specimen (ppm) =

$$\frac{C \times V}{M \times 1000}$$

C: concentration of mercury in the test specimen by the calibration curve (ng/mL).
V: final constant volume of the test specimen (mL).
M: weight of the test specimen (g).

(6303) Determination of Residue of Sulfur Dioxide

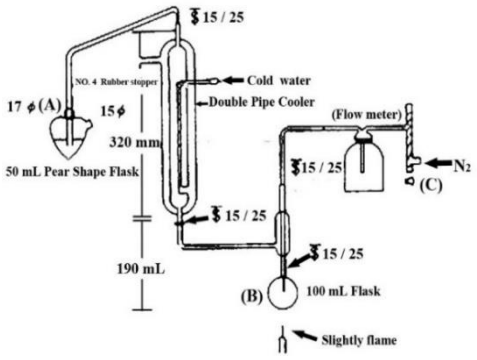
Method: Alkali Titration Method

Apparatus: Ventilation distillation apparatus

Reagents:

1. Hydrogen peroxide, phosphoric acid is guarantee grade reagents. Methyl red, methylene blue, ethanol, sodium hydroxide are chemical pure grade.
2. Water: Dechlorinated by boiling, use immediately after it cooled.
3. Mixed indicator: Dissolve 0.2 g of methyl red and 0.1 g of methylene blue in ethanol to 100 mL.
4. 0.3 % Hydrogen peroxide: Dissolve 1 mL of 30% hydrogen peroxide in water to 100 mL. Freshly prepared before use.
5. 0.1N and 0.01 N sodium hydroxide solution, and freshly prepared before use.

Preparation of the sample solution: Fine-cut the solid sample (less 2mm), weigh accurately a quantity of 1.0~5.0 g, add 20 mL of water. Weigh 20.0 g of the liquid sample, place it in a 100 mL round-bottom flask (B), and add 2 mL of ethanol, 2 drops of silicon oil and 10 mL of 25 % phosphoric acid, rapidly connect the apparatus. Add 10 mL of 0.3% hydrogen peroxide in (A) flask, add 3 drops of the mixed indicator (the color change to violet), add 1~2 drops of 0.01 N sodium hydroxide until the color of the solution change to olive green, connect the apparatus. Adjust the (C) part, the nitrogen pass through at rate of 0.5~0.6 L/min, the flame of microburner is the height of 4 ~5 cm or heater, heat the (B) flask for 10 minutes, remove the flask (A). Wash the tip of glass tube with small amount of water into flask (A), serve as the sample solution.



Distillation Apparatus

Assay: The sample solution prepared above is titrated with 0.01N sodium hydroxide, until the color of the solution changes to olive green, make a blank test, and determine the content of sulfur dioxide in the solution.
0.01 N sodium hydroxide 1 mL= 0.32 mg of SO_2.

(6305) Determination of Pesticides Residues

The method is used gas chromatographic for the determination the total amount of BHC, DDT, PCNB, organochlorine pesticides residue in herbal medicines.

Test solution: Weigh accurately 20 g of sample powder, place it in a stirring flask, add 80 mL of water and mix, stand for 20 minutes. Add 200 mL of acetonitrile, high speed stirring for 1 minute, pour it in a Buchner funnel with filter paper, suction filtration in a covered glass cylinder (500-mL), rinse the residue with acetonitrile, combine the filtrate, and add acetonitrile to 350 mL constant volume. Take 100 mL of the filtrate in a covered glass cylinder (150 mL), add 15.0 g of sodium chloride and shake 1 minute, stand 20 minutes for layer separation, record the volume of acetonitrile in the upper layer (V_1 mL). Take 10 mL of the upper filtrate, dry under nitrogen gas at 40℃ until slightly dry, dissolve in 2 mL of *n*-hexane, inject in florisil cartridge which is advance moistened by 5 mL of the mixture of acetone and *n*-hexane (1:9, v/v), for solid phase extraction, elute twice with 5 mL of the mixture of acetone and *n*-hexane (1:9, v/v), collect the eluent in a glass tube, dry under nitrogen gas at 40℃ until slightly dry, dissolve it in *n*-hexane to constant volume 2 mL, as the sample solution.

Standard Solution: Take 100 mg of each standard pesticides: *α*-BHC, *β*-BHC, *γ*-BHC, *δ*-BHC, *o,p′*-DDT, *p,p′*-DDT, *p,p′*-DDD, *p,p′*-DDE, PCNB, pentachloroaniline and methyl pentachlorophenyl sulphide, weigh accurately, dissolve respectively in *n*-hexane to constant volume 100 mL as a standard stock solutions. Mix a quantity of each standard stock solution, dilute with *n*-hexane to a suitable concentration, and serve as a standard solution.

Assay: Take 2 μL of each sample solution and standard solution, measure it by GC, compare and identify standard solutions and sample solutions by the retention time of the peaks. Make a calibration curve by examining the standard solutions as described above, and then use the equation below to determine the content of each pesticide and the total quantity of BHC, DDT and PCNB.

Content of pesticides residue in sample (ppm) =

$$C \times \frac{V_2}{10} \times \frac{V_1 \times 350}{100 \times W}$$

C: the concentrations of each pesticides residue by calibration curve of each pesticide (μg/mL).
V_1: after adding NaCl, record the volume of acetonitrile layer (mL).
V_2: final constant volume of the sample (2 mL).
W: the weight of the sample (20.0 g).

Total content of BHC = the content of α-BHC (ppm) ＋ the content of *β*-BHC (ppm)＋the content of *γ*-BHC (ppm) ＋the content of *δ*-BHC (ppm).
Total content of DDT = the content of *o,p′*-DDT (ppm) ＋ the content of *p,p′*-DDT (ppm)＋the content of *p,p′*-DDD (ppm) ＋the content of *p,p′*-DDE (ppm).
Total content of PCNB = the content of PCNB (ppm)＋ the content of pentachloroaniline (ppm)＋the content of methyl pentachlorophenyl sulphide (ppm).

Identification test: Pesticides containing organochlorine required reexamination by using gas chromatography-mass spectrometry for confirmation analysis.

Reference conditions for gas chromatography determination:
Detector: Electron Capture Detector, ECD
Column: Silica capillary column, inner diameter is 0.53 mm, length is 30 m, the inner wall coating with 5% Phenyl-methylpolysiloxane whose thickness is 1.50 μm, or other column, inner diameter is 0.53 mm, length is 30 m, the inner wall coating with 35% Phenyl methyl-polysiloxane, thickness is 0.83 μm.
Column temperature: After injection, maintain in 210℃ for 6 minutes, and then raise to 270℃ with the rate of 8℃ per minute, keep 25 minutes.
Detector temperature: 300℃.
Injection temperature: 250℃.
Carried gas: He, 6 mL/min.
Auxiliary gas: N_2, 25 mL/min.

Reference conditions for gas chromatography mass spectrometry:
Analyzer: Ion Trap Analyzer or Quadruple Analyzer.
Column: Silica capillary column, inner diameter is 0.25 mm, length is 30 m, and the inner wall coating is 0.25 μm of 5% Phenyl dimethylpolysiloxane.
Column temperature: After injection, keep in 50℃ for 1 minute, raise to 270℃ with the rate of 20℃ per minute, keep 13 minutes
Injector temperature: 250℃.
GC/MS interfacial temperature: 250℃.
Ion Trap Analyzer temperature: 180℃, or Quadruple Analyzer temperature: 20℃.
Carried gas: He, 0.8 mL/min.
Mass range: 50~500 amu.

(6307) Determination of Aflatoxins (Mycotoxins)

The method is used high performance liquid chromatography for the determination of aflatoxin in herbal medicines.

Solvent of mobile phase: Mix water and methanol at the ratio of 55: 45 (v/v), filter by filter membrane, take the filtrate as the solvent for mobile phase.

Standard solution: Take 1 mL of a mixed reference standard (marked concentration at 1000 ng/mL of aflatoxin B_1, 300 ng/mL of aflatoxin B_2, 1000 ng/mL of aflatoxin G_1 and 300 ng/mL of aflatoxin G_2), dilute with 50 % methanol solution to constant volume 20 mL, serve as standard stock solution. Before use, dilute aflatoxin B_1 and aflatoxin G_1 with 50 % methanol5011 solution to 0.1~50 ng/mL, dilute aflatoxin B_2 and aflatoxin G_2 with 50 % methanol solution to 0.05~15 ng/mL, serve as standard solution.

Sample solution: Take 25.0 g of grinded and mixed sample, weigh accurately, place it in a homogenizer, add 5.0 g of sodium chloride, and add 100.0 mL of 80 % methanol, homogenate at 15000 rpm for 2 minutes, filter with filter paper. Accurately take 10 mL of filtrate and mix with 40 mL of water, filter with glass microfiber filter. Accurately take 10 mL of filtrate, pass through an immunoaffinity column at the rate of 1 drop per second, after all filtrate pass through the column, wash the column twice with 10 mL of water at the rate of 1 drop per second. After driving out the water from the column, add 1 mL of methanol, elute at the rate of 1 drop per second, collect the eluent, add water and mix to constant volume 2 mL, filter by syringe filters, and the filtrate serves as a sample solution.

Chromatographic apparatus: HPLC with Fluorescence detector (360 nm excitation wavelength and a 440 nm emission wavelength), photoreactor and 4.6 mm × 25 cm of chromatographic column (octadecylsilane chemically bonded silica; filling diameter is 5 μm), the rate of mobile phase is 1.0 mL per minute.

Assay: Take 50 μL of sample solution and standard solution, inject respectively in the chromatographic apparatus, record the chromatogram, compare and identify the retention time of the peaks in sample solution and standard solution, and calculate the content of aflatoxin in the sample (ppb):

The content of aflatoxin in the sample (ppb) =

$$\frac{C \times V \times F}{M}$$

C: the concentration of aflatoxin (ng/mL).in the sample by the calibration curve
V: final volume of the sample solution (mL)
F: 50.
M: weight of the sample (g).
Total content of aflatoxin (ppb) = the content of B_1(ppb) + the content of B_2(ppb) + the content of G_1 (ppb) + the content of G_2 (ppb).

(6501) Determination of Swelling Capacity

Swelling capacity is an index to indicate the swelling property of drugs. It is defined as the volume (mL) of 1.0 g of dry drug swell in water or in other specified solvent at a definite time and temperature. It is mainly used for the natural drugs contained mucilage, gelatin and hemicellulose.

Assay: Weigh accurately a quantity of drug by the monograph, follow the monograph to crush if necessary, weigh, put in a assay tube (160 mm in total length. 16 mm in inner diameter, 125 mm long in the scale portion, scale is 0.2 mL), add 25 mL of water or specified solvent at 20~25℃, stopper tightly, shake and stand. Unless otherwise directed, shake every 10 minutes in the first hour, then stand for 4 hours, read the volume of the test specimen after swelling, and read again after standing for 1 hour, until the volume difference is less than 0.1 mL between two readings. Measure three test specimens for each drug, and calculate the average value (accurate to the first decimal place).

$$S = \frac{V}{W}$$

S: swelling capacity.
V: swelling volume of the test specimen (mL).
W: weight of the test specimen calculated in dry basis (g).

(6503) Microscopic Identification

I. Theory of microscopic sectioning:

The internal structure of plants has its uniqueness. In order to observe under the microscope for identification, tissue sectioning is an important step. There are two types of botanical sections, temporary and permanent section. Temporary section is usually carried by free-hand section. Not preserve the sections after observing. The permanent preservation method for section is dehydrated the plant tissue and replaced with balsam, resin or other substance. After dehydrating, stain the tissue with one or several types of dyes in order to facilitate the observation and preserved the section for future observation.

II. Fixation:

The first step is to fix the crude drug. The term "fixation" is to have the live botanical tissue fixed with the fixatives. The fixative also has the function of preservation, anticorrosion and rapidly penetrating activity. The fixation has to be made rapidly in order to remain the fixed structure as faithfully as possible compared to the living state. In order to penetrate rapidly, the sample size is also an important factor. Before placing tissue in the fixative, the specimen should be cut into a suitable size, less than $0.6\times0.6\times0.6$ cm^3. Gas in the plant material may impede the penetration of the liquid. There are two common methods to remove the gas, boiling method and degas method. Boiling method usually applies on hard and tough material, boil for thirty minutes to one hour. Degas method usually applies on finely divided material. Fixatives cause condensation and hardening on the inner parts of the tissue and facilitate slicing.

Commonly used fixatives:

(1) Ethanol: Commercially available ethanol is about 95 %. Absolute alcohol easily absorbs water vapor in the air and changes the concentration. Alcohol is weakly alkaline, the feature of ethanol is infiltrating the tissue rapidly. However, rapid infiltration has a disadvantage which may cause the material atrophy and excessive hardening, and it also can't preserve the fine components within the cytoplasm and cause the roughness of cytoplasm and nucleus. When only using alcohol, the concentration is usually 50%~70%. Alcohol usually use with other reagents. Due to its rapid penetration, it can harden the soft material and facilitate the slicing.

(2) Formalin: Formalin is an aqueous solution contained 36%~40% of formaldehyde. Formalin causes less atrophic to the cell and can preserve the fine structure in the cytoplasm. However, it also causes tissue hardening and brittleness and makes cell wall broken off. To avoid these phenomena, the concentration of formalin should be below 50%.

(3) Acetic acid: Glacial acetic acid contains about 100% acetic acid, is a common fixative for nuclear components such as chromosomes, it infiltrates rapidly and softens plant tissues. However, it can't preserve the structure of cytoplasm and may easily cause the cell walls and chromosomes swelling.

(4) Chromic acid: Low concentration (about 1%) of aqueous chromic acid solution is commonly used in the fixation of lower-class plants (ex. algae). It can preserve the cytoplasm and nucleus components (except mitochondria) to a certain extent. It also causes less swelling and atrophy. The disadvantage of chromic acid is slow infiltration, chromic ion (heavy metal) which usually combines with the tissue is hard to remove, the chromic ion deposits in the structure and interferes with the dying, so the test specimen which contains heavy metal has to be rinsed with the water 8 to 12 hours.

Commonly used mixed fixatives:

1. F.A.A fixative:

Content	Volume
50%~70% alcohol	90 mL
Glacial acetic acid	5 mL
Formalin	5 mL

Glacial acetic acid causes tissue swelling and formalin makes it atrophic, mixture of two obtains better effect. The fixed time is at least 4 hours (depend on the infiltration characteristic of fixatives). Before dehydration, rinse the tissue with 50% ethanol for half an hour.

2. Craf III fixative:
Solution A contains 30 mL of 1% chromic acid and 20 mL of 10% glacial acetic acid.
Solution B contains 10 mL of formalin and 40 mL of water.
Mix solution A with solution B (1:1) before use. Because the formalin is a strong reducing agent and chromic acid is a strong oxidative agent, the solution turns to dark green or dark brown solution. The mixture does not contain alcohol, therefore the atrophy or hardening effect to plant tissue in Craf Ⅲ is less than that in FAA. It is the ideal fixative for the soft structure such as meristem and reproductive organ. The main disadvantage of the fixative is slow penetration (fixation takes about 12 hours). Due to the existence of chromium (heavy metal), it needs more time to rinse (rinsing 8 – 12 hours is required before dehydration).

III. Dehydration and staining:

The steps of dehydration and staining: use the reagents (ethanol, *t*-butanol, etc.) to replace the water in the tissue gradually, from low concentration to high concentration to achieve a completely waterless. Common organic reagents used in the dehydration are ethanol and *t*-butanol (*tert*-Butylalcohol). This type of organic reagents often leads to the alteration on tissue morphology. The concentrations of reagent used for dehydration depends on concentrations of fixatives and the natures of specimen. Relatively soft and tender materials may start with lower concentration of alcohol for dehydration (about 20%). Relatively hard materials may start with higher concentration of alcohol for dehydration (about 50%~70%). It should also fit or close to the concentration of fixatives. For example, using FAA as fixative, may start with 50% alcohol. If Craf III is used as fixative, we may start with 20%~30% of alcohol, from 20% → 30% → 50% → 70% → 85% → 95% → 100%. The interval between each step varies with material sizes.

Staining may be carried out during the process of dehydration. All dyes must be dissolved in a suitable solvent to achieve the purpose of coloring. When to stain depends on the solvent concentration, for example, the dyes which are soluble in 50% ethanol add into the test specimen can be dyed during the step of 50% ethanol dehydration process.

IV. Free-hand sectioning:

Free-hand sectioning is the most basic and easy method in sectioning techniques. It is used for preliminary observations for crude drug, or rapid identification. To make the section, hold the knife which has relatively stable blade with one hand, and hold materials with another hand, then process serial sectioning. Allow cut material floating on the beaker contained water, and then select the proper thickness section, put the section in a fixative. The fixative can be 50%~70% of alcohol. The alcohol is seldom used as the fixative alone, but it can be used in the free-hand sectioning. Alcohol does not cause obvious damage to the tissue and simplify the fixation process. Because during the free-hand sectioning, cytoplasm or intracellular compounds often prolapse from the incision, the remaining part are mostly cell wall, thus preservation of the cytoplasm is not a crucial point to the choice of the fixatives. After fixation with alcohol 4~12 hours, dehydration and staining can be carried out, the steps as follow:

1. 50% alcohol solution contained 0.5% safranin for 3 hours to overnight.
2. Rinse with 50% alcohol for 3 times.
3. 70% alcohol for 10 minutes.
4. 85% alcohol for 10 minutes.
5. 0.1% Fast-green in 95% alcohol solution for less than 5minutes (varies with different materials).
6. Rinse with95% alcohol for 3 times.
7. Dehydrated alcohol for 5 minutes.
8. Dehydrated alcohol for 5 minutes.
9. Dehydrated alcohol and xylene (1:1) for 10 minutes.
10. Xylene for 10 minutes.

Transfer it to glass slides, add one drop of balsam (commonly used the Canada balsam) and cover with cover slips. Each step is carried out in a small petri dish. After drying the glass slides, it can be preserved for a long period and observe anytime.

V. Temporary slice making method

Hold one end of the slide in the left hand and go into the beaker obliquely. Be careful not to pinch the fingerprint on the slide by holding it horizontally with your thumb and finger, so that the fingerprint will not be printed on the slide. Use a crochet needle to move the section in the liquid to the center of the slide with your right hand. Gently press the upper end of the slice with a crochet needle, move both hands up at the same time, slowly take out the slide from the liquid to prevent the slice from overlapping or breaking, and then use filter paper to absorb the surrounding liquid.

Add a drop of mounting agent such as glycerin water (glycerin: water = 1:1) to the slice, hold a corner of a clean glass slide with your right hand, and slowly cover the slice, do not let air bubbles be sealed on the slice. If there are too many bubbles, you must recap or tilt the glass slide slightly, and then tap one end of the cover glass with a crochet hook. A few remaining bubbles may escape from the other end with less pressure. After sealing, use filter paper to wrap around the cover glass. Exhaust the excess blocking agent to absorb dry, adjust the position of the cover glass so that it is in the center of the glass slide, and can cover the entire section. At this time, the section is suitable for low-power microscope observation: such as cell arrangement, cell content, distribution of starch granules or pigments, etc. After the initial microscopy observation, we can choose various appropriate stains or reagents to stain a certain part of the tissue with a special color or make the cell content have a special chemical reaction. Add a small amount of reagent to the edge of one end of the cover glass. The other end is supported with filter paper, without moving the cover glass, and gradually achieves the purpose of color rendering, dissolution or other microchemical purposes. Generally, the operation for beginners is relatively simple and reliable before the blockade.

VI. Paraffin method:

1. Fixation:
   In this method, the material is buried in the wax block, slice the materials with wax block together and then remove the wax. This method involves more steps and is more complicated than free-hand sectioning staining as described above. However, this method is commonly applied due to the better result at slicing. Before dipping into wax, this material requires the steps of fixation, rinsing and dehydration. These steps can be operated more conveniently in vials. Before the dehydration operation, remove the bubbles in the tissue by a suction device (for soft tissue). Sometimes

the materials may sink to the bottom of solution, there is still gas left in the cell or in the cell intercellular spaces. The bubbles remain in the tissue may also be removed during the dehydration, but some of bubbles may still remain. Remaining bubbles form voids in the wax block and lead damage in the surrounding tissues during slicing. For meristematic tissue, bubbles can be removed more easily.

2. Dehydration:
Many reagents can be used for dehydration. The most common reagents are mixture of *t*-Butanol (*tert*-Butyl alcohol) and alcohol (TBA-series). Transfer the specimen to the solution as follows. The penetration of wax may start from the sixth step.

*TBA-Series			
	t-butanol	95% ethanol	H_2O
First step	10	40	50
Second step	20	50	30
Third step	35	50	15
Fourth step	55	45	0
Fifth step	75	25	0
Sixth step	100	0	0

The time to every step of the dehydration varies with the size of tissue, from one to several hours. To medium hard material 0.5 × 0.3 × 0.3 cm^3 in size, each step takes about two hours. For the sixth step, it may preferably take eight to twelve hours. The melting point of *t*-butanol is 25℃, therefore it should be operated near the thermostat during winter.

3. Infiltration of paraffin:
After dehydration, *t*-butanol is gradually replaced with pure wax. This step is called infiltration of paraffin. The infiltration of paraffin is operated in a 60~65℃ thermostat. There is more than one way for infiltration of paraffin. Gradually add the small solid wax blocks in a fixed bottle three to five times. Each time add the wax blocks should not exceed one third of liquid in the bottle. Incomplete dehydration may cause incomplete infiltration of paraffin. Direct contact the material with wax blocks may cause rapid infiltration of paraffin which causes atrophy to the tissue. Use the method described above to avoid rapid infiltration of paraffin. In order to avoid direct contact the material with wax blocks, slowly melt the wax on a filter paper and the wax runs down through the filter paper to the bottom. The larger wax block has the slower melting speed.
Notice that the temperature in the thermostat should be embedding as lower as possible (but higher than the melting point of the wax). The infiltration of paraffin should be at an appropriate time duration and speed. Fast infiltration of paraffin will cause incompletion in infiltration of paraffin. The time cannot be too long either, especially fort the soft and tender tissue which are quite vulnerable in hot wax may be damaged in long time infiltration of paraffin. It is suitable for medium hard material take about twelve to twenty-four hours.
The last adding of wax blocks, open the fixed bottle after 2 hours, *t*-butanol in the bottle should be completely evaporated in 8 to 12 hours, leaving only the pure wax in liquid state.

4. Embedding:
Pour the material and liquid wax into a model, place in cold water for rapid cooling and the solidification of wax block. The most economical model is homemade carton, but using ceramic or stainless metal materials are preferable. During embedding, notice the arrangement, direction of the materials, distance between materials, and labels in the wax block. It is difficult to identify materials buried in the wax. If the material is too small or transparent, a small amount of Safranin powder can be added in the sixth step of dehydration. The pink dye on the material will not fade during slicing.

Choices of wax: The quality of the wax and correspondence with materials show a great effect on the section.

(1) Composition: The wax used for biological tissue section is often the mixture of paraffin wax, beeswax, gum and rubber. Wax prepared for slicing are sold by major biological material supplier such as Ex Histowax (R. Jung Gmb H), Tissuemat and Bioloid.
(2) Melting point: Use high melting point wax for hard materials, and low melting point wax for delicate materials. If the room temperature is high during slicing, use a high melting point wax. The melting point of common wax is about 55 ℃.
(3) Texture: Wax is a crystalline material, the smaller crystalline particles show less impact on the tissue, wax which is used for several slicing can still be reused.

5. Sectioning:
Before slicing with a microtome, remove the excess wax block and fix it on a small piece of wood or special support material for easy binding on the microtome. There are two types of microtome involved in the embedding material slicing, rotary microtome and sliding microtome. Hard materials require special treatments and are more appropriate to use sliding microtome. When using a rotary microtome, the rotating speed should be kept at constant, 1~1.5 turns per second is more appropriate. The advantage of the sample is that pieces of wax can be connected into a continuous band of wax. The thickness of each slide is fixed. The thickness of the section depends on the purpose of the research, the slice for general cell tissue is about 10~15 μm. The

thickness of each section can be adjusted on the microtome. However, errors may occur from microtome. The thinner the section is, the larger the errors occur. The length of the wax may also generate errors because of compression phenomenon.

6. Gluing sectioning:
First, glue the section with adhesive, stain the section and the slides together, not only obtain a continuous section, but also accompany with easy operation and high efficiency in this procedure. The more ideal homemade adhesive is Mayer's Adhesive, the composition are as follows: albumin, glycerol and a small amount of thymol and phenol as preservatives. According to the preparation of Mayer, the ratio of filtered albumin (stir well) and glycerol is 1:1. Glycerol is used for preventing dryness. If the humidity in environment is high, the ratio may swift to 2:1.

Before gluing wax band on the slide, the slide must be coated with a little bit adhesive, excessive coating leads protein dyed during staining process. Too little coating leads hard or thick material shedding during dehydration dye process. Drop an appropriate amount of 3%~4% of formalin on the adhesive agent coated slide before placing the cut wax band. Wax band is cut into the appropriate length, place it on the slide by using a small scalpel dipped with formalin, stick to the bottom of the wax band and carefully transfer to the slide, arrange in neat row. Formalin between the wax band and the slide can be replaced by water or other liquid, the main function of the liquid is extending the compressed section and the compressed wax band, dilute formalin is the best liquid which is small surface tension and anti-corrosion. Transfer the slides filled with wax band and formalin solution to heating board at about 45℃, wax band began to stretch after heating, use the needle to line the wax band and pull the wax band gently, allow it to stretch evenly. Remove dilute formalin solution, leave it under 40~45℃ for one to several days (depends on the amount of adhesive).

7. Staining and dehydration:
All the procedures of staining, dehydration and cover with coverslip are the same as described above in free-hand sectioning. However, in this method, wax band must be dissolved in xylene before transferring the wax band in the high concentration alcohol for staining. As described above, all those steps are carried out in the staining bottle. For example, a simplified procedure for Safranin-fast Green staining is given below:

Dissolve wax band:
Fill the staining bottles with the following reagents. Move slides with wax band for each reagent:
(1) Xylene for 10 minutes.
(2) Xylene: absolute alcohol (1:1) for 3 minutes.
(3) Absolute alcohol for 3 minutes.
(4) 95% alcohol for 3 minutes.
(5) 85% alcohol for 3 minutes.
(6) 70% alcohol for 3 minutes.
(7) 50% alcohol for 3 minutes.
(8) 1% safranin solution in 50% alcohol for 3-24 hours and wash excess dye with distilled water.
(9) 50% alcohol for 3 minutes.
(10) 70% alcohol for 3 minutes.
(11) 85% alcohol for 3 minutes.
(12) 85% alcohol for 3 minutes.
(13) 95% alcohol for 3 minutes.
(14) 0.5% fast green solution in 95% alcohol (may vary with materials used), rinse excess fast green off with 95% alcohol twice.
(15) Absolute alcohol twice, 3 minutes each time.
(16) Absolute alcohol: xylene (1:1) for 3 minutes.
(17) Xylene for 5 minutes.
Drop balsam and cover with coverslip.

VII. Vitrification:

Study the trend of vascular bundle in the botanicals, especially the distribution of the veins, the vitrification is the most ideal method. Regardless of fresh or herbal specimens, good sections can be produced by this method. The purpose of this method is made the most of the inner leaf tissue transparent and only dyed at veins, the veins or tissue with thick-walled cells is more obvious than other parts which are transparent. The steps are as follows:

1. Put the materials in 95% hot alcohol to dissolve chlorophyll. For dried sample, boil it with clean water and allow the material to sink to bottom of the bottle.
2. Transfer the material to a container with 3%~5% sodium hydroxide (relatively delicate material use lower concentration of NaOH).
3. Place it in incubator at 40℃ (1 to several days). Replace NaOH every day until the materials change to transparent and yellow, rinse with clean water for several times (these materials are easily broken).
*If the material still remains opaque, put the materials in the clear reagent as below: 250.0 g chloral hydrate/100 mL of distilled water. Place in the incubator as the indicator above.
4. The material rinsed with clean water can store in 50% alcohol or process dehydration.
5. Dehydration and staining: Switch from low concentrations to high concentrations of alcohol and stain the material at an appropriate concentration as follows (carried out in a small culture):
(1) 50% alcohol for 30 seconds to 1 minute.
(2) 1% Safranin in 50% alcohol solution for several minutes.
(3) 70% alcohol for 10 minutes.
(4) 85% alcohol for 10 minutes.
(5) 95% alcohol for 10 minutes.
(6) Absolute alcohol for 10 minutes.
(7) Absolute alcohol: xylene (1:1) for 10 minutes.
(8) Xylene for 10 minutes
6. Sealing: Press the coverslip to flatten the material.

This method can be applied on fresh material, fixed material or dry sample specimen. The quality of sections varies from different type of materials. Fresh material usually gives the best result and the fixed sample specimen gives the worst result. When fresh material contains excessive wax, dry before operating as method described above, has better result on the purpose of vitrification.

VIII. Maceration:

Plant tissue composed of multiple cells. In order to study and understand the botanical tissue cells in various forms, cell size, shape, the variety patterns on cell walls and the structure of pits, need to cell separation is needed before observation. Cell separation is done by dissolving middle lamella connected each cell with macerating fluid. There are many kinds of macerating fluid, each one with different capabilities. Agents can be applied according to the research purposes and the botanical tissue characteristics.

Time and materials can be easily controlled in this method for dissociation of wood and secondary tissue. This is an excellent dissociation method as it has a characteristic of minimum material wastage, due to the complete dissociation requires additional pressure after dissociation. The permanent microscopic sections can be produced by dehydrating, staining and sealing after dissociation.

1. Cutting wood into the thickness size equals to half of a match stick, length is one centimeter, take ten pieces of wood and placed in a fixed bottle contained a mixture of the follows: Prepare the mixture by the ratio (1:4:5).

Content	Volume
Hydrogen peroxide solution (30% H_2O_2)	one part of volume
Distilled water	four parts of volumes
Glacial acetic acid	five parts of volumes

2. Tighten the fixed bottle, stand for 3~5 days (places in an incubator at 56℃, gives a better dissociation result), check constantly until the materials dissociate completely. For complete dissociation, the dissociating agent presents as transparent and the material is translucent or slightly white.
3. Rinse with water three times, each interval is about two hours. If the materials are hard to settlement, use low-speed centrifuge, then remove the upper layer of water with a straw.
4. Separate dissociated materials by a needle, pave evenly on a clean slide.
5. A drop of 10% safranin (dissolve in 50% alcohol) Add a drop of 10% safranin (dissolve in 50% alcohol) and stain for 5~10 minutes, the material must be covered in safranin. Place a petri dish on the slide, avoid the dye evaporates to dryness.
6. Remove the dye, drop 95% alcohol, rinse the dye and dehydrate simultaneously, refresh 95% alcohol.
7. As described above, rinse with absolute alcohol and dehydrate four times.
8. As described above, rinse with xylene twice.
9. Drop balsam and seal the section.

IX. Frozen section

1. Softening of inspected material:
   Wet and soften the dried medicinal materials or immerse them in water, and cut them into appropriate sizes. Soften, the material until they are easy to be sliced.
2. Slicing:
   Cut the wetted inspection material into appropriate size (less than 1.5 cm), and cut the upper and lower surfaces neatly, place the cut into the appropriate size inspection material in an aluminum foil container, add OCT glue (Optimum Cutting Temperature Compound), and place the inspected material in the cryostat. The whole is embedded and quickly frozen (-20℃). After the OCT glue has completely frozen and turned white, take out the inspection block from the aluminum foil container, stick the inspection block on the stage with OCT glue, use a slicing knife to cut the surface of the inspection block, and
   Cut until you see the surface of the medicinal material completely appear. Adjust the thickness of the slice (about 10-20 μm), stick the test sample slice on the glass slide, and add a few drops of glycerin water to cover the surface of the slice to complete.
3. Dyeing and dehydration:
   Commonly used dyes:
   (1) Safranin solution: Add 1.0 g of safranin to 100 mL of 50% ethanol.
   (2) Fast-green solution: Add 0.5 g of fast-green and to 100 mL of absolute ethanol. Place the cut slides of the test samples on a petri dish, wash them with 50% ethanol 2~3 times, 1~2 minutes/time, and dry the dilute glycerin slightly. Add the safranin solution for 2 to 15 minutes, and close the lid while waiting to prevent the ethanol from evaporating. Wash with 60% ethanol 2~3 times, 0.5~1 minute/time, and wash until there is no red outflow. Wash with 80% ethanol 2~3 times, 0.5~1 minute/time. Wash with 95% ethanol for 1 to 2 times, 0.5 to 1 minute/time. Drop the fast-green solution to dye for 0.5 to 2 minutes, wash with absolute ethanol until there is no green outflow, and then soak the slide in absolute ethanol for about 30 seconds.
4. Transparency:
   Commonly used reagents:
   (1) Reagent A: Take a mixed solution of absolute ethanol: xylene = 2:1.
   (2) Reagent B: Take a mixed solution of absolute ethanol: xylene = 1:1.
   (3) Reagent C: Take a mixed solution of absolute ethanol: xylene = 1:2.
   (4) Reagent D: Take xylene as the solution.
   The steps for transparency are as follows:

Reagent A: 1 time for 3 minutes
Reagent B: 1 time for 3 minutes
Reagent C: 1 time for 3 minutes
Reagent D: 2 times for 3 minutes

5. Mounting:
Put 1 drop of acacia gum on the inspection material of the slide glass, and cover the cover glass with a 45-degree angle. During this process, avoid air bubbles.
6. Drying:
Put it in the fume cupboard for about 2~3 days. After it is dried, then observe and take pictures under the microscope.

VII. Reagents and Test Solutions

Reagents are substances used for chemical tests or microscopic identification.

Test Solutions, abbreviated "TS," are solutions of reagents in such solvents and of such definite concentrations as to be suitable for the specified purposes.

Indicators are reagents used to determine the specified end-point in a chemical reaction or to measure hydrogen-ion concentration (pH).

Indicators test papers are the papers saturated with indicators to measure hydrogen-ion concentration (pH).

Colorimetric Solutions, abbreviated "CS", are solutions of such definite concentrations used in the preparation of colorimetric standards for comparison purposes.

Volumetric Solutions, abbreviated "VS" and known also as standard solutions, are solutions of reagents of known concentration intended primarily for use in quantitative determinations. Concentrations are usually expressed in terms of normality.

The purity of certain drugs contained in the body of the Pharmacopoeia is in compliance with the regulations. Those who can provide test or test solutions are not listed in this article. The test drug is not contained in the text, or its purity is higher than the text, as explained below. The reagents and solutions listed in this publication may be referred to the International Pharmacopoeia or other pharmacopoeia. If it is verified that it does not affect the correctness of the test, it should be selected as appropriate.

Reagents, test solutions, indicators, colorimetric solutions and volumetric solutions should be preserved in containers made of glass with low alkali release, high hydrolytic resistance, and without arsenic and lead. The containers should be hermetic for preventing the concentration changing from evaporation. Light-sensitive reagents or solutions should be stored in light-blocking containers. Stoppers and stopcocks brought into contact with substances capable of attacking or penetrating their surfaces may be given a protective coating of a thin film of wax or a suitable lubricant unless specifically interdicted.

Please refer to the other pharmacopeias for the reagents and solutions that are not listed in these sections.

(7001) Reagents

Unless otherwise specified, use the determination described below.

I. Limit Test for Insoluble Substance

Add a quantity of sample in a beaker, and dissolve in 100 mL of hot water unless otherwise directed. Cover the beaker with a watch glass, warm on a boiler for 1 hour, and filter the hot solution through a tared sintered-glass crucible or Gooch crucible. Wash the residue with hot water, dry at 105~110℃, and weigh.

II. Limit test for chloride

Chloride standard solution: Dissolve 165.0 mg of dry sodium chloride in an appropriate amount of water to 1000 mL, produce a solution contained 0.10 mg of chloride per mL.
Assay: Dissolve a quantity of sample in 25 mL of water, as prescribed under individual monograph. If the solution is alkaline, neutralize with nitric acid dropwise until litmus paper as neutral, and then add 3 mL more of nitric acid. If necessary, filter with the wet filter which does not contain chloride. Add 1.0 mL of silver nitrate to the filtrate, mix well, and stand for 5 minutes protected from direct light. If there has turbidity, the solution can't be concentrated than the control group of standard chloride solution which has the same concentration as the chloride limitation.

If the solution of barium salts is alkaline, neutralize with nitric acid dropwise, add 3 more drops of nitric acid, and follow the method as described above.

If the test solution has color, dissolve 2.0 g of test specimen in 25 mL of water, add 3 mL of nitric acid, if necessary, filter with a wet filter paper which does not contain chloride, divide the filtrate into two equal parts, to one part add 1.0 mL of silver nitrate, mix and stand for 10 minutes. If the solution is turbidity, filter with wet filter papers until the filtrate is perfectly clear.

The filtrate which is filtered after divided is as the control solution, the other one is as the test solution. Follow the method as described above to operate.

III. Limit test for total heavy metals

Lead standard solution: Refer to (General rule 6301), produce a solution contained 0.01 mg of lead per mL.
Assay: If the limit of total heavy metals is 5 ppm, dissolve 6.0 g of test specimen in an appropriate amount of water to 42 mL. Take 7 mL of the solution to Nessler cylinder, add a quantity of lead standard solution (the content of

lead should be equivalent to 4.0 g of test specimen), dilute with water to 40 mL and add 2 mL of dilute acetic acid as the control solution. To other cylinder add 35 mL of the solution, dilute with water to 40 mL, and add 2 mL of dilute acetic acid. To each cylinder add 10 mL of hydrogen sulfide and mix well. Compare the color by viewing down the vertical axis of the two cylinders with a white background. The color formed in the test solution should not be darker than the color in control solution.

If the limit of total heavy metal is 10 ppm or more, or the solubility is limited, dissolve 4.0 g of test specimen in water to 40 mL, if necessary, heat gently. To 10 mL of the solution, add a quantity of standard lead solution (equal to the lead content in 2.0 g of test sample), dilute to 40 mL. Dilute 30 mL of remaining solution with water to 40 mL. Carry out the method as described above.

If the test specimen tested for heavy metals is salt of aliphatic organic acid, when making the solution, replace the dilute acetic acid by 1 N hydrochloric acid.

IV. Limit test for iron

Iron standard solution: Add 863.4 mg of ferric ammonium sulfate in an appropriate amount of water, add 10 mL of dilute sulfuric acid, dilute with water to 100.0 mL, transfer the solution to a 1000-mL volumetric flask, add 10 mL of dilute sulfuric acid, add water to volume and mix well. Produce a solution contained 0.01 mg of iron per mL.

Assay: Dissolve a quantity of test specimen as described under individual monograph in 45 mL of water, or prepare test solution as indicated then dilute with water to 45 mL. Add 2 mL of hydrochloric acid, mix well, and add 50 mg of ammonium sulfate and 3 mL of ammonium thiocyanate solution, if the red color appears. The color of the test specimen should not be darker than the control solution contained a volume of standard iron solution as described under individual monograph.

V. Limit Test for Phosphates

Phosphate standard solution: Dissolve 143.0 mg of potassium dihydrogen phosphate in water to 1000 mL. The solution contains 0.10 mg of phosphates per mL.
Phosphate reagent I: Dissolve 5.0 g of ammonium molybdate in 1 N sulfuric acid to 100 mL.
Phosphate reagent II: Dissolve 200 mg of 4-Methylaminophenol sulfate in 100 mL of water, add 20.0 g of sodium hydrogen sulfite and mix well. This reagent stores in a glass bottle with stopper tightly, and it can't use after a month.
Assay: Weigh a quantity of the test specimen as described under individual monograph, dissolve in 20 mL of water, heat if necessary, add 2 mL of 25% sulfuric acid (or dissolve the test specimen or residue in 20 mL of 0.5 N sulfuric acid), and add 1 mL of reagent Ⅰ and reagent Ⅱ, dilute to 25 mL with water , mix well and stand for 2 hours. If the blue color is produced, the color of the test specimen should not be darker than the control solution contained a volume of standard phosphate solution as described under individual monograph and subjected to the same treatment.

VI. Limit test for sulfates

Sulfate standard solution: Dissolve 181.0 mg of potassium sulfate in water, and add an appropriate amount of water to 1000 mL. Produce a solution contained 0.10 mg of sulfates per mL.
Assay: Dissolve a quantity of test specimen as described under individual monograph in 25 mL of water, if the solution is alkaline, neutralize with hydrochloric acid, use litmus paper as an indicator, add 1 mL of 1 N hydrochloric acid, filter with a wet filter paper if necessary, add 2 mL of barium chloride to the solution, mix well and stand for 10 minutes. If the solution is turbidity, the concentration of the test specimen is not more concentrated than the control solution contained a volume of standard sulfate solution as described under individual monograph and subjected to the same treatment.

VII. Determination of residue on ignition

Weigh accurately 1~2 g of test specimen, put in a crucible that previously has been ignited, cooled, and weighed. Ignite the sample slowly at first and then strengthen firepower, until the organic portion is thoroughly charred, and the inorganic portion completely volatilize. If the monographs do not point out using sulfuric acid, the test specimen can be ignited directly at 800±25℃ to constant. If the monographs point out using sulfuric acid, cool the crucible, add the specified amount of sulfuric acid, slowly heat until no smoke, and ignite the crucible at 800±25℃ to constant.
Ignition should be in a well-ventilated hood but protected from air current, and the temperature is as low as possible to completely combust the carbon. A muffle furnace may be used, ignited at 800 ± 25℃ is recommended to use muffle furnace.

The reagents and standard for this pharmacopoeia is as follow.

Acetic Acid

CH_3COOH molecular weight: 60.05

Acetic acid is a solution containing 36.0~37.0% of CH_3COOH.

Characters:
1. General nature: A clean, colorless liquid; odor, irritate; with acidic reaction on litmus paper.
2. Solubility: Miscible with water, ethanol, or glycerin.
3. Specific gravity: The specific gravity of acetic acid is about 1.045 (General rule 1841).

Identification: It responds to the acetate tests (General rule 2191).

Impurities and other requirementss:
1. Nonvolatile residue: Add 10 mL of acetic acid in a

tared porcelain dish, evaporate to dryness on a boiler, dry at 105℃ for 1 hour, the weight of the residue is not more than 1.0 mg. Keep the residue for the following test.

2. Chloride: Add 5 drops of silver nitrate to 10 mL of acetic acid solution (1 in 10): no opalescence is formed.
3. Sulfate: Add 5 drops of barium chloride to 10 mL of acetic acid solution (1 in 10): no turbidity is produced.
4. Arsenic: Follow the rule (General rule 2211) to determine, and the limit of arsenic is 2 ppm.
5. Heavy metals: To the residue obtained in the test (1), add 8 mL of 0.1 N hydrochloric acid, warm gently until residue is completely dissolved, make up to 100 mL with water. Use 25 mL of solution for testing by method I (General rule 6301), the limit of heavy metals is 10 ppm.
6. Readily oxidizable substances: Add 4 mL of acetic acid in a glass bottle with stopper, then add 20 mL of water and 0.3 mL of 0.1 N potassium permanganate, and the liquid should not turn into brown from pink color immediately, and should not fade or turn into brown color less than 30 seconds.

Assay: Add 6 mL of acetic acid in a tared glass bottle with stopper, and weight accurately. Dilute to 40 mL with water, then add phenolphthalein as indicator, titrate with 1 N sodium hydroxide. The titer of 1 N sodium hydroxide equals to 60.05 mg per mL of acetic acid.

Acetic Anhydride

$(CH_3CO)_2O$ molecular weight: 102.09

It contains more than 97% of $(CH_3CO)_2O$.

Characters: a clear, colorless liquid; odor, irritate; the boiling temperature is about 140℃.

Impurities and other requirementss:

1. Nonvolatile residue: Add 30 mL of acetic anhydride in a tared porcelain dish, evaporate to dryness on a boiler, dry at 105℃ for 1 hour, the weight of the residue is not more than 1.0 mg.
2. Chloride: Add 37 mL of acetic anhydride, dilute to 200 mL, mix well. The quantity of chloride in 10 mL of the solution should not exceed 0.01 mg. (General rule 7001). Keep the left solution for further test.
3. Phosphate: To 10 mL of the solution (2), evaporate to dryness on steam bath, and dissolve the residues in 25 mL of 0.5 N sulfuric acid. The weight of phosphate in the solution should not exceed 0.02 mg. (General rule 7001)
4. Sulfate: Add 50 mL of the solution (2) to a beaker, add 10 mg of sodium carbonate, evaporate to dryness on steam bath. The weight of the sulfate in the residues is not over 0.05 mg. (General rule 7001)
5. Total heavy metals: Add 50 mL of the solution (2) to a beaker, add 10 mg of sodium carbonate, evaporate to dryness on steam bath. The total heavy metals limit is 2 ppm in the residues (General rule 7001).
6. Iron: Add 10 mL of the solution (2) to a beaker, add 10 mg of sodium carbonate, evaporate to dryness on steam bath. The iron content in the residues should not exceed 0.01 mg (General rule 7001).
7. Readily oxidizable substances: To 1.0 mL of the solution (2), add 0.4 mL of 0.1 N potassium permanganate, the pink color appear and the color does not disappear in 5 minutes.

Assay: Add about 2.0 mL of the acetic anhydride in a tared glass bottle with stopper, and weight accurately. Add 10 mL of water which boiled and cooled, stopper and stand for 30 minutes, the solution of phenolphthalein is indicator, and titrate with 1 N sodium hydroxide. Then the percentage of the quantity of acetic anhydride is calculated by the equation below:

$$A = \frac{34.03V}{W} - 566.7$$

A: The percentage of the quantity of acetic anhydride.
V: the value of mL of the solution of sodium hydroxide.
W: the value of g of the test.

Acetone

CH_3COCH_3 molecular weight: 58.08

Acetone contains least 99.5% of CH_3COCH_3.

Characters: Clear, colorless liquid; odor, irritate, miscible with water, ethanol, ether, and most of organic solution.

Impurities and other requirementss:

1. Distilling range: To 100 mL of acetone, according to the method II of the boiling point (General rule 1003), all the distillate drive-off at 55.5~57℃. The deviation of the distilled temperature is less than 0.5℃ from 20th drop to 95 mL.
2. Nonvolatile residue: Add 125 mL of the sample in a tared porcelain dish, steam bath to dryness, dry at 150℃ for 1 hour. The weight of the residue is not more than 1.0 mg (0.001%).
3. Determination of the dilution: To 25 mL of acetone, add 25 mL of boiled and cooled water, mix well. The solution should keep clarify in 30 minutes, retain the solution.
4. Acidity: To the solution which is retained, add two drops of phenolphthalein as indicator, titrate with 0.1 N sodium hydroxide. The consumption of the alkali solution is less than 0.1 mL (0.003% of CH_3COOH).
5. Alkalinity: Add 25 mL of acetone in 25 mL of water. Mix well, and add one drop of methyl red. If the yellow color is produced, titrate with 0.1 N sulfuric acid, the acid consumption should not exceed 0.1 mL (0.001% of NH_3).
6. Aldehyde: To 10 mL of acetone, add 5 mL of ammoniacal silver nitrate, stand for 15 minutes in dark at 50℃. The solution should not appear brown

color or form a precipitate.

7. Methanol: To 1 mL of acetone, dilute to 20 mL with water. To 5 mL of the solution, add 0.5 mL of phosphoric acid and 2 mL of potassium permanganate solution, stand for 10 minutes, add 15 mL of oxalic acid (1 in 10), until the solution is colorless, add 5 mL of 25% sulfuric acid and 5 mL of fuchsin sulfurous acid reagent, the blue or the violet color should not be formed within 10 minutes (0.1%).
8. Readily oxidizable substances: To 10 mL of acetone, add 0.05 mL of 1.0 N potassium permanganate. The red color is produced, and the color should not disappear within 15 minutes.

Assay: The specific gravity of acetone is not more than 0.788 (General rule 1841).

Acetonitrile

CH_3CN molecular weight: 41.05

Characters: Clear, colorless liquid, miscible with water, and the specific gravity is 0.780~0.783.

Impurities and other requirementss:

1. Acidity or alkalinity: To 10% (v/v) of acetonitrile should be neutral to litmus solution.
2. Distilling range: Follow the determination of boiling point (General 1003) to distill, the distillate is produced at 80~82℃ and the concentration should be above 95%.
3. Determination of the absorbance: Test the acetonitrile with spectroscopy, the wave length at 250~280 nm, and use the 1 cm of cell to determine with suitable spectrophotometer, comparison of the reference of air is below 0.01.

Alcohol

C_2H_5OH molecular weight: 46.07

Synonyms: Ethanol, Ethyl alcohol

When the product is at 15.56℃, the C_2H_5OH should be 92.3~93.8%(w/w), or 94.9~96.0% (v/v).

Characters:

1. General nature: This product is a colorless, clarified, easy to flow, volatile liquid. Smelly and special, the taste is burning. This product is easy to burn and is also volatile at low temperatures.
2. Solubility: This product can be mixed with water, ether or chloroform.
3. Boiling point: The boiling point of this product is about 78℃ (General rule 1003).

Identification:

1. This product is measured by the specific gravity method (General rule 1841), and the specific gravity at 15.56℃ is 0.812~0.816.
2. This product is determined by the liquid absorption method of infrared spectrophotometry (General rule 1197), and its absorption spectrum is measured by the same method as the standard of this product, and the maximum absorption is only at the same wavelength.

Impurities and other requirementss:

1. Nonvolatile residue: Take 100 mL of this product, place it in an evaporating dish, evaporate it on a water pot lid, and dry it at 100~105℃ for one hour. The weight of the residue should not exceed 2.5 mg.
2. Organic impurities:
   Test solution A: alcohol
   Test solution B: Take 4-methyl-2-pentanol 300 μL/L dissolved in test solution A.
   Standard solution A:
   Take methyl alcohol 200 μL/L dissolved in test solution A.
   Standard solution B:
   Take 10 μL/L of methyl alcohol and 10 μL/L of acetaldehyde dissolved in the test solution A.
   Standard solution C:
   Take acetal 30 μL/L dissolved in test solution A.
   Standard solution D:
   Take benzene 2 μL/L dissolved in test solution A.
   Chromatography device:
   Gas chromatography device with flame ion detector, a 0.32 nm × 30 m tantalum capillary, coated with a layer of 1.8 mm thick, containing 6% cyanophenyl-propyl and 94% dimethyl polyfluorene, with a split ratio of 20:1. The column temperat ure is shown in table 1. The inlet temperature is 200℃, the detector is 280℃, and the helium is the carrier gas. The linear flow rate is about 35 cm per second and the injection volume is 1 μL.

Table 1

Initial temp. (℃)	Temp. Ramp (℃/min)	Final temp. (℃)	Hold time at final temp. (min)
40	0	40	12
40	10	240	10

System suitability:
The resolution between the first major peak (acetaldehyde) in the standard solution B and the second major peak (methanol) should be greater than 1.5.

Assay: Inject the test solution A, B and standard solution A, B, C, D respectively.
Calculate the methanol content according to the following formula:

$$(r_U / r_S)$$

r_U =Methanol wave peak in test solution A
r_S =Methanol wave peak in standard solution A
Calculate the acetaldehyde content (sum of acetaldehyde and acetal) as follows:

$$\{[A_E/(A_T-A_E)] \times C_A\} + \{[D_E/(D_T-D_E)] \times C_D \times (V_{r1}/M_{r2})\}$$

A_E = peak value of acetaldehyde in test solution A

A_T = peak value of acetaldehyde in standard solution B

C_A = concentration of acetaldehyde in standard solution B (μL/L)

D_E = peak value of acetal in test solution A

D_T = peak value of acetal in standard solution C

C_D = concentration of acetal in standard solution C (μL/L)

M_{r1} = molecular weight of acetaldehyde (44.05)

M_{r2} = molecular weight of acetal (118.2)

Calculate the benzene content according to the following formula:

$$[B_E/(B_T-B_E)] \times C_B$$

B_E = peak value of benzene in test solution A

B_T = peak value of benzene in standard solution D

C_B = concentration of benzene in standard solution D (2 μL/L)

(Note: Other suitable chromatographic systems (stationary phases of different polarities) can be used to identify benzene if necessary.)

Calculate the impurity content according to the following formula:

$$(r_U/r_M) \times C_M$$

r_U = peak value of individual impurities in test solution B

r_M = peak value of 4-methyl-2-pentanol in test solution B

C_M =concentration of 4-methyl-2-pentanol in test solution B (μL/L)

The allowable range is shown in Table 2.

3. Ultraviolet absorptiometry (General rule 1197):
   The analysis wavelength is 235~340 nm, the length of the measuring tube is 5 cm, the blank reference is water, the allowable range of absorbance is not more than 0.40 at 240 nm, not more than 0.30 between 250 nm and 260 nm, and not more than 0.10 between 270 nm and 340 nm. The spectrum should exhibit a steady decreasing curve with no visible peaks.

Table 2

Impurity	Allowable range
Methanol	Not more than 100 μL/L
Ethanol and Acetal	Not more than 10 μL/L
Bezene	Not more than 2 μL/L
Other impurities	Not more than 300 μL/L
Note: Ignore any peak less than 9 μL/L (0.03 times the relative peak value of 4-methyl-2-pentanol in the sample solution B chromatogram)	

4. Solution clarity:
   Hydrazine solution: Configure 10 mg/mL hydrazine sulfate solution and let stand for 4 to 6 hours.
   Hexamine solution: Take 2.50 g of hexamine in a 100 mL flask, add 25 mL of water, cover with a glass stopper, and stir until dissolved.
   Original milky white suspension: Take 25 mL of a hydrazine solution to a 100 mL flask containing hexamine solution, and the mixture was allowed to stand for 24 hours. If the suspension is stored in a glass container without surface defects, it will remain stable for two months. This suspension must be mixed well before use and must not be absorbed onto the glass.
   Milky white standard: 15 mL of the original milky white suspension was placed in a 1000 mL volumetric flask and diluted with water to volume. The suspension was used within 24 hours after preparation.
   Standard suspension A: milky white standard and water (1:20).
   Standard suspension B: milky white standard and water (1:10).
   Test solution A: alcohol
   Test solution B: Take 1 mL of test solution A, dilute to 20 mL with water, and let stand for 5 minutes before use.
   Blank test solution: water
   Determination method: a sufficient amount of the test solution A and the test solution B are respectively added to a colorless transparent, neutral glass test tube having a flat bottom and an inner diameter of 15~25 mm and a depth of 40 mm. Standard suspension A, standard suspension B and black solution are also added to the same size test tubes. The test tubes of test solution A, the test solution B, the standard suspension A, the standard suspension B, and the blank test solution were compared under the scattered sunlight at an angle perpendicular to the black background. The scattered light must be able to easily distinguish between standard suspension A, standard suspension B and water. The test solution A and the test solution B should exhibit the same clarity as the water or the milky white color of the liquid should be less pronounced than the standard suspension A. (Note: The test solution should be compared with the standard suspension A and water under scattered sunlight in five minutes after the standard suspension A is configured.)
5. pH:Hydrogen ion concentration:
   0.10 g of phenolphthalein was dissolved in 80 mL of ethanol, and diluted with water to 100 mL to form a phenolphthalein solution. Take 20 mL of ethanol, add 20 mL of water cooled immediately after boiling, and 0.1 mL of phenolphthalein solution, and the resulting solution should be colorless. Finally add 1mL of 0.01N sodium hydroxide, the solution should be pink (equivalent to less than 30μL/L of acetic acid)
6. Solution color:
   Standard stock solution: Mix 3 mL of ferric chloride colorimetric solution, 3 mL of cobalt chloride colorimetric solution, 2.4 mL of copper sulfate

colorimetric solution, and 1.6 mL of dilute hydrochloric acid (10 g/L).
Standard solution: Take 1 mL of the standard stock solution into a 100 mL volumetric flask and dilute with dilute hydrochloric acid (10 g/L), this solution should be configured before use.
Test solution: alcohol.
Blank test solution: water
Determination method:
Add a sufficient amount of the test solution to a colorless transparent, neutral glass test tube with a flat bottom and an inner diameter of 15~25 mm and a depth of 40 mm. The standard solution and the blank test solution are also added to the same size test tubes. The tubes of test solution, standard solution and blank test are observed with scottered sunlight in an angel perpendicalar to the white background. The test solution should have the same appearance as the water or the color of the test solution lighter than the standard solution.
Storage method: This product should be placed in a tight container to protect from light and fire.
Use classification: Formulation adjuvant.

Alcohol, Dehydrated

C_2H_5OH molecular weight: 46.07

Alcohol, dehydrated contains 99.5% (v/v) or above of C_2H_5OH.

Characters:
This product is a colorless, transparent and easy-to-flow volatile liquid with a special odor and burning odor, and is extremely hygroscopic.

Impurities and other requirementss:
Except for the determination as described below, the other item should be conformed to the provision of the determination of alcohol impurity (General rule 7001).

1. Evaporation residue: Add 60 mL of alcohol, dehydrated to steam on steam bath, and dry at 105°C for 1 hour, the weight of the residue is not more than 0.5 mg (0.001%).
2. Alkalinity: Take 25 mL of the alcohol, dehydrated, dilute with 25 mL of water, add 1 drop of methyl red, and titrate with 0.02 N sulfuric acid until the pink color is produced, the acid consumption is not over than 0.2 mL (0.0003% of NH3).
3. Readily carbonizable: Add 10 mL of sulfuric acid to a conical flask, and cool down to 10°C, then take 10 mL of alcohol, dehydrated, drips slowly, and the color of the solution should not be darker than brown.

Assay: The specific gravity of the substance is not more than 0.7900 (25°C/25°C), that means the C_2H_5OH contained in the test product should be above 99.5% v/v.

Alcohol, Neutralized

To a quantity of alcohol, add 2~3 drops of phenolphthalein as indicator, titrate with 0.02 N or 0.1 N sodium hydroxide until the pink color is formed. Prepare freshly before use.

Alcohol, Aldehyde-free

Add 1000 mL of alcohol to a glass bottle with stopper, add 5 mL of lead acetate (1 in 2) and mix well. Add 5.0 g of potassium hydroxide to 25 mL of warm ethanol, cool down, slowly add it to potassium hydroxide-ethanol solution, stand for 1 hour, shake hard and stand overnight. Pour out the supernatant liquid, and distill.

Ammonium Molybdate

$(NH_4)_6Mo_7O_{24} \cdot 4H_2O$ molecular weight: 1235.95

Ammonium molybdate contains about 81%~83% of MoO_3.

Characters: Colorless, slightly green or yellow crystals. Soluble in water; insoluble in ethanol.

Impurities and other requirementss:

1. Insoluble matter: To 10.0 g of ammonium molybdate, dissolve with 100 mL of hot water, cover a watch glass, place in a tared porcelain dish on a steam bath for one hour, filter (reserve the filtrate for later use), rinse the residue, dry at 105°C for 1 hour. The weight of the residue is not more than 1.0 mg (0.01%).
2. Chloride: To 1.0 g of ammonium molybdate, dissolve with 20 mL of water, then slowly infuse the solution in 5 mL of nitric acid, this solution contains less than 0.02 mg (0.002%) of chloride (General rule 7001).
3. Nitrate: To 1.0 g of ammonium molybdate, dissolve with 10 mL of water which contains 5 g of sodium chloride, and add 0.1 mL of indigo carmine TS and 10 mL of sulfuric acid, the blue color of the solution should not disappear completely within 5 minutes (about 0.003% of NO_3).
4. Phosphate: To filtrate of (1), add 10 mL of ammonia TS, infuse in the solution which is combined with 50 mL of nitric acid and 75 mL of water, shake 5 minutes at 40℃, stand for 1 hour. If the turbidity is produced, the concentration of PO_4 of the sample should not be higher than 0.05 mg (about 0.0005% of PO_4) in control test solution. (General rule 7001).
5. Sulfate: To 1.0 g of ammonium molybdate, dissolve with 10 mL of hot water, add 5 mL of nitric acid, evaporate to dryness on a steam bath, add 1 mL of hydrochloric acid and 10 mL of water to the residues and filter. Wash the filtered residue with water, and the volume of water and filtrate to 50 mL. The 10 mL of the filtrate contains less than 0.6 mg of SO_4 (0.03%) (General rule 7001).
6. Total heavy metals: To 1.0 g of ammonium molybdate, dissolve with 25 mL of water, add 10 mL of 10 % sodium hydroxide and 2 mL of ammonia TS, and dilute with water to 40 mL. The total heavy metals

limit is 20 ppm (General rule 7001).

7. Magnesium and cognate cation: To 5.0 g of ammonium molybdate, dissolve with 50 mL of water, filter if necessary, add 500 mg of sodium carbonate and 10 mL of sodium hydroxide (1 in 10) to the filtrate, boil it slowly for 5 minutes. If the precipitate is produced, then cool, filter, wash the precipitates with the solution of ammonia (1 in 40) and ignite. The weight of the residue is not more than 1.0 mg (0.02%).

Assay: Weigh accurately 1 g of ammonium molybdate in a mixture of 10 mL of water and 1 mL of concentrated ammonia in a 250-mL volumetric flask, dilute with water to 250 mL and mix. Transfer 50.0 mL of the solution (filter it, if necessary) to a 600-mL beaker. Add 250 mL of water, 20.0 g of ammonium chloride, 15 mL of hydrochloric acid, and few drops of methyl orange, heat nearly to the boil. Add 18 mL of lead acetate solution, add a saturated solution of ammonium acetate slowly with constant stirring, until the solution becomes alkaline, and then add 15 mL of saturated solution of ammonium acetate. Heat just below the boiling point until the precipitate has settled. Filter through a tared, porous porcelain crucible, wash seven times with ammonium acetate solution (mixture of 10 mL nitric acid and 1000 mL ammonium acetate solution) and then wash with three successive portions of hot water. Ignite to constant weight at 600℃. The weight of the residue multiply 0.3921 is equal to the quantity of the test specimen which contains MoO_3.

Aniline

$C_6H_5NH_2$ molecular weight: 93.13

Characters: A colorless or pale yellow, clear liquid, the specific gravity is 1.02, slightly soluble in water and miscible with ethanol and ether.

Impurities and other requirementss:

1. Distilling range: To 100 mL of specimen, follow the method II of determination of boiling point (General rule 1003) to distill, the distillate produce at 183~186 ℃ should reach 95 % or above.
2. Ignite residue: To 20 mL of test specimen, ignite after evaporating it to dryness. The residue is not more than 1.0 mg (0.005%).
3. Hydrocarbon and nitrobenzene: To 5 mL of test specimen, mix with 10 mL of hydrochloric acid, the hot solution should be clear, dilute with 15 mL of water and the solution should maintain clear.

Antimony Trichloride

$SbCl_3$ molecular weight: 228.13

Characters: Colorless or translucent crystals; easy deliquescence. Hydrolysis with water and produce antimony oxychloride. Also soluble in hydrochloric acid, ethanol, or chloroform, the melting point is 72℃ and the boiling point is 230℃.

Impurities and other requirementss:

1. Solubility in chloroform: To 5.0 g of test specimen, add 10 mL of chloroform, the clean or slightly turbidity solution is produced.
2. Arsenic: To 0.5 g of test specimen, dissolve with 10 mL of acidic stannous chloride, stand for 1 hour, the light brown color is formed in the solution.
3. Hydrogen sulfide: To 1.0 g of specimen, dissolve with 3 mL of hydrochloric acid, dilute with water to 100 mL, antimony is totally precipitated by adding hydrogen sulfide, filter it (reserve the precipitate for later use). To 5 mL of the filtrate, add few drops of sulfuric acid, ignite it after evaporating the solution to dryness. The residue is not more than 1.0 mg (0.2%). Reserve the residue for later use.
4. Iron: To the residue of (3), add 2 mL of hydrochloric acid and few drops of nitric acid, place in a tared porcelain dish on a steam bath, then add 4 mL of hydrochloric acid and dilute with water to 10 mL. To 5 mL of the solution, dilute with water to 50 mL. The quantity of Fe which contains in the solution is not more than 0.025 mg (0.01%) (General rule 7001).
5. Other total heavy metals: To the precipitate of (3), add the red solution of ammonium sulfide, the precipitate dissolve completely.

Benzene

C_6H_6 molecular weight: 78.11

Characters: A colorless, clear, and inflammable liquid, odor, the specific gravity is about 0.876, insoluble in water, miscible with ethanol or ether.

Impurities and other requirementss:

1. Distilling range: To 100 mL of test specimen, follow method II of the determination of boiling point (General rule 1003), the distillate is produced at 79.5~80.5℃ and the distillate should be above 95 mL.
2. Freezing point: The freezing point of the test specimen is above 5.2℃. (General rule 1001)
3. Nonvolatile residue: Evaporate 115 mL of test specimen in a tared porcelain dish on a steam bath, dry at 105~110℃ for 30 minutes: The weight of the residue is not more than 1.0 mg (about 0.001%).
4. Moisture: Place 10 mL of test specimen in a tube (16×150 mm), stopper, immerse in crushed ice, and the solution is clear for 3 minutes.
5. Sulfide: Place 30 mL of potassium hydroxide which is made by ethanol in a conical flask, add 6 mL of test specimen, connect on a reflux condenser, and boil it slowly for 30 minutes. Remove the condenser, dilute with 50 mL of water, place in a tared porcelain dish on a steam bath, and the benzene and the ethanol are removed. Add 50 mL of bromine, heat for 15 minutes. Then the solution transfers to a beaker, neutralize with dilute hydrochloric acid (1 in 4), add 1 mL more of dilute hydrochloric acid, concentrate it to 50 mL, filter if necessary, boil the filtrate, add 5 mL of barium chloride, place in a tared porcelain dish on a steam bath, heat for 2 hours, place it overnight. If the

precipitate is produced, then filter by a small filter, wash the residue with water, until the precipitate is not formed when the washing liquid contacts with silver nitrate, then ignite it. The quantity of the residue is calibrated by a blank test. The quantity is not more than 2.0 mg (0.005% of S).

6. Readily carbonizable substance: To 25 mL of the test specimen, add 15 mL of sulfuric acid, shake for 15~20 seconds, stand until it is separated, the acidic liquid or the liquid of benzene should not be dark. Reserve the mixed liquor for later use.
7. Thiophene: To the mixed liquor of upper item, shake well, stand for 1 hour, the blue or green color is not formed in the acidic layer.

Boric Acid

H_3BO_3 molecular weight: 61.84

Boric Acid contains 99.5~115.0% of H_3BO_3, calculate on the dried basis.

Characters:

1. Characteristics: Colorless crystals or crystalline powder; with pearl-like luster. Odorless, slightly acid and bitter taste followed with sweet taste. A slightly smooth feel when your fingers twist it, no change exposed to air, the litmus paper has acid reaction in the solution.
2. Solubility: 1.0 g of the test specimen can dissolve with 18 mL of water, 4 mL of boiling water, 18 mL of ethanol, 6 mL of boiling ethanol or 4 mL of glycerol.

Identification: It responds to the tests for borate (General rule 2191).

Impurities and other requirementss:

1. Water insoluble: Add 25 mL of water to 1.0 g of the test specimen, the solution is clear.
2. Ethanol insoluble: Add 10 mL of boiling ethanol to 1.0 g of the test specimen, the solution should be clear.
3. Chloride: To 1.0 g of the test specimen, determine it by the determination of chloride (General rule 2221). If the turbidity is produced, the concentration of the test specimen should not be higher than 0.5 mL of 0.02 N hydrochloric acid of the control test.
4. Sulfide: To 2.5 g of the test specimen, determine it by the determination of the sulfide (General rule 2221). If the turbidity is produced, the concentration should not be higher than 1.5 mL of 0.02 N sulfuric acid of the control solution.
5. Arsenic: Determine it by the determination of the arsenic (General rule 2211). The quantity limit of arsenic is 5 ppm.
6. Total heavy metals: To 1.0 g of the test specimen, dissolve with 23 mL of water, add 2 mL of dilute acetic acid, determine it by the method I of determination of the total heavy metals (General rule 6301). The limit of total heavy metals is 20 ppm.

Assay: To about 1.5 g of boric acid, dry for 5 hours by silent gel, weigh accurately. Add 15 g of *d*-sorbitol and 10 mL of water, heat and dissolve it. After cooling, use phenolphthalein solution as indicator and titrate with 1 N sodium hydroxide. Each mL of 1 N sodium hydroxide is equivalent to 61.84 mg of H_3BO_3.

n-Butyl Alcohol

C_4H_9OH molecular weight: 74.12

Characters: Clear, colorless liquid, odor. Miscible with dehydrated alcohol and ether, the specific gravity is about 0.81.

Impurities and other requirementss:

1. Distilling range: To the test specimen, follow the method II of determination of boiling point (General rule 1003) to distill it, the distillate is produced at 115~118°C and above 95%.
2. Solubility in ethanol or ether: Mix 5 mL of the test specimen with 25 mL of absolute ethanol or ether, the solution should be clear.
3. Distillation residue: Evaporate 25 mL of the test specimen in a tared porcelain dish on a steam bath to dryness, and then dry at 105℃ for 1 hour: The weight of the residue is not more than 2 mg (about 0.01%).
4. Acidity: Add 25 mL of neutral ethanol to 10 mL of the test specimen, mix well, add 2 drops of phenolphthalein, and titrate with 0.1 N sodium hydroxide until the pink color appears. The volume of alkaline consumption should not exceed 0.2 mL.
5. Aldehyde: Add 20 mL of water and 2 mL of magenta sulphurous acid to 0.5 mL of the test specimen, mix well, stand for 10 minutes, and prepare the other blank solution. If the color appears in the test solution, the color of the test solution should not be darker than the color of the blank solution.

Carbon Disulfide

CS_2 molecular weight: 76.14

Characters: Clear, colorless, volatile liquid, inflammable, odorless for new products. When it contacts the air, it changes to yellow and produces odor. Slightly soluble in water, and easily soluble in ethanol, chloroform, or ether, the specific gravity is about 1.26.

Impurities and other requirementss:

1. Distilling range: To 100 mL of the test specimen, follow the method II of determination of boiling point (General rule 1003) to distill it, the distillate is produced at 46 ~ 47℃, and the distillate is above 95 mL.
2. Distillation residue: To 40 mL of the test specimen dry at 50~ 60℃, and then dry at 60℃ for 1 hour: The weight of the residue is not more than 1 mg (0.002%).
3. Other sulfide and dissolved sulfuric: Place 2 mL of the test specimen in a dried tube, add a small amount

of mercury, shake for 2 minutes, the color of mercury ball changes slightly, but remain the original luster.
4. Sulfite and sulfate: Place 10 mL of test specimen in a fraction collector, add 10 mL of water, shake for 5 minutes, stand until liquids are separated, and remove the separation of carbon disulfide. Add 1 drop of 0.1 N iodine solution, the color of the solution become yellow or violet, add 1 mL of barium oxide. It should not be turbidity within 15 minutes.
5. Moisture: Place 10 mL of test specimen in a tube, cool down to 0℃. The solution should not be turbidity or produce droplets.

Chloroform

$CHCl_3$ molecular weight: 119.39

Anesthetized with chloroform: Anaesthetic chloroform
The substance is trichloromethane, which contains 1.0 ~ 2.0 % (v/v) of ethanol.

Characters:
1. General Characteristics: Colorless, odor, volatile liquid, taste burning and slightly sweet.
2. Solubility: Slightly soluble in water, miscible with ethanol, ether, fixed oil, volatile oil.
3. Boiling point: The part of the substance with boiling point below 60℃ does not exceed 5.0% (v/v); the boiling point of the other part is about 60~62℃ (General rule 1003).
4. Specific gravity: the specific gravity is 1.474~1.478 (General rule 1841).

Identification: The substance is nonflammable, green, toxic and special smell flame is produced when the vapor lead in a Bunsen burner. Add 1 drop of aniline and 1 mL of sodium hydroxide (1 in 6) to 1 drop of the test specimen, heat it and release the odor of phenyl isocyanide (Note: the product is toxic).

Impurities and other requirementss:
1. Acidity, chloride, free chlorine: Add 20 mL of boiled and cooled water to 10 mL of the test specimen, shake for 3 minutes, stand for dividing to two layers. The water layer determine by the test below.
   (1) Acidity: Add 0.1 mL of neutral litmus solution to 5 mL of the solution. The color of the test specimen should be same with the color of the reference which adds 0.1 mL of neutral litmus and 5 mL of boiled and cooled water.
   (2) Chloride: Add 5 mL of water and 0.2 mL of silver nitrate to 5 mL of the solution, opalescence should not be produced.
   (3) Free chlorine: Add 1 mL of cadmium iodide and 2 drops of starch TS to 10 mL of the solution, the blue color should not be produced.
2. Aldehyde: Add 5 mL of water and 0.2 mL of alkali mercuric potassium iodide to 5 mL of test specimen, place the solution in a glass bottle and shake, stand for 15 minutes in dark, then pale yellow is produced.
3. Decomposition products: Place 20 mL of the test specimen in a glass-stopped bottle which is washed with sulfuric acid, and add 15 mL of sulfuric acid and 4 drops of methyl aldehyde. Shake for 30 minutes in dark, stand for 30 minutes, and the pale color is formed in the layer of sulfuric acid.
4. Other organic substances and other chlorine compounds: Place 20 mL of test specimen in a glass-stopped bottle washed by sulfuric acid which does not contain chloride, add 10 mL of sulfuric acid which does not contain chloride, shake for 5 minutes, stand for 30 minutes in dark, no color should be produced in both of layers.
5. Other organic substances: To 2 mL of sulfuric acid which is from the layer of sulfuric acid, after adding 5 mL of water, the solution should be clear and odorless. Add more 10 mL of water and 0.2 mL of silver nitrate, the opalescence should not be produced.
6. Other chlorine compounds: To 15 mL of the solution from the layer of chloroform, put the solution in the glass bottle, add 30 mL of water and shake for 3 minutes, stand for dividing to two layers. Add 0.2 mL of silver nitrate to the water layer, stand for 5 minutes in dark, the opalescence should not be produced.
7. Eliminate the Stink: Place 10 mL of the test specimen on a filter paper, vaporize in the warm place, it should not be stink.
8. Non-volatile matter: Place 25 mL of the test specimen in an evaporating dish and evaporate it to dryness, and then drying at 105℃, the quantity of the residue is not more than 1 mg.

Cyclohexane

C_6H_{12} molecular weight: 84.16

Characters: Clear, colorless liquid, odor of the benzene, insoluble in water, miscible with organic reagents, the specific gravity is 0.7760~0.780.

Impurities and other requirementss:
1. Distilling range: Distill it by the method II of determination of boiling point (General rule 1003), the distillate is more than 95% at 80 ~ 82℃.
2. Freezing point: Determine it by the determination of the freezing point (General rule 1001), and the temperature should be 4.5~6.5℃.
3. Light absorbance: Use the radiation with 250 nm above wavelength, the solution should be colorless and continuous absorption.

Dextrose

$C_6H_{12}O_6 \cdot H_2O$ molecular weight: 198.18

Synonyms: *D*-Glucose

It may contains one molecule of hydration water or be anhydrous.

Characters:
1. General characters: Colorless crystal.

2. General Characteristics: Colorless crystal, white crystal powder or particle powder, without odor, taste sweet.
3. Solubility: Soluble in water easily, especially in boiling water, soluble in boiling ethanol, slightly soluble in ethanol.
4. Specific rotation: After drying at 105˚C for 16 hours, add 0.2 mL of ammonia TS to 10.0 g of test specimen, add water to 100 mL. Determined the specific rotation by specific rotation (General rule 1781), the specific rotation is between +52.5˚~ +53˚.

Identification: Add a few drops of the test specimen (1 in 20) to 5 mL of hot alkaline cupric tartrate, a red precipitate of cuprous oxide is produced.

Impurities and other requirements:
1. Color of the solution: To 25.0 g of test specimen, add sufficient volume of water to 50 mL, the color should not darker than the color of the reference which is prepared as described below. The control solution prepared by mixing 1.0 mL of cobaltous chloride, 3.0 mL of ferric chloride, and 2.0 mL of cupric sulfate, add water to 10 mL, mix well. When starting colorimetric test, dilute 3 mL of this solution with water to 50 mL, serve as control solution. Make the comparison by viewing the test solutions and the control solution downward in matched colorimetric tubes on a white surface.
2. Acidity: Dissolve 5.0 g of test specimen in 50 mL of boiled and cooled water. Add 3 drops of phenolphthalein, and titrate with 0.02 N sodium hydroxide to the production of a distinct pink color, the alkali solution consumption is not more than 0.30 mL for neutralization.
3. Loss on drying: After drying at 105°C for 16 hours, the loss of hydrous water is between 7.5%~9.5% of its weight, and the anhydrous form is not more than 0.5% of its weight. (General rule 1733)
4. Residue on ignition: After igniting it, the residue is not more than 0.1% (General rule 2281).
5. Chloride: Determine 2.0 g of test specimen by test for chlorides (General rule 2221). If the turbidity is produced, the concentration should not be higher than 0.5 mL of 0.02 N hydrochloric acid (180 ppm) in control solution.
6. Sulfate: Determine 2.0 g of test specimen by tests for sulfates (General rule 2221). If the turbidity is produced, the concentration should not be higher than 0.5 mL of 0.020 N sulfuric acid (250 ppm) in control solution.
7. Arsenic: Dissolve 3.0 g of the test specimen in water to make 35 mL of solution, determine it by the determination of arsenic (General rule 2211). The limit of arsenic is 1.3 ppm.
8. Total heavy metals: Dissolve 5.0 g of the test specimen in 23 mL of water to make the solution, determine it by the determination of total heavy metals method I (General rule 6301). The limit of the total heavy metals is 5 ppm
9. Dextrin: To 1.0 g of test specimen fine powder in the flask, add 20 mL of alcohol, reflux to boil, the test specimen should be dissolved completely.
10. Soluble starch and sulfites: To 1.0 g of the test specimen, dissolve in 10 mL of water, add 1 drop of iodine TS, the liquid color is yellow only.

p-Dimethylaminobenzaldehyde

$(CH_3)_2NC_6H_4CHO$ molecular weight: 149.20

Characters: White or pale yellow crystals, or crystalline powder. Slightly soluble in water, soluble in ethanol, ether, dilute hydrochloric acid, the melting point is 73 ~ 75℃.

Impurities and other requirements:
1. Residue on ignition: After igniting, the residue is not more than 0.1% (General rule 7001).
2. Solubility in ethanol: Dissolve 1.0 g in 25 mL of ethanol, completely dissolved.
3. Solubility in hydrochloric acid: Add 1.0 g of the test specimen to 20 mL of dilute hydrochloric acid, the solution should be colorless or slightly yellow.

2,4-Dinitrophenylhydrazine

$C_6H_3(NO_2)_2NHNH_2$ molecular weight: 198.15

Characters: Reddish orange crystal, the monomer is citron yellow capillary crystal under the observation of microscope. Hard soluble in water and slightly soluble in ethanol, soluble in dilute mineral acid. The melting point is 197~200℃.

Impurities and other requirements:
1. Solubility in sulfuric acid: Add 500 mg of the test specimen to the mixture of 25 mL of sulfuric acid and 25 mL of water, the solution should be clear or slightly turbidity.
2. Residue on ignition: After igniting 500 mg of the test specimen, no residue remains (General rule 7001).

Ether

$(C_2H_5)_2O$ molecular weight: 74.12

Anaesthetic Ether.

Ether contains 96.0%~98.0% of $(C_2H_5)_2O$, the other components are alcohol and water.

NOTE**:**
1. Ether is highly volatile and flammable. Its vapor mixed with air may explode when contact with fire.
2. Ether which is used for anesthesia must be preserved in the tight container which is not more than 3-kg capacity, if it has been removed from the original container longer than 24 hour, and it is not to be used for anesthesia. Ether at the time of packaging in the large container should meet the requirements of the tests of this Pharmacopeia.

Characteristics:

1. General Characteristics: Colorless, easily volatile and flammable liquid. Odorous, taste burning and sweet. Slowly oxdized to peroxide by light and air. Boiling point is about 35°C.
2. Solubility: Soluble in water; miscible with ethanol, benzene, chloroform, petroleum benzine, fatty oil, volatile oil.
3. Specific gravity: Specific gravity of the test specimen is 0.713~0.716 (General rule 1841).

Impurities and other requirements:

1. Acidity: Place 10 mL of 80 % ethanol in a 50-mL glass- stopper flask, and add 0.5 mL of phenolphthalein and 0.02 N sodium hydroxide until the pink color remains after shaking for 30 seconds. Add 25 mL of ether, stopper, and shake slowly. If no pink color remains, titrate with 0.02 N sodium hydroxide until the pink color is restored and persists. The second times alkali solution consumption is not more than 0.4 mL.
2. Non-volatile matter: To 50 mL of test specimen to a tared dish, evaporate spontaneously, and then dry at 105℃ for 1 hour. The weight of the residue is not more than 1 mg (30 ppm).
3. Odor: To 10 mL of test specimen, and place on a dry clean evaporating dish, allow to spontaneously to 1 mL, odorless. Place the residue on a filter paper, evaporate until trace of residue remain, it should be odorless except with ethanol smell.
4. Aldehyde: Place 20 mL of the test specimen in a glass- stopper cylinder, and add 7 mL of the mixture solution which is made by 1 mL of alkaline mercuric-potassium iodide TS and 17 mL of a saturated solution of sodium chloride. Stopper, shake vigorously for 10 seconds, and then stand for 1 minute: the water solution should not show turbidity.
5. Peroxide: Place 10 mL of the test specimen in a 25-mL graduated cylinder with glass-stopper, add 1 mL of new made potassium iodide solution (1 in 10). Place it in dark, shake for 1 hour, view on the white background, the layers of water and ether is colorless.

Ether Absolute

$C_2H_5OC_2H_5$ molecular weight: 74.12

Characteristics: The test specimen should meet with requirements of ether and requirements listed below.

Impurities and other requirements:

1. Specific gravity: Not more than 0.710 (General rule 1841).
2. Evaporated residue: Allow 100 mL of test specimen to evaporate spontaneously in a tared evaporating dish, and dry at 105℃ for 1 hour, the weight of the residue is not more than 1.0 mg (0.0015%).
3. Odor: To 10 mL of test specimen, evaporate to 1 mL in evaporating dish, odorless. Place the residue in a wet filter paper, evaporate. No foreign odor.
4. Acidity: Place 10 mL of 80 % ethanol in a 50-mL glass-stopper flask, and add 0.5 mL of phenolphthalein and 0.02 N sodium hydroxide until a pink color persists for 30 seconds. Add 25 mL of ether, and shake slowly to mix. If no pink color remains, titrate with 0.02 N sodium hydroxide until the pink color is restored and persists after shaking 30 seconds. Not more than 0.2 mL of alkali solution is consumed at second time.
5. Aldehyde: Add 5 mL of 1 N potassium hydroxide to 10 mL of the test specimen. Keep the temperature at 25℃. Shake for 1 hour and avoid from light, no color present.
6. Peroxide: Place 10 mL of the test specimen in a clean glass-stopper (risen by the test specimen), add 1 mL of new made potassium iodide solution (1 in 10), stand for 1 hour. The yellow color should not appear in ether layer and water layer. The peroxide of the test is about 0.001% by hydrogen peroxide calculated. The new made ether can meet the provision, but may produce the peroxide after several months stored.
7. Readily carbonizable substance: To 10 mL of sulfuric acid, cool to 10℃, slowly drop 10 mL of test specimen, stirring constantly, the pale color appear in the mixture.

Ethyl Acetate

$CH_3COOC_2H_5$ molecular weight: 88.11

Characters: Clear, colorless, flammable liquid. Soluble in water, miscible with ethanol, ether, fatty oil, volatile oil. The specific gravity is 0.896 ~ 0.898.

Impurities and other requirementss:

1. Boiling point: Determine 100 mL of test specimen by boiling point method Ⅱ (General rule 1003) : the distillate is above 95% at 76~77.5℃.
2. Evaporated residue: Allow 20 mL of the test specimen to evaporate spontaneously from a tared evaporating dish, and then dry at 105℃ for 1 hour. The weight of the residue is not more than 1.0 mg (0.005%).
3. Acidity: It should not turn moist blue litmus paper red.
4. Other ester: Moisten a filter paper with 5 mL of test specimen, allow the test specimen evaporate. No foreign odor is detected after the evaporation.
5. Readily carbonizable substance: Carefully pour 5 mL of the test specimen on the surface of 5 mL of sulfuric acid along tube wall. The interface between the two liquids is without dark color.

Ferrous Sulfate

$FeSO_4 \cdot 7H_2O$ molecular weight: 278.03

It complies with the provisions of the specified Ferrous Sulfate, and it also complies with the provision as described below.

1. Insoluble matter: Dissolve 10.0 g of the test

specimen in 100 mL of boiled and cooled water which contains 1 mL of sulfuric acid. The insoluble matter should not exceed 1 mg (0.01 %) (General rule 7001).

2. Ferric: Determine the ferric iron by the impurities of ferrous ammonium sulfate (General rule 7001). The quantity of the ferric in control solution (General rule 7001) is changed to 0.05 mg, the limit of the ferric in the test is 0.05%.

Formic Acid

HCOOH molecular weight:46.03

Formic acid contains more than 88 % of HCOOH.

Characters: Colorless liquid, highly pungent odor, strong corrosive, miscible with water or ethanol. The specific gravity is about 1.2.

Impurities and other requirements:

1. Evaporated residue: Allow 40 mL of the test specimen to evaporate spontaneously on a boiler, and dry at 105℃ for 2 hours: The weight of the residue is not more than 1.0 mg (0.002%).
2. Ammonium salt: To 10 mL of test specimen, dilute with water to 100 mL. To 1.7 mL of the dilute solution, add 5 mL of sodium hydroxide (1 in 10), dilute with water to 50 mL and add 2 mL of mercuric-potassium iodide TS. If the color is present, it should not be darker than standard solution prepared with 0.01 mg of NH_4 (0.0005%) (standard solution prepared from NH_4Cl).
3. Dilute test: Dilute 5 mL of the test specimen in 15 mL of water, should not be turbidity within 1 hour.
4. Acetic acid: Dilute 1 mL of the test specimen with water to 100 mL. To 10 mL of the solution, add 1.5 g of hydrargyri oxydum navum, place it in a boiler, and filter after heating for 20 minutes. The filtrate is tested by blue litmus paper, and the litmus paper should not change to red in 30 seconds (about 0.4 % CH_3COOH).
5. Chloride: Dilute 2 mL in 20 mL of water, and add 3 mL of nitric acid and 1 mL of silver nitrate solution. If the solution is turbidity, it is not deeper than the standard test added with 0.025 mg of Cl (0.001%).
6. Sulfate: Add 10 mL of anhydrous sodium carbonate to 2 mL of test specimen, and place it in a boiler, evaporate to dryness. Dissolve the residue in 5 mL of water and 1 mL of 1 N hydrochloric acid and filter it, if necessary. Dilute the filtrate in water to 10 mL, add 1 mL of barium chloride, and stand for 10 minutes. If the turbidity is produced, the concentration should not be higher than 0.05 mg of SO_4 (0.002 %) (General rule 7001) in control solution.
7. Sulfite: Add 25 mL of water to 25 mL of the test specimen, add 0.1 mL of 0.1 N iodine solution, the solution appear as yellow (0.001 % of SO_2).
8. Total heavy metals: Place 5 mL in a boiler, evaporated to dryness. Dissolve the residue in 2 mL of dilute acetic acid, and dilute in water to 40 mL. Add 10 mL of hydrogen sulfide. If the brown color is produced, the color should not be darker than the color of the standard test added with 0.03 mg of Pb (0.0005 %) (General rule 7001).
9. Iron: Place 5 mL of the test specimen in a beaker, add 10 mg of anhydrous sodium carbonate, transfer it to a boiler, evaporate to dryness, dissolve the residue in 6 mL of hydrochloric acid and wash it in a volumetric cylinder, dilute in water to 60 mL. The quantity of Fe in 20 mL of the solution is not higher than 0.01 mg or 0.0005% (General rule 7001).

Assay: To a flask with 10 mL of water, weigh accurately, quickly add 1 mL of the test specimen, accurately weighed again. Dilute in 50 mL of water, add phenolphthalein solution as an indicator, titrate it with 1 N sodium hydroxide. Each mL of 1 N sodium hydroxide is equal to 46.03 mg of HCOOH.

Fuller's Earth, Chromatographic

Characteristics: Gray powder or granule, the main component is hydrous magnesium silicate.

Impurities and other requirements:

1. Fineness of powder: See (General rule 1177), the fineness of powder.
2. Loss on drying: Dry it at 105℃ for 6 hours, the loss weight is 7.0 %~10.0 %.
3. Soluble: Add 50 mL of cold water to 20.0 g of the test specimen and filter. After evaporated the filtrate to dryness, the residue does not exceed 60 mg (0.3 %). To 20.0 g of the test specimen, add 50 mL of cold ethanol and filter, after evaporated the filtrate to dryness, the residue is not more than 14 mg (0.07 %).

NOTE: If water content need to be adjusted, dry under lower pressure at room temperature to obtain the desired water content and shake for 2 hours to uniform.

Gallic Acid

$C_6H_2(OH)_3COOH \cdot H_2O$ molecular weight:188.14

Characteristics: White crystal or powder, slightly soluble in cold water, easily soluble in boiled water or ethanol.

Impurities and other requirements:

1. Tannin: Add ferrite solution to the cold saturated solution of the test specimen, the color or precipitate is not produced; then add gelatin solution, the precipitate is not produced.
2. Ignite residue: Add 0.5 mL of sulfuric acid to 1.0 g of the test specimen, ignite it to constant weight, the residue is not more than 1.0 mg or 0.1% (General rule 7001).
3. Sulfate: Dissolve 1.0 g of test specimen in 50 mL of hot water, cool in cold water, filter. Add 1 mL of 1 N hydrochloric acid and 2 mL of barium chloride to the filtrate, the solution should not be turbidity in 5 minutes (about 0.02 % of SO4).

Gelatin

Gelatin is a product obtained by the partial hydrolysis of collagen derived from the skin, white connective tissue, and bones of animals.

Characters:

1. General characters: Faintly yellow or amber translucent sheets, strip or powder. Odor as meat soup. Dried substance does not change in exposure to air, it can be decomposed by microorganisms when moisten or prepared as solution.
2. Solubility: Insoluble in cold water, it becomes swollen and soften by soaking in water for a long time, gradually absorbs 5~10 times quantity of water; soluble in hot water, it becomes gelling after cooling ; also soluble in hot mixture of water and acetic acid or hot water and glycerin; insoluble in ethanol, chloroform, ether, fatty oil, or volatile oil.

Identification:

1. To 10 mL of gelatin solution (1 in 100), add a mixture of 4 mL potassium dichromate (1 in 15) and 1 mL of dilute hydrochloric acid, a yellow precipitate is formed.
2. To gelatin solution (1 in 100), add trinitrophenol TS, a yellow precipitate is formed.
3. To gelatin solution (1 in 5000), add tannic acid, turbidity is produced.

Impurities and other requirements:

1. Residue on ignition: Ignite 5.0 g of the test specimen without using sulfuric acid, the weight of the residue should not exceed 100 mg (2%) (General rule 2281). Reserve the residue for later used.
2. Odor and water-insoluble substances: Dissolve 500 mg of the test specimen in 20 mL of water and heat, a hot solution does not have any disagreeable odor. Pour the hot solution into a glass container to make up the 2 cm thick layer, view the layer which is slightly opalescent.
3. Sulfur dioxide: To 20.0 g of test specimen in a distillation flask, dissolve with 150 mL of water, add 3~5 drops of silicon resin, add 5 mL of phosphoric acid and 1.0 g of sodium bicarbonate, connect the flask with a condenser immediately. Immersed the outlet of condenser into 50 mL of 0.1 N iodine solution, heat and distill. Collect 50 mL of distillate. Acidify the distillate with a few drops of hydrochloric acid, add 2 mL of barium chloride TS, and heat on a boiler until the liquid is nearly colorless. If a precipitate of barium sulfate is formed, filter, wash with water and ignite the precipitate. The residue should not be more than 3 mg, correspond to sulfur dioxide residue is not more than 40 ppm. A blank test is made for any sulfate that may be present in 50 mL of 0.1 N iodine, make suitable calibration.
4. Arsenic: Mix 1.5 g of the test specimen with 10 mL of pepsin solution in an arsine generator flask, add 10 mL of nitric acid and 10 mL of perchloric acid, heat carefully, the strong fume of perchloric acid is formed. Cool, wash the sides of the generator with water, add 10 mL of nitric acid, heat again until the strong fume is formed. Cool, wash the sides of the generator with water, heat again until the strong fume is formed. Then cool, dilute it with water to 52 mL, add 3 mL of hydrochloric acid. Determine it by determination of arsenic (General rule 2211) (bypass the step of adding 20 mL of dilute sulfuric acid), the limit is 0.8 ppm.
5. Total heavy metal: To the residue obtained from the test for residue on ignition, add 2 mL of hydrochloric acid and 0.5 mL of nitric acid, and evaporate on a boiler to dryness. Add 1 mL of 1 N hydrochloric acid and 15 mL of water to the residue, and warm for few minutes. Filter and wash the residue with water to make the filtrate measure at 50 mL, mix. Determine 25 mL of filtrate by total heavy metals method Ⅰ (General rule 6301), the limit is 50 ppm.
6. Gel strength: Place accurately weighed 1.0 g of test specimen in a 200-mL flask, add 99 mL of water, after stand for 15 minutes, transfer it to a boiler at the temperature of 60°C, constantly spin the flask until the test specimen be dissolved totally. Place 10 mL of the solution in a tube which inner diameter is 12 mm, cool in a cold boiler, make sure the surface of the test specimen is lower than the surface of the water in the cold boiler, place the cold boiler in a freezer, maintain the temperature at 0℃. After 6 hours, take the tube from a freezer and invert it, the gel in a tube should be solid and not vibrate.
7. Limit of microorganisms: Determine the test specimen by limit of microorganisms (General rule 3061). The total plate count of each g should not exceed 1000 CFU, *escherichia coli* and salmonella should not present.

Glacial Acetic Acid

CH_3COOH molecular weight: 60.05

Glacial Acetic Acid contains 99.5 %~100.5 % (w/w) of CH_3COOH by weight.

Characters:

1. General Characteristics: Colorless, clear liquid, strong odor, acidity still present after diluting with sufficient water.
2. Solubility: Miscible with water, ethanol, or glycerol.
3. Freezing point: The freezing point is not less than 15.6°C (General rule 1001).
4. Specific gravity: The specific gravity is about 1.049 (General rule 1841).
5. Boiling point: The boiling point is about 118℃ (General rule 1003).

Identification: A mixture of 1 volume of the test specimen with 2 volumes of water responds to the test for acetate (General rule 2191).

Impurities and other requirements:

1. Limit of nonvolatile residue: Evaporate 20 mL of the

test specimen in a tared dish, and dry at 105°C in boiler for 1 hour, the weight of the residue is not more than 1.0 mg. Reserve the residue for later used.
2. Chloride: Dilute 1.0 mL of the test specimen with 20 mL of water, and add 5 drops of silver nitrate, no opalescence is produced.
3. Sulfate: Dilute 1.0 mL of the test specimen with 10 mL of water, and add 1 mL of barium chloride, no turbidity is produced.
4. Arsenic: Determine the test specimen by determination of arsenic (General rule 2211), the limit is 6 ppm.
5. Total heavy metal: To the residue obtained in (1), add 8 mL of 0.1 N hydrochloric acid, heat gently until the residue is completely dissolve, add water to 100 mL. To 25 mL of the solution, determine by determination of total heavy metals (General rule 6301), the limit is 10 ppm.
6. Readily oxidizable substances: Dilute 2 mL of the test specimen in a glass-stopper vessel with 10 mL of water, and add 0.1 mL of 0.1 N potassium permanganate, the pink color should not change to brown within 2 hours.

Assay: To about 2 mL of glacial acetic acid into a glass-stopper flask, accurately weigh. Dilute with water to 40 mL, use phenolphthalein solution as an indicator, and titrate with 1 N sodium hydroxide. Each mL of 1 N sodium hydroxide is equivalent to 60.05 mg of $C_2H_4O_2$.

n-Hexane

The substance is a mixture of several kinds of hexane isomers, mainly *n*-hexane and methylcyclohexane (C_6H_{12}), suitable for use in UV spectrophotometry.

Hexanes Solvent

Characteristics: Clear, volatile liquid, similar odor like ether or petroleum ether, barely insoluble in water, soluble in absolute alcohol, miscible with ether, chloroform, benzene, and most fixed and volatile oils.
NOTE: It is easily flammable. Keep it away from flames, and store in tight containers in a cool place.

Impurities and other requirements:
1. Appearance and color: Before taking the test specimen, shake well in the original container. To 100 mL of test specimen in a 100 mL colorimetric tube to compare with a standard solution containing platinum and cobalt. Two solutions should all be clear, with no suspension and precipitates. The color of the test solution should not be darker than the standard solution under light transmitting.
2. Odor: Should be odorless without unpleasant odor like thioalcohol or thiophenol.
3. Distilling range: To 100 mL of the test specimen determine it by determination of boiling point method Ⅱ (General rule 1003) at 30℃ or above, completely distilled at 30 ~ 60℃.
4. Limit of nonvolatile residue: Evaporate 150 mL of the test specimen to dryness, and dry at 105°C for 30 minutes, the weight of the residue is not more than 1 mg (0.001%).
5. Acidity: To 10 mL of test specimen, add 5 mL of water, and shake for 2 minutes and allow two solvents to separate. The water layer should not turn the blue litmus paper to red within 15 seconds.
6. Heavy hydrocarbon oil: Slowly pour 10 mL of test specimen in the center of the filter, should not remain the unpleasant odor and the speck of grease after 30 minutes.
7. Spectral purity: The test specimen is used for chromatography which should meet with the requirements as described below. Place the test specimen in 1 cm cell, at the wavelength of 300 nm, the air as the control group, the absorbance should not exceed 0.08.

Hydrazine Sulfate

$(NH_2)_2 \cdot H_2SO_4$ molecular weight: 130.13

Dry in a sulfuric acid desiccator for 2 hours, it contains more than 99 % of $(NH_2)_2 \cdot H_2SO_4$.

Characteristics: Colorless crystal or a white crystalline powder. Soluble in water about 40 minutes, insoluble in ethanol.

Impurities and other requirements:
1. Residue on ignition: After igniting, the residue is not more than 0.1 % (General rule 7001).
2. Chloride: Cl content is not more than 0.01 % (General rule 7001).
3. Total heavy metal: Dissolve 1.0 g of test specimen in 40 mL of warm water, add 10 mL of hydrogen sulfide solution, the solution does not appear dark colors.
4. Iron: To the solution obtained from upper item, alkalize by adding ammonia solution, if the green color is formed, the color should not be darker than the control solution with 0.01 mg of Fe (General rule7001).

Assay: Place it in a sulfuric acid desiccator, dry for 2 hours, weigh accurately 100 mg, dissolve it in 20 mL of water. Add 1.0 g of sodium bicarbonate to the solution, shake to dissolve, titrate with 0.1 N iodine solution, add starch as an indicator when it close to end point. Each mL of 0.1 N iodine solution is equivalent to 3.253 mg of $(NH_2)_2 \cdot H_2SO_4$.

Hydrochloric Acid

HCl molecular weight: 36.46

Hydrochloric Acid contains 35 %~38.0 % of HCl by weight.

Characters: Colorless, fume liquid, irritating odor, the specific gravity is about 1.18.

Impurities and other requirements:

1. Appearance: Shake in original container, place 10 mL in a 20 × 15 mm tube. Compare with the other tube filled with water, both of two liquids are clear, should not contain suspended matters. The color should not be different.
2. Residue on ignition: Place 85 mL of the test specimen in an platinum dish, evaporate to dryness, add 1 drop of sulfuric acid, and ignite for 5 minutes, cool and weigh, the remain of residue is not more than 0.5 mg (about 0.0005%).
3. Free chlorine: To 25 mL of test specimen, add 25 mL of boiled water and cool, add 2 more drops of potassium iodide (1 in 5) (not containing iodate) and 1 mL of carbon disulfide, shake well, the pink color is not produced within 30 seconds (about 0.0001 %).
4. Sulfate: To 20 mL of the test specimen add 100 mg of sodium carbonate, evaporate to dryness, the SO_4 in residue is not more than 0.05 mg (0.0002 %) (General rule 7001).
5. Sulfite: To 0.05 mL of 0.1 N iodine solution and several drops of starch TS add to 50 mL of boiled and cooled water, add the mixture of 5 mL of the test specimen and 50 mL of boiled and cooled water, shake and mix, the blue color does not disappear.
6. Arsenic: Dilute 17 mL (20.0 g) of the test specimen with triple volume of water, place it in a bigger gas generator, and determine it by determination of arsenic (General rule 2211). The arsenic spots are produced, it should not be more than the arsenic spots obtained in the blank test added with 0.002 mg of As_2O_3 (General rule 2211).
7. Total heavy metal: Place 17 mL of the test specimen in a beaker, add 10 mg of sodium carbonate, evaporate to dryness in a boiler, dissolve the residue in 2 mL of dilute acetic acid, and dilute with water to 40 mL, add 10 mL of hydrogen sulfide, if the dark color is formed, should not be darker than the control test added with 0.02 mg of Pb (0.0001%) (General rule 7001).
8. Iron: Place 17 mL of the test specimen in a glass dish or porcelain dish, add 10 mg of sodium carbonate, evaporate to dryness in a boiler, dissolve the residue in 2 mL of the test specimen, dilute with water to 50 mL, the solution containing Fe should not exceed 0.01 mg (0.00002%) (General rule 7001).
9. Ammonium salt: Place 4.2 mL of hydrochloric acid in a distillation flask, previously tared while containing about 30 mL of cold water, cool in crushed ice, carefully add 20 mL of sodium hydroxide (1 in 10), keep in the low temperature, cool. Add 20 mL of sodium hydroxide, the distillation flask connect with the condenser, let the tip of the tube under the surface of 10 mL of 0.1 N hydrochloric acid, then heat and distill, collect about 35 mL of the distillate, add 2 mL of alkaline mercuric iodide, if the yellow color is produced, it is not deeper than the control test added with 0.015 mg of NH_4 (0.0003%) (prepared by pure ammonium salt).

Assay: Place about 3 mL of hydrochloric acid in a glass-stopper flask, previously tared while containing about 30 mL of water, and weigh again to obtain the weight of the substance under assay. Dilute to 50 mL with water, add methyl orange, and titrate with 1 N sodium hydroxide. Each mL of 1 N sodium hydroxide is equivalent to 36.46 mg of HCl.

Hydrogen Peroxide (30%)

H_2O_2 molecular weight: 34.02

Hydrogen Peroxide contains 29.0 %~32.0 % of H_2O_2 by weight.

NOTE: It can not mix with any organic substances, in order to avoid explosion. Preserve in partially-filled containers with a small vent in the closure, and store in a cool place. The solution is corrosion to skin.

Characteristics: Colorless liquid, miscible with water, the specific gravity is about 1.1.

Impurities and other requirements:

1. Non-volatile residue: To 18 mL of test specimen, evaporate to dryness in a boiler and dry at 105 °C for 2 hours. The residue should not exceed 1.0 mg (about 0.005 %).
2. Acidity: Dilute 9 mL (10.0 g) of the test specimen with 90 mL of boiled and cooled water, add several drops of methyl red solution, titrated with 0.02 N sodium hydroxide. The quantity of the alkaline liquid is calibrated by the blank test, not more than 0.3 mL of alkali solution is used for neutralization (0.003 %).
3. Chloride: Dilute 1 mL of the test specimen with 5 mL of water, add 1 mL of nitric acid and 1 mL of silver nitrate. If the solution is turbidity, it is not more concentrated than 0.01 mg of Cl in the control test.
4. Nitrate: To 1 mL of test specimen, add 10 mg of sodium carbonate, evaporate to dryness in a boiler, add 2 mL of phenol disulfonic acid, heat for 15 minutes in a boiler, cool and dilute it to 30 mL, the solution is alkalized by adding ammonia solution. If the yellow color is produced, it should not be darker than the control test added with 0.01 mg of NO_3 (prepared by pure potassium nitrate salt).
5. Phosphate: To 3.6 mL (4.0 g) of the test specimen, evaporate to dryness in a boiler, the residue of PO_4 should not exceed 0.02 mg (0.0005 %) (General rule 7001).
6. Sulfate: To 9 mL of test specimen, evaporate to dryness in a boiler. Dissolve the residue in 10 mL of water, and add 1 mL of dilute hydrochloric acid (1 in 20). Transfer it to a colorimetric tube, and add 1 mL of barium chloride. If the solution is turbidity, it is not more concentrated than 0.05 mg of SO_4 (0.0005%) in the control test. (General rule 7001).
7. Ammonium salt: Add 2 drops of sulfuric acid to 1 mL of test specimen, and evaporate to dryness in a boiler. Dissolve the residue in 45 mL of water, transfer it to a colorimetric tube, add 3 mL of sodium hydroxide (1

in 10) and 2 mL of alkaline mercury potassium iodide. If the yellow color is produced, it should not be darker than the control test added with 0.01 mg of NH_4 (0.001%) (Solution prepared by pure ammonium salt).

Assay: Accurately weigh about 1 mL of the test specimen in a tared volumetric flask, previously tared while containing about 5 mL of water, dilute with water to 100 mL, and mix. To 20.0 mL of the solution, add 20 mL of dilute sulfuric acid, and titrate with 0.1 N potassium permanganate. Each mL of 0.1 N potassium permanganate is equivalent to 1.701 mg of H_2O_2.

Hydrogen Peroxide Solution

Hydrogen Peroxide Solution contains 2.5~3.5 g of H_2O_2 in each 100 mL. It can be used as a suitable preservative, it contains not more than 0.05 %.

Characters:

1. General Characteristics: Clear, colorless liquid, acidic reaction with litmus paper, odorless or odor like ozone with slightly sour taste. Put on the sunlight, store for a long time, heat, contact with oxidizing and reducing agent, or continue stir will make the hydrogen peroxide deteriorate.
2. Specific gravity: The specific gravity is about 1.01 (General rule 1841).

Identification:

1. Shake 1 mL of test specimen which is added with 10 mL of water contained 1 drop of dilute sulfuric acid, and add 2 mL of ether, add a drop of potassium dichromate TS, produce a blue color in the water layer, and then the color is evanescent. Agitate and standing, the ether layer is blue.
2. To the test specimen, add sodium hydroxide solution, the solution becomes alkaline, decompose it to foam. A large quantity of oxygen is produced by heating.

Impurities and other requirements:

1. Nonvolatile residue: To 20 mL of test specimen, place on a boiler, evaporate to dryness, and then dry the residue at 105°C for 1 hour. The weight of the residue should not exceed 30 mg.
2. Acidity: To 25 mL of test specimen, add phenolphthalein TS as an indicator, and titrate with 0.1 N sodium hydroxide to neutral, not more than 2.5 mL of the alkali solution is used for neutralization.
3. Arsenic: To 1 mL of test specimen, add 1 mL of ammonium hydroxide TS, evaporate to dryness in a boiler, determine the residue by determination of arsenic (General rule 2211), the limit is 2 ppm.
4. Barium: To 10 mL of test specimen, add two drops of dilute sulfuric acid, no turbidity or precipitate is produced within 10 minutes.
5. Total heavy metal: Dilute 5 mL of test specimen with 20 mL of water, add 2 mL of ammonium hydroxide TS, and slowly boil the solution until the volume is reduced to about 5 mL. Add 3 mL of dilute acetic acid and dilute with water to 25 mL, determine it by determination of total heavy metal method I (General rule 6301), the limit is 5 ppm.
6. Limit of preservative: To 100 mL of solution in a separator, respectively extraction with 50 mL, 25 mL and 25 mL of mixture solution of chloroform and ether (3:2). Combine the extracts at room temperature in a tared evaporating dish, evaporate spontaneously to dryness, and dry in a sulfuric acid desiccator for 2 hours. The residue weight should not exceed 50 mg.

Assay: Accurately pipette 2.0 mL of the test specimen into a suitable flask contained 20 mL of water. Add 20 mL of dilute sulfuric acid and titrate with 0.1 N potassium permanganate. Each mL of 0.1 N potassium permanganate is equivalent to 1.701 mg of H_2O_2.

Storage: Preserve in tight, light-resistant container, store in a dark and cool place.

Hydroxylamine Hydrochloride

$NH_2OH \cdot HCl$ molecular weight: 69.50

Hydroxylamine Hydrochloride contains not less than 96 % of of $NH_2OH \cdot HCl$ by weight.

Characteristics: White or colorless, crystalline powder, very soluble in water, soluble in ethanol.

Impurities and other requirements:

1. Acidity: Dissolve 10.0 g of test specimen in 50 mL of water, add 3 drops of bromophenol blue, titrate with 0.5 N sodium hydroxide until the green color is produced, not more than 5 mL of alkali solution is used for neutralization.
2. Residue on ignition: To 2.0 g of test specimen, add 0.5 mL of sulfuric acid, ignite it to constant weight. The residue should not exceed 0.1 mg (0.05 %). Reserve the residue for later used.
3. Solubility in ethanol: To 1.0 g of test specimen, add 25 mL of ethanol, the solution which is well dissolved becomes clear and colorless. Reserve the solution for later used.
4. Sulfate: Place 1.0 g of test specimen in a beaker, dissolve it in 10 mL of water contained 10 mg of sodium carbonate, add 2 mL of nitric acid and 2 mL of 30% hydrogen peroxide. The beaker cover with a watch glass, heat it in a boiler until the reaction stop. Remove the watch glass, evaporate to dryness, and dissolve the residue in 10 mL of water. The SO_4 contained in the solution should not exceed 0.05 mg (General rule 7001) (0.005%).
5. Ammonium salt: To the remained solution of (3), add 1 mL of platinum chloride, the solution remain clear within 10 minutes.
6. Total heavy metal: The limit is 20 ppm (General rule 7001).
7. Iron: To the remain residue of (2), add 3 mL of dilute hydrochloric acid (1 in 2), the evaporating dish covers with a watch glass, heat it in a boiler for 15 ~

20 minutes, remove the watch glass, evaporate to dryness, dissolve the residue in 2 mL of hydrochloric acid, dilute to 50 mL. The Fe contained in the solution should not exceed 0.01 mg (5 ppm) (General rule 7001).

Assay: Place 200 mg of the test specimen in a sulfuric acid desiccator, dried over night. To accurately weighed 100 mg of the test specimen, dissolve it in 20 mL of water, add the solution made of 5.0 g of ferrous ammonium sulfate and 20 mL of water, add 15 mL of dilute sulfuric acid, boil for 5 minutes. Dilute with 200 mL of water, titrate with 0.1 N potassium permanganate. Each mL of 0.1 N potassium permanganate is equivalent to 3.475 mg of $NH_2OH \cdot HCl$.

Isopropyl Alcohol

$(CH_3)_2CHO$ molecular weight: 60.10

The $(CH_3)_2CHO$ contained in this product should be 99.0% or more.

Identification:

1. This product is determined by the liquid absorption method of infrared absorbance measurement method (General rule 1197), and its absorption spectrum is measured by the same method as the standard of this product, and the maximum absorption is only at the same wavelength.
2. The retention time of the main wave front of the test solution in the content determination should be the same as the retention time of the isopropanol wave front in the system suitability solution.

Impurities and other requirements:

1. Volatile impurities:
   System suitability solution, test solution, chromatography device and system suitability: According to the content determination.
   Assay:
   The system suitability solution is used to identify peaks of individual impurities in the test solution.
   Calculate the percentage of individual impurities contained in isopropyl alcohol:

$$\text{Result} = (r_U/r_T)\times 100$$

   r_U = Peak value of individual impurities in the test solution
   r_T = The sum of all wave peaks in the test solution
   shall not exceed 0.1% of any individual impurities, and the sum of impurities shall not exceed 1.0%.
2. Non-volatile matter:
   Take 50 mL of this product, place it in an evaporating dish, evaporate it on a water bath, and heat it to 105 °C for 1 hour. The weight of the residue should not exceed 2.5 mg (0.005%).
3. Specific weight:
   The Specific weight of this product is 0.783~0.787(General rule 1841).
4. Refractive index:
   The refractive index of this product is 1.376~1.378 at 20 °C(General rule 1831).
5. Acidity:
   Take 50 mL of isopropanol, dissolved in 100 mL of water containing no carbon dioxide, add two drops of phenolphthalein test solution, and titrate with 0.020 N sodium hydroxide until the solution is pink for 30 seconds, and the volume of 0.020 N sodium hydroxide used should not be more than 0.7 mL.
6. Moisture:
   Take 5.0 g of this product and measure it according to the Fisher's Moisture Method (General rule 1921). The moisture content of the product should not exceed 0.5%.

Assay:

Sample solution: Pure isopropyl alcohol

Chromatography device:

Gas chromatography device with flame ion detector, 0.25 mm x 60 m melting capillary, coated with a layer of 1.4 μL, containing 6% cyanophenyl and 94% dimethyl polyfluorene, split ratio is 50:1. The column temperature is shown in Table 1. The main inlet temperature is 150 °C, the detector is 200°C, the helium is the carrier gas, the flow rate is 2.3 mL/min, the injection volume is 1.0 μL, and the measurement time is about 22 minutes.

Table 1

Initial temp. (℃)	Temp. Ramp (℃/min)	Final temp. (℃)	Hold time at final temp. (min)
35	—	35	5
35	1	45	—
45	10	100	1

System suitability:

he system suitability solution composition is shown in Table 2. The resolution between acetone and isopropanol shall not be less than 1.5; the relative deviation of isopropanol wave front shall not be more than 2.0%, the tailing factor shall not be greater than 2.0; The noise ratio of any of the ether, acetone, isopropanol, isopropyl ether, n-propanol and 2-butanol must not be less than 10.

Table 2

Chemical name	Relative retention time
Ether	0.7
Acetone	0.9
Isopropanol	1.0
Isopropyl ether	1.4
n-Propanol	1.5
2-Butanol	2.0

Assay:
Calculate the percentage of isopropanol contained in the test solution:

$$\text{Result} = (r_U/r_T)\times 100$$

r_U = Peak value of isopropanol
r_T = Total peak value

Storage method:
This product should be placed in a tight container and stored from light and fire.

Use classification: Formulation adjuvant

Lead Acetate

$Pb(CH_3COO)_2 \cdot 3H_2O$ molecular weight: 379.35

Characteristics: Colorless crystal, heavy white crystal or granular crystal, slightly acetic acid odor. Lose the water of crystallization when exposing in air, and absorbing carbon dioxide cause incompletely dissolve in water. Dissolve 1.0 g of the test specimen in 1.6 mL of water, or in 30 mL of ethanol, aqueous solutions has the alkaline reaction with litmus paper.

Impurities and other requirements:

1. Insoluble matter: Dissolve 10.0 g of the test specimen in 100 mL of boiled and cooled water which is added 2 drops of glacial acetic acid, shake. If there has insoluble matter, filter with a tared filter crucible, the residue wash thoroughly by boiled and cooled water, dry at 105℃ for 2 hours and weigh, the quantity of the residue should not exceed 1.0 mg (0.01 %).
2. Chloride: To 2.0 g of the test specimen, determine it by the limit of chloride (General rule 7001), the quantity of Cl should not exceed 0.01 mg (0.0005%).
3. Nitrate: Dissolve 1.0 g of the test specimen in 10 mL of water, add 5 mg of sodium chloride, 0.2 mL of indigo carmine TS and add 10 mL of sulfuric acid, stirring thoroughly, stand for 10 minutes. The blue color clarified liquid in the upper layer should not disappear completely.
4. Copper: Dissolve 5.0 g of test specimen in a mixture of 42 mL of water and 3 mL of glacial acetic acid, add 5 mL of sulfuric acid, and stand for 10 minutes and filter. To 25 mL of the filtrate, add 50 mg of alum and a little of ammonium persulfate, neutralize the solution with ammonia solution, and then add few more drops of ammonia solution, boil, allow to cool and filter, retain the residue for later used. Add glacial acetic acid in the filtrate, the solution is neutral by the test with phenolphthalein, add 0.25 mL more of acetic acid, then add 0.25 mL of new made potassium ferricyanide, if the pink color is produced, it should not be darker than the control solution (prepared by 0.5 mg of cupric sulfate) added with 0.125 mg of Cu.
5. Iron: To the residue of the (4), rinse with water to remove acetate, dissolve in 10 mL of dilute hydrochloric acid by heating, rinsing the filter with water. Dilute the filtrate with water to 45 mL, add 50 mg of ammonium persulfate and 3 mL of ammonium thiocyanate solution, if the red color is produced, it should not be darker than the control solution added with 0.025 mg of Fe (General rule 7001).
6. No precipitate of hydrogen sulfide: To 20 mL of the filtrate (4), dilute with water to 100 mL, add hydrogen sulfide, all precipitates of lead are produced, and then filter it. To 50 mL of the filtrate, place in a boiler, evaporate to dryness, and slowly ignited to constant volume, the residue should not exceed 0.5 mg (0.05 %).

Methyl Alcohol

CH_3OH molecular weight: 32.04

Methyl Alcohol contains not less than 99.5 % (v/v) of CH_3OH.

Characteristics: Colorless, clear liquid, odor, flammable, miscible with water, ethanol and ether.

Impurities and other requirements:

1. Distilling range: To 100 mL of test specimen, determine it by determination of boiling point method Ⅱ (General rule 1003), only 1°C difference between 20 drops of distillate production to 95 mL of distillate production, the boiling point at 760 mm of Hg is 64.6 ℃.
2. Dilute test: Mix 15 mL of the test specimen with 45 mL of water, stand for 1 hour, the solution should be clear.
3. Nonvolatile residue: Evaporate 125 mL of test specimen in a boiler to dryness, and dry at 105℃ for 30 minutes, the weight of the residue should not exceed 1.0 mg (0.001 %).
4. Acidity: To 10 mL of test specimen, mix 25 mL of water, add 0.5 mL of phenolphthalein TS, and titrate with 0.02 N sodium hydroxide, until the color is slightly pink, persist after shaking for 30 seconds. Add 25 mL of the test specimen, after mixing well, titrate with 0.02 N sodium hydroxide until a slightly pink color appear, not more than 0.5 mL of alkali solution is used to produce a pink color in second titration.
5. Alkalinity: Dilute 25 mL of the test specimen with 25 mL of water, add 1 drop of methyl red, and titrate with 0.02 N sulfuric acid until the pink color appear, not more than 0.20 mL of acid solution is used to produce a pink color.
6. Acetone and aldehydes: To 1 mL of the test specimen, add 4 mL of water and 5 mL of alkaline mercuric-potassium iodide. If the turbidity is produced, the concentration of the test specimen should not be higher than the mixture of 5 mL water contained 0.03 mg of acetone and 5 mL of alkaline mercuric-potassium iodide.
7. Readily oxidizable substances: To 20 mL of test specimen, cool to 15℃, add 0.1 mL of 0.1 N potassium permanganate, stand for 5 minutes at 15℃, the pink color does not completely disappear.
8. Readily carbonizable substances: Cool 10 mL of sulfuric acid in a small conical flask to 10℃, add 10 mL of test specimen, shake constantly, the color of

the solution should not be darker than slightly brown.

Assay: The specific gravity is not more than 0.790.

α-Naphthol

$C_{10}H_7OH$ molecular weight: 144.17

Characteristics: Colorless, or slightly pink crystal or crystalline powder, odor, insoluble in water, soluble in ethanol, benzene, or ether. The melting temperature is 95 ~ 97℃.

Impurities and other requirements:
1. Acidity: To 1.0 g of the test specimen, add 50 mL of water, shake for 10 minutes and filter, the filtrate is neutral in the reaction with the litmus papers.
2. Residue on ignition: The residue should not exceed 0.05 % (General rule 7001).

β-Naphthol

$C_{10}H_7OH$ molecular weight: 144.17

Characteristics: White lobular or crystalline powder, slightly odor, the color is changed when exposed to light, slightly soluble in water, soluble in ethanol, ether, chloroform, or alkali metal hydroxide. The melting range is 121 ~ 123℃.

Impurities and other requirements:
1. Solubility in ethanol: To 1.0 g of test specimen, add 10 mL of ethanol, mix well, dissolve completely into a colorless solution.
2. Residue on ignition: after ignition, the residue should not exceed 0.05 % (General rule 7001).
3. Acidity: To 1.0 g of test specimen, add 50 mL of water, and shake for 15 minutes constantly and filter. The filtrate should be neutral to the litmus papers.
4. α-Naphthol: To 100 mg of test specimen, add 10 mL of water, boil it until dissolve completely. Allow to cool and filter, add 0.3 mL of 1 N sodium hydroxide and 0.3 mL of 0.1 N iodine solution to the filtrate, the violet color should not be produced.
5. Ammonia insoluble substance: To 500 mg of test specimen, add 30 mL of ammonia solution, shake to dissolve completely, the color of the solution should not be darker than slightly yellow.

Nitric Acid

HNO_3 molecular weight: 63.02

Nitric Acid contained is between 68.0 %~71.0 % of HNO_3 by weight.

Characteristics: Colorless, clear liquid, the specific gravity is about 1.4.

Impurities and other requirements:
1. Appearance: Shake the test specimen in its original container, and transfer it to 10 mL test tube. Compare with the similar test tube contained water, the test specimen is equally clear and free form suspended matter, when viewed with transmitted light, it exhibits no apparent difference in color.
2. Residue on ignition: Place 140 mL of test specimen in a platinum kettle, and evaporate to dryness. Ignite it to cherry red, cool for 5 minutes, and weigh, the weight of the residue should not exceed 1.0 mg (0.0005 %).
3. Chloride: To 5 mL of test specimen, dilute with equivalent volume of water, add 1 mL of silver nitrate TS. If the solution is turbidity, it should not be more concentrated than mixture of 0.005 mg of Cl in 9 mL of water, 1 mL of dilute nitric acid (1 volume nitric acid and 9 volume water) and 1 mL of silver nitrate TS.
4. Sulfate: Add about 10 mg of anhydrous sodium carbonate to 28 mL of nitric acid. Evaporate to dryness in a boiler, dissolve the residue in 25 mL of water, the SO_4 in the solution should not exceed 0.04 mg (0.0001 %) (General rule 7001).
5. Arsenic: To 215 mL of test specimen, add 5 mL of sulfuric acid and mix well. Evaporate until the white fumes of concentrated sulfur trioxide release. Cool and dilute with 10 mL of water, and evaporate until the release of sulfur trioxide white fume, repeat the procedure as described until all nitrate had been removed, follow the Determination of Arsenic (General rule 2211), the arsenic content should not exceed 0.003 mg (0.000001%).
6. Total heavy metal: Place 14 mL (20.0 g) of the test specimen in a boiler, evaporate to dryness. Add 2 mL of dilute acetic acid to the residue, heat it warm, dilute with water to 40 mL. Add 10 mL of hydrogen sulfide, if the color is produced, it should not be darker than control solution added with 0.02 mg of Pb (General rule 7001).
7. Iron: Evaporate 7 mL (10.0 g) of the test specimen to dryness in a boiler, the limit of Fe in the residue is 0.01 mg (1ppm) (General rule 7001).

Assay: Weigh accurately about 2 mL of nitric acid in a tared, glass-stopper conical flask, and dilute with 25 mL of water. Add methyl red as the indicator, and titrate with 1 N sodium hydroxide. Each mL of 1 N sodium hydroxide is equivalent to 63.02 mg of HNO_3.

Petroleum Benzin

Synonyms: Petroleum Ether

Petroleum Benzin is a mixture of hydrocarbons from petroleum, most of them are alkane, it is produced from the fractional distillation of petroleum at 35 ~ 80℃.

NOTE: Freely flammable, when its vapor is mixed with air, contact with fire occur violent explosion.

Characteristics:
1. General Characteristics: Colorless, clear, no

fluorescence, volatile liquid. Odor like ether or slightly like petroleum. It is very flammable, when its vapor mix with air, contact with fire occurs violent explosion. It is neutral in the reaction with the wet litmus paper.
2. Solubility: It is practically insoluble in water, freely soluble in anhydrous alcohol, miscible with ether, chloroform, benzene, fat oil (except castor oil), or volatile oil.
3. Specific gravity: The specific gravity is 0.634 ~ 0.660 (General rule 1841).

Impurities and other requirements:
1. Distilling range: Determine it by determination of boiling point method Ⅱ (General rule 1003), it is totally distilled at 35 ~ 80℃.
2. Residue on evaporation: Evaporate 50 mL of test specimen on the tared evaporating dish to dryness at below 40°C, and dry the residue at 105℃ 1 hour and weigh. The mass of residue should not exceed 1 mg.
3. Fatty oil and sulfur compounds: To 10 mL of test specimen, drop on wet odorless filter paper (place on a previously warmed glass plate), let it evaporate spontaneously until left a little bit of solution, no foreign odor or sulfur compounds odor produce. After evaporate completely, no oil spot left.
4. Sulfur compounds and reducing substances: To 10 mL of test specimen, add 2.5 mL of ammonia-ethanol and several drops of silver nitrate, boil for several minutes, no brown color produce.
5. Benzene: Place 40 drops of sulfuric acid and 10 drops of nitric acid in a tube, add 5 drops of test specimen, heat to warm for about 10 minutes, stand for 30 minutes, transfer the mixture to a shallow dish, and dilute with water. No odor of nitrobenzene is perceptible.

Phosphomolybdic Acid

$20MoO_3 \cdot 2H_3PO_4 \cdot 48H_2O$

molecular weight: 3939.77

Characteristics: Bright yellow crystal or crystalline powder, freely soluble in water.

Impurities and other requirements:
1. Insoluble matter: To 5 g of the test specimen, not more than 1 mg of insoluble matter (0.02 %) (General rule 7001).
2. Chlorides: Dissolve 1.0 g of the test specimen in 50 mL of water, add 1 mL of nitric acid and filter. The filtrate is divided into two equal parts. One part is added 0.5 mL of silver nitrate, stand for 10 minutes, and filter repeatedly until the solution is clear. Add standard chloride solution which volume equals to 1 mg of chloride (General rule 7001) to the filtrate. Prepare another filtrate as control, add 0.5 mL of silver nitrate. If the turbidity is produced, the concentration of test solution should not be higher than control solution (0.02 %).
3. Nitrate: Dissolve 200 mg of the test specimen in 10 mL of water, add 0.1 mL of indigo carmine TS, add 10 mL of sulfuric acid, the blue color should not disappear within 5 minutes.
4. Sulfate: Dissolve 200 mg of the test specimen in 20 mL of water, add 0.5 mL of dilute hydrochloric acid and 2 mL of barium chloride, the turbidity is not produced within 1 minute.
5. Ammonium salt: Dissolve 500 mg of the test specimen in 5 mL of water, add 10 mL of sodium hydroxide (1 in 10), heat in a boiler, no odor of ammonia is perceptible.
6. Calcium: Dissolve 500 mg of the test specimen in 10 mL of hot water, alkalized by adding ammonia solution, add 1 mL of ammonium oxalate, the turbidity is not produced within 10 seconds.

Phosphoric Acid

H_3PO_4 molecular weight: 98.00

Phosphoric Acid contains more than 85.0 % of H_3PO_4 by weight.

Characteristics: Colorless, odorless, syrupy-liked liquid, miscible with water or ethanol.

Impurities and other requirements:
1. Chlorides: Not more than 0.025 mg (0.0005%) of Cl in 3 mL (5.0g) of phosphoric acid (General rule 7001).
2. Nitrate: Dilute 2 mL of the test specimen with water to 10 mL, add 5 mg of sodium chloride, 0.1 mL of indigo carmine TS solution, and 10 mL of sulfuric acid, the blue color does not totally disappear within 5 minutes (about 0.001 % of NO_3).
3. Sulfate: Dilute 12 mL (20.0 g) of the test specimen with 190 mL of water. Boil, add 10 mL of barium chloride, stand overnight, if the precipitate is produced, filter and wash the residue, and ignite the residue to constant mass. The quantity of the residue should not exceed 1.5 mg of the control solution.
4. Reducing substance: Dilute 10 mL of the test specimen with 5 mL of water, add 0.2 mL of 0.1 N potassium permanganate, heat until boiling, place it in a boiler for 10 minutes, the pink color is produced, and the color does not disappear completely.
5. Volatile acid: Dilute 25 mL of the test specimen with 75 mL of boiled and cooled water, heat and distill, collect 50 mL of distillate, add 3 drops of phenolphthalein and titrate with 1 N sodium hydroxide until the pink color is produced, not more than 0.1 mL of alkali solution is used for neutralization.
6. Alkali metals and other phosphates: Dilute 1.8 mL (3.0 g) of the test specimen with 100 mL of water, add the solution which is added 15.0 g of lead acetate in 25 mL of water, stir constantly, dilute it with water to 200 mL, filter. Take 100 mL of filtrate add hydrogen sulfide until the precipitate of lead is totally produced. Filter, the residue is washed with 20 mL of

water, the filtrate add 2 drops of sulfuric acid, evaporate to dryness, ignite slowly and weigh. The residue should not exceed 3.0 mg of the reference test (0.2 %).

7. Total heavy metal: Dilute 1.5 mL of the test specimen with 10 mL of water, add 3 drops of phenolphthalein as indicator, neutralize with ammonia solution, add 25 mL of 1 N sulfuric acid, dilute with water to 45 mL, add 5 mL of hydrogen sulfide. If the brown color is produced, it is not deeper than the control solution added with 0.025 mg of Pb (10 ppm) (General rule 7001).
8. Iron: Dilute about 20 mL of the test specimen with water to 50 mL. To 10 mL of this solution, dilute it to 40 mL with water, add 4 mL of concentrated ammonia solution and 5 mL of hydrogen sulfide. If the green color is produced, it is not deeper than the control solution added with 2.5 mL of dilute phosphoric acid and 0.025 mg of Fe (50 ppm) (General rule 7001).

Assay: Weigh accurately about 1 g of phosphoric acid in a tared, glass-stopper flask, and dilute it with water to about 100 mL. Add 0.5 mL of thymolphthalein TS, and titrate with 1 N sodium hydroxide. Each mL of 1 N sodium hydroxide is equivalent to 49.00 mg of H_3PO_4.

Phosphorus Pentaoxide

P_2O_5 molecular weight: 141.95

Phosphorus pentaoxide contains not less than 98 % of P_2O_5 by weight.

Characteristics: White amorphous powder, freely deliquescence, soluble in water and turn to phosphoric acid, also soluble in ethanol.

Impurities and other requirements:

1. Insoluble matter: Dissolve 5.0 g of the test specimen in 40 mL of water, if necessary, warm it to promote dissolve. If it has insoluble residue, filter it by filtered crucible (retain the filtrate for later used). Rinse the residue with water, dry it at 105℃ for 2 hours and weigh, the residue does not exceed 1.0 mg (0.02 %).
2. Diphosphorous trioxide: To the filtrate above, dilute with water to 100 mL. To 60 mL of the dilute solution, add 0.2 mL of 0.1 N potassium permanganate, heat until boiling, and place in a boiler for 10 minutes. The pink color does not disappear completely. Retain the filtrate for later used.
3. Ammonium salt: Dilute 10 mL of the dilute solution obtained above with water to 40 mL, add 10 mL of sodium hydroxide (1 in 10) and 2 mL of alkali mercuric potassium iodide. If a color is produced, it should not be darker than the control solution added with 0.5 mg of NH_3 (standard solution made by NH_4Cl).
4. Arsenic: The limit of arsenic in 1 mL of dilute solution (2) is 60 ppm (General rule 2211).
5. Total heavy metal: Dilute 10 mL of the dilute solution (2) with water to 30 mL, boil for 5 minutes, add 1 mL of ammonia TS and dilute it to 50 mL. To 10 mL of the dilute solution, add 0.025 mg of Pb (General rule 7001), dilute it to 40 mL as solution A. Dilute 30 mL of other solution with water to 40 mL as solution B. To A and B solution, each add 10 mL of hydrogen sulfide, the color of solution B should not be darker than the color of the solution A.

Potassium Biphosphate

KH_2PO_4 molecular weight: 136.09

Characteristics: Colorless or white crystal, soluble in water, insoluble in ethanol.

Impurities and other requirements:

1. Insoluble matters and precipitates of calcium and ammonia: Dissolve 10.0 g of the test specimen in 100 mL of water, add 5 mL of ammonium oxalate and 15 mL of ammonia solution, stand overnight. If the precipitate is produced, filter and rinse the residue, ignite it and weigh, the weight of the residue should not exceed 1.0 mg (0.01 %).
2. Loss on drying: Weigh accurately 2 g of test specimen, dry for 24 hours in a sulfuric acid desiccator, the losing weight should not exceed 0.2 %. Retain the dry product for later use.
3. Residue on ignition: To the dry product above, ignite carefully to its constant weight, the losing weight is about 13.15% ~13.35 %.
4. pH value: Make the test specimen into 0.2 M solution, determine it by determination of pH (General rule 1793), the pH value is about 4.2~4.5. To four tube A, B, C, D each add 10 mL of the test solution as described above, add 5 drops of 0.04 % bromophenol blue to A, B, add 5 drops of 0.02 % methyl red to C and D. Add 0.05 mL of 0.1 N hydrochloric acid to A, add 0.05 mL of 0.1 N sodium hydroxide to C. The color of A changes more obvious than the color of B. The color of C changes more obvious than the color of D.
5. Chloride: The content of Cl in 2.0 g of test specimen should not exceed 0.02 mg (0.001 %) (General rule 7001).
6. Nitrogen compounds: Place 2.0 g of the test specimen in a Kieldahl flask, dissolve it in 40 mL of water, cool the flask in ice, add 15 mL of sodium hydroxide (1 in 10) and 500 mg of small pieces of thin aluminum, stopper tightly stand for 1 hour. Slowly distill it, add the distillate to 5 mL of water contained 2 drops of dilute hydrochloric acid. Collect 35 mL of distillate, dilute it with water to 50 mL, add 2 mL of sodium hydroxide (1 in 10) and 2 mL of alkali mercuric potassium iodide. The color should not be darker than the control solution added with 0.02 mg of N (standard solution prepared by NH_4Cl).
7. Sulfate: Dissolve 10.0 g of the test specimen in 100 mL of water, add 1 mL of hydrochloric acid and boil, add 5 mL of barium chloride. Stand for overnight, the precipitate is not produced.
8. Total heavy metal: Dissolve 2.5 g of the test specimen

in 20 mL of water, add 2 drops of phenolphthalein as an indicator, neutralized it with ammonia solution, and then add 20 mL of 1 N sulfuric acid and 5 mL of hydrogen sulfide, dilute to 50 mL with water. If the brown color is produced, it is not deeper than the control solution added with 0.025 mg of Pb (General rule 7001).

9. Iron: Dissolve 2.75 g of the test specimen in 50 mL of water, dilute 10 mL of the solution with water to 40 mL, and add 2 mL of concentrated ammonia solution and 5 mL of hydrogen sulfide. If the color is produced, it should not be darker than the control solution added with 1 mL of the test solution and 0.010 mg of Fe (General rule 7001).
10. Sodium: Dipped the test specimen solution with platinum wire (1 in 10), ignite it in a colorless flame, the yellow color is not produced.

Potassium Chloride

KCl molecular weight: 74.56

Characteristics: Colorless crystals or white granular powder, odorless, freely soluble in water, slightly soluble in ethanol.

Impurities and other requirements:

1. Insoluble matter: Not more than 0.5 mg (0.005%) (General rule 7001) of insoluble matter in 10.0 g of the test specimen. Retain the filtrate for later use.
2. Acidity and alkalinity: Dissolve 5.0 g of the test specimen in 50 mL of freshly boiled and cooled water, and add 3 drops of phenolphthalein TS. No pink color is produced. Then add 0.2 mL of 0.02 N sodium hydroxide, and the solution should turn pink.
3. Chlorate and Nitrate: Dissolve 2.0 g of the test specimen in 10 mL of water, add 0.1 mL of indigo carmine TS and 10 mL of sulfuric acid, the blue color does not disappear within 10 minutes.
4. Nitrogen compounds: To 1.0 g of test specimen, determine it by impurities of anhydrous potassium carbonate (4), the weight of nitrogen compounds should not exceed 0.01 mg (0.001 %) (General rule 7001).
5. Phosphate: The content of PO_4 in 2.0 g of the test specimen should not exceed 0.02 mg (0.001 %) (General rule 7001).
6. Sulfate: The content of SO_4 in 2.0 g of the test specimen should not exceed 0.1 mg (0.005%) (General rule 7001).
7. Barium: Dissolve 4.0 g of the test specimen in 20 mL of water, filter, if necessary, the filtrate is divided into two equal parts. Add 2 mL of dilute sulfuric acid to one part, the other one is added 2 mL of water, stand for 2 hours, the clarity of two liquid is equal.
8. Calcium, magnesium or ammonia precipitates: To the retained filtrate (1), add 5 mL of ammonium oxalate, 2 mL of ammonium phosphate and 25 mL of ammonia solution, stand overnight. Filter, rinse the residue with 2.5 % ammonia solution, then ignite and weigh it, the weight of the residue should not exceed 0.5 mg (0.005 %).
9. Total heavy metal: Limit of total heavy metals is 5 ppm (General rule 7001).
10. Iron: The content of Fe in 3.0 g of the test specimen should not exceed 0.01 mg (3 ppm) (General rule 7001).
11. Sodium: Dipped the solution with platinum wire (1in10), ignite it in a colorless flame, and the yellow color is not produced.

Potassium Ferricyanide

$K_3Fe(CN)_6$ molecular weight: 329.26

Characteristics: Dark red crystals, freely soluble in water.

Impurities and other requirements:

1. Insoluble matter: Dissolve 10.0 g of the test specimen in 50 mL of cold water, the weight of insoluble matter should not exceed 1.0 mg (0.01 %) (General rule 7001).
2. Chloride: Dissolve 2.0 g of the test specimen in 175 mL of water, add a solution which is made with 2.5 g of the crystalline copper sulfate without chloride in 25 mL of water, mix well, and stand for 15 minutes. To 10 mL of the clear solution on upper layer, add 10 mL of water, 2 mL of nitric acid, and 1 mL of silver nitrate. If the turbidity is produced, the concentration should not be higher than 0.01 mg of Cl in control test (General rule 7001).
3. Sulfate: Dissolve 5.0 g of the test specimen in 100 mL of water, shake and filter. Add 5 drops of glacial acetic acid and 5 mL of barium chloride to the filtrate, the turbidity should not produce within 10 minutes.
4. Ferrous compounds: To 400 mL of water, add 10 mL of 25 % sulfuric acid, mix well, and add 0.1 N potassium permanganate until the pink color remain 1 minute. Dissolve 4.0 g of the test specimen in the solution as described above, add 0.10 mL of 0.1 N potassium permanganate, the solution is still pink.

Potassium Ferrocyanide

$K_4Fe(CN)_6 \cdot 3H_2O$ molecular weight: 422.41

Characteristics: Yellow transparent crystal, freely soluble in water, insoluble in ethanol.

Impurities and other requirements:

1. Insoluble matter: Dissolve 10.0 g of the test specimen in cold water and shake, the weight of the insoluble mater should not exceed 1.0 mg (0.01 %) (General rule 7001).
2. Chloride: Determine it by ferricyanide impurities (General rule 7001), the content of Cl should not exceed 0.01 %.
3. Sulfate: Determine it by ferricyanide impurities (General rule 7001), it should meet the requirements.

Potassium Hydroxide

KOH molecular weight: 56.11

Potassium hydroxide contains not less than 85 % of KOH, not more than 3 % of K_2CO_3.

Characteristics: White fused lump, small pellets, flakes, sticks, and other forms. It rapidly absorbs carbon dioxide and moisture in air, and then deliquesced.

Impurities and other requirements:

1. Chlorides: Dissolve 50.0 g of the test specimen in boiled and cooled water, cool and dilute it to 500 mL, the content of Cl should not exceed 0.1 mg (0.01 %). (General rule 7001) Retain the solution for later use.
2. Nitrogen compounds: Place 20 mL of the retained solution above in a distillation flask, dilute it with water which does not have nitrogen to 50 mL, then connect the condenser, the outlet of the condenser is immersed under the surface of 10 mL of water contained 2 drops of dilute hydrichloric acid. To other distillation flask, add 50 mL of water contained no ammonia. 10 mL of the test solution is equal to 0.01 mg of ammonium salt, each add 500 mg of small piece of thin aluminum wire, stand for 1 hour, distill, and filter it. Collect 35 mL of the filtrate separately, each add 2 mL of freshly boiled sodium hydroxide (1 in 10), dilute to 50 mL with water, add 2 mL of alkali mercuric potassium iodide. The color of the test solution is not deeper than the color of the control solution.
3. Phosphate: To 20 mL of retain solution (1) add 5 mL of hydrochloric acid, evaporate to dryness in a boiler, the PO_4 in the residue should not exceed 0.02 mg (0.001 %) (General rule 7001).
4. Sulfate: To 20 mL of retain solution (1), add 5 mL of hydrochloric acid, evaporate to dryness in a boiler, add 1 mL of 1 N hydrochloric acid to the residue, dilute it with water to 25 mL, filter it if necessary, add 2 mL of barium chloride in the filtrate. If the turbidity is produced, the concentration of the test specimen should not be higher than control solution contained 0.10 mg of SO_4 (General rule 7001).
5. Precipitate of ammonia solution: Dissolve 10.0 g of the test specimen in 100 mL of water. Take 12 mL of sulfuric acid add in 12 mL of water carefully, cool, add the sulfuric acid solution in the test solution , evaporat to produce the dense smoke of SO_3. Cool, dissolve the residue in 130 mL of hot water, add 2 drops of methyl red, and then add ammonia solution until the color of the solution is yellow, heat until boiling. If the precipitate is produced, filter, the residue rinse with hot water, ignite it and weigh, the weight of the residue should not exceed 0.02 %.
6. Total heavy metal: To 50 mL of retaining solution from (1), add 10 mL of nitric acid as solution A. To other 10 mL of retaining solution from (1), add 12 mg of Ag (the standard solution made by $AgNO_3$), add 10 mL of nitric acid carefully as solution B. Evaporated two solutions A and B to dryness with a small flame, the residue rinse with 20 mL of water, each add 1 drop of phenolphthalein, and neutralized with 0.1 N sodium hydroxide, each add 1 mL of 1 N acetic acid, and dilute it to 40 mL, then add 10 mL of hydrogen sulfide, the color of A shold not be darker than the color of B.
7. Iron: To 5 mL of retaining solution from (1), add phenolphthalein solution as an indicator, neutralized with hydrochloric acid, add 2 mL more of hydrochloric acid, then dilute it with water to 50 mL as solution A. Take a quantity which same as 0.01mg Fe of standard iron salt solution (General rule 7001), add a quantity which same as for netutralizing of hydrochloric acid, evaporate to dryness in a boiler, add 2 mL of hydrochloric acid in the residue, dilute it with water to 50 mL as solution B. Add 50 mg of ammonium persulfate and 3 mL of ammonium thiocyanate in the solutions A and B, if the red color in A is produced, the color should not be darker than the color of B.

Assay: To 25~30 g of potassium hydroxide, weigh accurately, dissolve in boiled and cooled water to 500 mL, mix well. Dilute 25 mL of the solution with boiled and cooled water to 200 mL, add 5 mL of barium chloride, shake and stand for several minutes, add phenolphthalein as an indicator, titrate with 1 N hydrochloric acid, and then add 2~3 drops of methyl orange, continue titrating to red color. In the endpoint of phenolphthalein, each mL of 1 N hydrochloric acid is equivalent to 56.10 mg of KOH. In the endpoint of methyl orange, each mL of 1 N hydrochloric acid is equivalent to 69.10 mg of K_2CO_3

Potassium Iodide

KI molecular weight: 166.01

Potassium Iodide contains 99.0 %~101.5 % of KI, calculated on the dry basis.

Characteristics:

1. General characteristic: Colorless translucent, white hexagonal crystal or white powder. Odorless; taste salty and bitter. Remain constant in exposure to dry air, deliquescence in the humid air. The solution is neutral or alkaline to litmus paper.
2. Solubility: Freely soluble in water, especially in hot water, soluble in glycerol and ethanol.

Identification: the solution of the test specimen meets the requirements of the tests for potassium and iodide (General rule 2191).

Impurities and other requirements:

1. Loss on drying: Dry the test specimen at 105°C for 4 hours, the lost should not exceed 1 % of its weight. (General rule 1733)
2. Alkalinity: Dissolve 1.0 g of the test specimen in 10 mL of freshly boiled and cooled water, and add 0.1 mL of 0.1 N sulfuric acid and 1 drop of phenolphthalein, the slightly red color is not produced.

3. Iodate: Dissolve 1.1 g of the test specimen in sufficient boiled and cooled water without ammonia and carbon dioxide to 10 mL, and transfer to a colorimetric tube. Add 1 mL of starch TS and 0.25 mL of 1 N sulfuric acid, mix, and compare the color with an equivalent volume control solution contained 100 mg of potassium iodide, 1 mL of standard iodate solution (prepare by diluting 1 mL of potassium iodate solution (1 in 2500) with water to 100 mL), 1 mL of starch TS, and 0.25 mL of 1 N sulfuric acid. Color produced in the test solution should not be darker than the control solution (4 ppm).
4. Limit of nitrate, nitrite, and ammonium: Add 1.0 g of test specimen in a 40-mL test tube, dissolved with 5 mL of water, add 5 mL of sodium hydroxide and about 200 mg of aluminum wire. Insert a pledget in the upper portion of the test tube, and place a piece of moistened red litmus paper on the mouth of the tube. Heat the test tube in a boiler for 15 minutes, no blue color is on the paper.
5. Arsenic: Determine by determination of arsenic, the limit of arsenic is 2 ppm. (General rule 2211)
6. Thiosulfate and barium: Dissolve 500 mg of the test specimen in 10 mL boiled and cooled water without ammonia and carbon dioxide, and add 2 drops of dilute sulfuric acid, no turbidity produce within 1 minute.
7. Total heavy metal: Dissolve 2.0 g of test specimen in 20 mL of water, add 2 mL of dilute acetic acid and dilute with water to 25 mL. Determine it by limit test of total heavy metals method I (General rule 6301), the limit is 10 ppm.

Assay: Take about 500 mg of potassium iodide, weigh accurately, dissolve in about 10 mL of water, and add 35 mL of hydrochloric acid and 5 mL of chloroform. Titrate with 0.05 M potassium iodate until the purple color of iodate vanishes in the chloroform layer, and shake well after adding each drop. Stand for 5 minutes, if the purple color is reproduced, titrate with potassium iodate as described above. Each mL of 0.05 M potassium iodate is equivalent to 16.60 mg of KI.

Potassium Permanganate

$KMnO_4$ molecular weight: 158.04

Potassium Permanganate contains 99.0 %~100.5 % of $KMnO_4$, calculated on the dry basis.

NOTE: Handle carefully, potassium permanganate may cause explosions if it is contacted with organic or other readily oxidizable substances, either in solution or the dry state.

Characteristics:
1. Gerneral Characteristics: Dark purple crystals with a metallic luster. Odorless, slightly sweet, astringent taste. No change as exposed to air.
2. Solubility: Soluble in water ; freely soluble in boiling water.

Identification:
1. As solution, dark purplish-red when concentrated and pink when highly diluted, add sulfuric acid, and then add the reducing reagent, the color is dissapear.
2. A solution of potassium permanganate shows the specific reaction of potassium salt and permanganate (General rule 2191).

Impurities and other requirements: Dry it in silica gel drying container for 18 hours, the lost weight is not more than 0.5%.

Assay: To 125 mg of test specimen, weigh accurately, dissolve in 25 mL of water, add a mixture of 2 mL of sulfuric acid and 5 mL of water, mix, accurately added 50 mL of 0.1 N oxalic acid, heat to 80℃, titrate with 0.1 N potassium permanganate. Each mL of 0.1 N oxalic acid is equivalent to 3.161 mg of $KMnO_4$.

Silver Nitrate

$AgNO_3$ molecular weight: 169.87

Silver Nitrate, powdered, and then dried in the silica gel desiccator in dark for 4 hours, contains 99.8%~100.5% of $AgNO_3$.

Characteristics :
1. Gerneral Characteristics: White or colorless crystal, turn grey or grey black gradully when exposed to light and store with organic substances.
2. Solubility: Freely soluble in water, more freely soluble in boiling water, sparingly soluble in ethanol, freely soluble in boiling ethanol ; slightly soluble in ether.

Identification:
1. Solution of test specimen (1 in 50) has the reaction to the tests for silver salt (General rule 2191).
2. To 5 mL of silver nitrate solution (1 in 10) in a test tube, add 1 drop of diphenylamine, mix, carefully add sulfuric acid along the tube wall to make the solution two layers , a deep blue color appears at the surface between two solutions.

Impurities and other requirements:
1. Clarity, color and pH of solution: Dissolve 2.0 g of test specimen in 20 mL of water, the solution is clear and colorless, with pH value 5.5 (General rule 1793).
2. Copper salt: To 5 mL of silver nitrate solution (1 in 10), slowly drop ammonia solution until the precipitate formed at first is dissolved, and the blue color should not appear in the solution.

Assay: Powder about 1.0 g of silver nitrate, and dry in the silica gel desiccator in dark for 4 hours. Weigh accurately about 700 mg of the dried salt, dissolve in 50 mL of water, add 2 mL of nitric acid and 2 mL of ferric ammonium sulfate, and titrate with 0.1 N ammonium thiocyanate. Each mL of 0.1 N ammonium thiocyanate is equivalent to 16.99 mg of $AgNO_3$.

Sodium Alizarinsulfonate

$C_{14}H_5O_2(OH)_2SO_3Na \cdot H_2O$ molecular weight: 360.28

Characteristics:
This product is yellow-brown or orange-yellow powder, easily soluble in water to form a yellow solution, slightly soluble in ethanol.

Impurities and other requirementss:
Sensitivity: Take three drops of this product (1→100), add to 100mL of water, and then add 0.5mL of 0.1N sodium hydroxide solution, the solution should be red. Then add 0.05 mL of 0.1N hydrochloric acid, the solution should be yellow.

Sodium Bicarbonate

$NaHCO_3$ molecular weight: 84.01

Sodium bicarbonate contains 99.0 %~100.5 % of $NaHCO_3$, calculated on the dry basis.

Characteristics:
1. Gerneral Characteristics: White crystalline powder, odorless, saline taste. Unchanged in dry air, slowly decompose in moist air. Fresly prepared solution without shaking is alkaline to litums paper, the alkalinity will increase after shaking, heating and long standing.
2. Solubility: Soluble in water, insoluble in ethanol.

Identification: Solution of sodium bicarbonate meets the requirements of the tests for sodium and for bicarbonate (General rule 2191).

Impurities and other requirements:
1. Insoluble matter: Dissolve 1.0 g of test specimen in 20 mL of water, it should dissolve completely as a clear solution.
2. Carbonate: Add 1.0 g of test specimen in 20 mL of freshly boiled and cooled water without shaking under 15℃, dissolve. Add 2 mL more of 0.1 N hydrochloric acid and 2 drops of phenolphthalein, the pink color should not appear immediately.
3. Ammonium salt: Place 1.0 g of test specimen in a tube and heat, the odor of ammonia should not be produced.
4. Loss on drying: Dry 4.0 g of accurately weighed test specimen, dry in silica gel desiccator for 4 hours, and the lost weight should not exceed 0.25% (General rule 1733).
5. Arsenic: Dissolve 1.5 g of test specimen in 20 mL of dilute sulfuric acid (1 in 5), add 35 mL of water, determine it by the test of arsenic (General rule 2211), the procedure of adding 20 mL of dilute sulfuric acid (1 in 5) can be omitted. The limit is 2 ppm.
6. Total heavy metal: Mix 4.0 g of test specimen with 5 mL of water and 19 mL of dilute hydrochloric acid, boil for 1 minute. Add 1 drop of phenolphthalein, then drop sufficient ammonium hydroxide till the solution has a faint pink color. Cool, add 2 mL of dilute acetic acid and dilute with water to 25 mL. Determine it by limit tests for total heavy metals I (General rule 6301), the limit is 5 ppm.
7. Chloride: To 0.35 g of test specimen, determine it by limit test for chlorides (General rule 2221). If the turbidity is produced, the concentration should not be higher than control solution which has 1.5 mL of 0.0010 N hydrochloric acid (150 ppm).
8. Sulfate: To 1.0 g of test specimen, determine it by limit test for sulfates (General rule 2221). If the turbidity is produced, the concentration should not be higher than the control solution which has 0.15 mL of 0.02 N sulfuric acid (150 ppm).

Assay: Weigh accurately about 3 g of sodium bicarbonate, add 100 mL of water, add methyl orange as an indicator, titrates with 1 N sulfuric acid. Each mL of 1 N sulfuric acid is equivalent to 84.01 mg of $NaHCO_3$.

Sodium Bisulfite

$NaHSO_3$ molecular weight: 104.07

This specimen is a mixture of sodium bisulfite and sodium pyrosulfite. It produces 58.5%~67.4% of sulfur dioxide.

Characteristics:
1. Gerneral Characteristics: Sodium bisulfite is white or yellow-white crystals, granular powder, with the odor of sulfur dioxide. It is slowly metamorphism in air.
2. Solubility: Freely soluble in water, slightly soluble in ethanol.

Identification: Solution of sodium bisulfite meets with the specify reactions of the tests for sodium and sulfite (General rule 2191).

Impuritiesand other requirements:
1. Arsenic: Place 500 mg of test specimen, in a 150-mL beaker, and add 2 mL of nitric acid, evaporated to dryness in a boiler. Dissolve the residue in 20 mL of dilute sulfuric acid (1 in 5), transfer to arsenic generating bottle, dilute it with water to 55 mL, determine it by determination of arsenic, the limit of arsenic is 3 ppm.
2. Total heavy metal: Dissolve 1.0 g of test specimen in 10 mL of water, add 5 mL of hydrochloric acid, and evaporate on a boiler to dryness. Dissolve the residue in 20 mL of water, add 2 more drops of phenolphthalein and an appropriate amount of 1 N sodium hydroxide until the pink color is produced. Add 2 mL of dilute acetic acid and water to make 25 mL, determine it by determination of total heavy metals (General rule 6301), the limit of total heavy metals is 20 ppm.
3. Iron: To 500 mg of test specimen, add 2 mL of hydrochloric acid, evaporate to dryness in a boiler. Dissolve the residue in 2 mL of hydrochloric acid and 20 mL of water, add several drops of bromine solution, remove bromine by boiling, cool, dilute with water to 25 mL, and add 50 mg of ammonium persulfate and 5 mL of ammonium thiocyanate. If the

red color is produced, the color should not be darker than the color of the control solution of iron standard solution added with 0.025 mg of Fe (50 ppm).(General rule 2191)

4. Lead: Dissolve 1.0 g of test specimen in 10 mL of water, add 5 mL of hydrochloric acid, evaporated to dryness in a boiler, dissolve the residue in 20 mL of water, determine it by determination of lead (General rule 2251), the limit of lead is 10 ppm.

Assay: Place 200 mg of accurately weighed sodium bisulfate in a glass-stopper bottle, accurately add 50.0 mL of 0.1 N iodine solution, stopper, stand for 5 minutes. Add 1 mL of hydrochloric acid, add starch TS as an indicator, titrate the excess iodine with 0.1 N sodium thiosulfate. Each mL of 0.1 N iodine is equivalent to 3.203 mg of SO_2.

Sodium Borohydride

$NaBH_4$ molecular weight: 37.83

Characters: White crystalline lump. Very freely soluble in water, soluble (react) in methanol, it decomposes quickly by boiling.

Assay:

Potassium iodate solution (0.25 N) : Dissolve 8.917 g of accurately weighed potassium iodate which is dried at 110℃ to constant weight in 1000 mL of water.

Procedure: Dissolve accurately weighed 500 mg of sodium borohydride in 125 mL of sodium hydroxide (1 in 5) in a 250-mL volumetric flask, and add water to its volume, mix well. To 10 mL of the solution, transfer it to a 250-mL iodine bottle, add 35.0 mL of potassium iodate solution, and mix well. Add 2.0 g of potassium iodide and add 10 mL of dilute sulfuric acid (1 in 10), stopper, and stand 3 minutes in the dark. Add 3 mL of starch TS, titrate with 0.1 N sodium thiosulfate to end point. Correct it by a blank test. Calculate the content of $NaBH_4$ (mg) as formula below, the content should not lower than 98 %.

$$\{〔(35.0)(0.25)〕-0.1\,V\}\,4.729$$

V: mL of 0.1 N sodium thiosulfate.

Sodium Carbonate

$Na_2CO_3 \cdot H_2O$ molecular weight: 124.01

It contains 99.5% ~ 100.5% of Na_2CO_3, calculated on the dry basis.

Characteristics:

1. Gerneral Characteristics: Colorless crystals or white crystalline powder. Odorless, with no change in the air. It removes crystal water in dried air above 50℃, and becomes anhydrous above 100℃.
2. Solubility: Freely soluble in water, more freely soluble in boiling water.

Identification:

1. The solution (1 in 10) is strong alkaline reaction with phenolphthalein solution.
2. The solution (1 in 10) meets to the tests for sodium and carbonate (General rule 2191).

Impurities and other requirements:

1. Water: Dry about 2.0 g of test specimen at 105℃ for 1 hour, the loss weight is about 12%~15%. (General rule 1921)
2. Arsenic: Dissolve 500 mg of test specimen in 20 mL of dilute sulfuric acid (1 in 5), add 35 mL of water, determine it by determination of arsenic (General rule 2211), the step of adding 20 mL of dilute sulfuric acid (1 in 5) can be omitted, the limit of arsenic is 3 ppm.
3. Total heavy metal: Dissolve 1.0 g of test specimen in 10 mL of water, add 7.5 mL of dilute hydrochloric acid, boil, add 1 drop of phenolphthalein, and drop sodium hydroxide until the solution is faint pink. Cool, add 2 mL of dilute acetic acid and water to 25 mL, then determine it by determination of total heavy metals method Ⅰ (General rule 6301), the limit of total heavy metals is 10 ppm.

Assay: Weigh accurately 2 g of the test specimen, place it in a flask, dissolve in 50 mL of water, add methyl orange as an indicator, titrates with 1 N sulfuric acid. Each mL of 1 N sulfuric acid is equivalent to 52.99 mg of Na_2CO_3.

Sodium Hydroxide

NaOH molecular weight: 40.00

Sodium hydroxide contains not less than 97 %, of NaOH, including not more than 2.5 % of Na_2CO_3.

Characteristics: White fused lumps, small pellets, sticks, or other forms. It easily absorbs carbon dioxide and water in air.

Impurities and other requirements:

1. Test solution: Dissolve 50.0 g ± 0.1 g of test specimen in freshly boiled and cooled water, cool, dilute it to 500 mL.
2. Chloride: The content of Cl in 10 mL of test specimen should not exceed 0.05 mg (0.005 %). (General rule 7001)
3. Nitrogen compounds: Place 20 mL of the test solution in a distillation flask, add 50 mL of water contained no ammonia, determine it by anhydrous sodium sulfate (5) (General rule 7001) the color should not be darker than 10 mL of test solution added with 0.01 mg of N (the solution made by NH_4Cl).
4. Phosphate: To 20 mL of the test solution add 5 mL of hydrochloric acid, and evaporate to dryness in a boiler. The PO_4 in residue should not exceed 0.02 mg (0.001 %). (General rule 7001)
5. Sulfate: To 20 mL of the test solution, add 5 mL of hydrochloric acid, evaporate to dryness in a boiler, dissolve the residue in 1 mL of 1 N hydrochloric acid, add an appropriate amount of water to 25 mL, and filter if necessary. Add 2 mL of barium chloride to the filtrate. If the turbidity is produced, it should not be

darker than the control solution added 0.1 mg of SO_4. (General rule 7001)

6. Ammonia precipitate: Dissolve 10.0 g of test specimen in 100 mL of water, add a mixture of 12 mL of sulfuric acid and 12 mL of water, and evaporate it until the fume of SO_3 is produced. Cool, dissolve the residue in 130 mL of hot water, add 2 drops of methyl red, and drop ammonia solution until the yellow color is produced. Boil, filter the insoluble substance if present, rinse the filtered residue with hot water completely, ignite and weigh, the weight of the residue should not exceed 2 mg (0.02 %).
7. Total heavy metal: To 50 mL of the test solution, add 10 mL of nitric acid carefully, evaporate to dryness on a small flame. Dissolve the residue in 20 mL of water, add 1 drop of phenolphthalein, neutralize with 0.1 N sodium hydroxide, add 1 mL more of 1 N acetic acid, dilute it to 40 mL with water, and add 10 mL of hydrogen sulfide. The color should not be darker than the color of control solution added with 10 mL of the test solution and 0.12 mg of Ag (the standard solution made by $AgNO_3$).
8. Iron: To 5 mL of the test solution, add phenolphthalein solution as an indicator, neutralize with hydrochloric acid, add 2 mL more of hydrochloric acid, and dilute it to 50 mL(S). To other solution which is equivalent to 0.01mg of Fe (General rule 7001), add same volume of hydrochloric acid which is used for neutralizing the test specimen. Evaporate to dryness in a boiler, transfer the residue by 2 mL of hydrochloric acid, and dilute it to 50 mL (C). To each S and C add 50 mg of ammonium persulfate and 3 mL of ammonium thiocyanate. If the color is produced in S, it should not be darker than the color of C.

Assay: Dissolve about 25.0~30.0 g of accurately weighed sodium hydroxide, dissolve it in freshly boiled and cooled water to 1000 mL. To 50 mL of this solution, dilute it with freshly boiled and cooled water to 200 mL, add 5 mL of barium chloride, stopper, and stand for 5 minutes. Add phenolphthalein as an indicator, and titrate with 1 N hydrochloric acid until the pink color disappears, add 2~3 drop of methyl orange as an indicator, and continue the titration until a persistent pink color is produced. Each mL of 1 N hydrochloric acid is equivalent to 40.00 mg of NaOH in the first titration, and each mL of acid consumed is equivalent to 53.00 mg of Na_2CO_3 in the second titration.

Sodium Lauryl Sulfate

Synonyms: Sodium Dodecyl Sulfate

Sodium lauryl sulfate is a mixture of sodium alkyl sulfates consisting mainly of sodium lauryl sulfate $CH_3(CH_2)_{10}CH_2OSO_3Na$. The combined content of sodium chloride and sodium sulfate should not exceed 8 %.

Characteristics:

1. Gerneral Characteristics: White or slightly yellow crystals, it has slightly odor.
2. Solubility: Freely soluble in water, the solution has an opalescent.

Identification:

1. Solution of test specimen (1 in 10) meets with the tests for sodium (General rule 2191).
2. Solution of test specimen (1 in 10) is added with hydrochloric acid to acidity, boil for 20 minutes, meets with the tests for sulfate (General rule 2191).
3. To 200 mg of the residue obtained in total alcohol content, add 4 mL of solution made with 100 mg of bromine in 100 ml of carbon tetrachloride, vortex shaking, add 300 mg of *N*-bromosuccinimide, and heat in a boiler at 80℃ for 5 minutes, a red color is produced.

Impurities and other requirements:

1. Alkalinity: Dissolve 1.0 g of test specimen in 100 mL of water, add phenol red, and titrate with 0.1 N hydrochloric acid, not more than 0.6 mL of acid is used for neutralization.
2. Arsenic: Determine the test specimen by determination of arsenic (General rule 2211), the limit of arsenic is 3 ppm.
3. Total heavy metal: Dissolve 500 mg of test specimen in 24 mL of water, and add 1 mL of dilute acetic acid. Determine it by determination of total heavy metals method I (General rule 6301), the limit of total heavy metals is 20 ppm.
4. Sodium chloride: To 5.0 g of accurately weighed test specimen, dissolve in 50 mL of water, add dilute nitric acid (1 in 20), the solution should be neutral to litmus paper. Add 2 mL of potassium chromate, and titrate with 0.1 N silver nitrate. Each mL of 0.1 N silver nitrate is equivalent to 5.844 mg of sodium chloride.
5. Sodium sulfate: Place accurately weighed 1.0 g of test specimen in a 400-mL beaker, add 10 mL of water, heat and stir until it dissolves completely. Add 100 mL of ethanol in this hot solution, stopper, and heat at a temperature just below the boiling point for 2 hours. Filter through a Gooch crucible while hot, and wash the residue with 100 mL of boiled ethanol. Dissolve the residue by washing with 150 mL of water, and collect the solution in a beaker. Add 10 mL of hydrochloric acid, heat to boil, add 25 mL of barium chloride TS, and stand overnight. Filter the barium sulfate by a tared filter crucible, and wash the residue until there is no chloride ion left, dry the precipitate, ignite and weigh. The quantity of barium chloride multiply 0.6086 is equivalent to the quantity of Na_2SO_4.
6. Unsulfated alcohol: Dissolve about 10.0 g of accurately weighed test specimen in 100 mL of water, and add 100 mL of alcohol. Transfer the solution to a separator, and extract with 50-mL of hexane three times. If an emulsion forms, add sodium chloride to promote separation. Combine the hexane extract, and wash with 50-mL of water three times, and dehydrate with anhydrous sodium sulfate. Filter the hexane

extract into a tared beaker, evaporate on a boiler until the odor of hexane no longer is perceptible, dry the residue at 105℃ for 30 minutes, cool and weigh. The weight of the residue should not exceed 4.0% of the weight of the sodium lauryl sulfate.

7. Total alcohol: Transfer about 5.0 g of accurately weighed of the test specimen to an 800-mL Kjeldahl flask, and add 150 mL of water, 50 mL of hydrochloric acid, and a few zeolites. Attach a reflux condenser to the Kjeldahl flask, heat carefully to avoid excessive frothing, and then boil for about 4 hours. Cool, rinse the condenser with ether, collect the solution in the flask, and transfer the solution to a 500-mL separator, rinsing the Kjeldahl flask twice with ether and adding the ether washings to the separator. Extract the solution with 75-mL of ether two times, combine ether extracts in a tared beaker, evaporate the extracts on a boiler, dry the residue at 105℃ for 30 minutes, cool, and weigh. The residue represents the total quantity of alcohols, and not less than 59.0% of the weight of sodium lauryl sulfate.

Sodium Nitrite

$NaNO_2$ molecular weight: 69.00

Sodium Nitrite contains more than 97.0 % of $NaNO_2$, calculated on the dry basis.

Characteristics:

1. Gerneral Characteristics: White or faint yellow granular powder, or white lumps or rods. Odorless, taste salty. It deliquescences in air. The solution has alkali reaction with litmus papers.
2. Solubility: Dissolve 1.0 g of test specimen in 1.5 mL of water, sparingly soluble in ethanol.

Identification: Solution of the test specimen meets with the tests for sodium and nitrite (General rule2191).

Impurities and other requirements:

1. Loss on drying: Dry the test specimen for 4 hours in a sulfuric acid desiccator, loss not more than 1 % of its weight (General rule 1733).
2. Arsenic: Determine the test specimen by determination of arsenic (General rule 2211), the limit of arsenic is 5 ppm.
3. Total heavy metal: Dissolve 1.0 g of test specimen in 6 mL of dilute hydrochloric acid, and evaporate on a boiler to dryness. Crush the residue to a coarse powder, and continue heating on the boiler until the odor of hydrochloric acid is no longer perceptible. Dissolve the residue in 23 mL of water, and add 2 mL of dilute acetic acid, determine it by determination of total heavy metals method I (General rule 6301), the limit of total heavy metals is 20 ppm.

Assay: Dry the test specimen for 4 hours in a sulfuric acid desiccator, weigh accurately 1 g, place it in a 100-mL volumetric flask, add an appropriate amount of water and make to 100 mL. Accurately take 10 mL of the solution, add into a mixture of 50.0 mL of 0.1 N potassium permanganate, 100 mL of water, and 5 mL of sulfuric acid. When adding the sodium nitrite solution, immerse the tip of the pipette beneath the surface of the permanganate mixture. Heat the liquid to 40℃, stand for 5 minutes, and add 25.0 mL of 0.1 N oxalic acid. Heat the mixture to about 80°C, and titrate with 0.1 N potassium permanganate. Each mL of 0.1 N potassium permanganate is equivalent to 3.450 mg of $NaNO_2$.

Dibasic Sodium Phosphate

$Na_2HPO_4 \cdot 7H_2O$ molecular weight: 268.08

Dibasic sodium phosphate contains 98.0 %~100.5 % of Na_2HPO_4, calculated on the dry basis.

Characteristics:

1. Gerneral Characteristics: Colorless or white granule. Odorless, taste salty. It loses the hydration water in warm, dry air. It has alkali reaction to phenolphthalein solution. The pH value of 0.1 M solution is 9.5.
2. Solubility: Freely soluble ina water, very slightly soluble in ethanol.

Identification: Solution of test specimen (1 in 20) meets with the tests for sodium and phosphate. (General rule 2191)

Impurities and other requirements:

1. Loss on drying: Dried the test specimen for 12 hours at 105℃, the loss weight is 43 %~50 %. (General rule 1733)
2. Insoluble matter: Dissolve 10.0 g of Na_2HPO_4 in 100 mL of hot water, filter through a tared filter crucible, wash the residue with hot water, and dry at 105℃ for 2 hours, the weight of the residue obtained should not exceed 20 mg.
3. Chloride: Determine 1.0 g of Na_2HPO_4 by limit test for chlorides (General rule 2221). If the turbidity is produced, the concentration should not be higher than control solution which has 0.4 mL of 0.02 N hydrochloric acid (280 ppm).
4. Sulfate: Determine 200 mg of Na_2HPO_4 by limit test for sulfates (General rule 2221). If the turbidity is produced, the concentration should not be higher than control solution which has 0.2 mL of 0.02 N sulfuric acid (1000 ppm).
5. Arsenic: Dissolve 1.25 g Na_2HPO_4 in water, determine it by determination of arsenic (General rule 2211), the limit of arsenic is 8 ppm.
6. Total heavy metal: Dissolve 2.0 g of Na_2HPO_4 in 10 mL of water, add 4 mL of dilute acetic acid and water to 25 mL, determine it by determination of total heavy metals method I (General rule 6301), the limit of total heavy metals is 10 ppm.

Assay: To 6.5 g of the test specimen which had heated 105°C for 12 hours, weigh accurately, place it in a 250 mL beaker, add 50.0 mL of 1 N hydrochloric acid and 50 mL

of water, stir until dissolved, titrate with 1 N sodium hydroxide by the potentiometric titration to about pH 4, record the buret reading. Calculate the volume A which the test specimen used to titrate 1 N hydrochloric acid. Continue the titration with 1 N sodium hydroxide to the inflection point at about pH 8.8, record the buret reading, and calculate the volume of 1 N sodium hydroxide required in the titration between the two inflection points (pH 4 to pH 8.8). When A is equal to or less than B, each mL of the volume A of 1 N hydrochloric acid is equivalent to 142.0 mg of Na_2HPO_4. When A is greater than B, each mL of the volume 2B minus A of 1 N sodium hydroxide is equivalent to 142.0 mg of Na_2HPO_4.

Sodium Sulfate, Anhydrous

Na_2SO_4 molecular weight: 142.05

Characteristics: White powder, odorless, it absorbs moisture in air, approach to 12%, soluble in 6 times of water, insoluble in ethanol or other organic solvent.

Impurities and other requirements:

1. Insoluble matter: Not more than 1.0 mg (0.01 %).
2. Residue on ignition: To 2 g of the test specimen, weigh accurately, place in a dish, ignite it in a small flame, the losing weight should not exceed 10 mg (0.5 %).
3. Acidity or alkalinity: Dissolve 5.0 g in 50 mL of freshly boiled and cooled water, add 3 drops of phenolphthalein, the pink color is not produced. Titrate with 0.1 N sodium hydroxide until the pink color is produced, the consumption of the alkali solution should not exceed 0.05 mL.
4. Chloride: Not more than 0.03 mg of Cl in 1 g of the test specimen (0.003 %). (General rule 7001)
5. Nitrogen compound: Determine by the determination of the nitrogen compound in potassium sulfate (General rule 7001). The color of the test specimen should not be darker than the color of the control solution added with 0.01 mg of N (the standard solution made by the NH_4Cl).
6. Arsenic: The limit of arsenic in 1 g of the test specimen is 4 ppm. (General rule 2211)
7. Calcium, magnesium and ammonia precipitate: Dissolve 5.0 g of the test specimen in 75 mL of water, add 5 mL of ammonium oxalate, 2 mL of ammonium phosphate and 10 mL of ammonia solution, stand overnight. If the precipitate is produced, filter, rinse with ammonia solution (2.5 %), ignite it to constant weight, the residue should not exceed 1.5 mg (0.03 %).
8. Total heavy metal: The limit of total heavy metals in the test specimen is 5 ppm. (General rule 7001)
9. Iron: 1.0 g of the test specimen should not contain more than 0.01 mg of Fe (General rule 7001).

Sodium Thiosulfate

$a_2S_2O_35H_2O$ molecular weight: 248.19

Characteristics: Colorless crystal, white crystalline powder or granule. 1.0 g sodium thiosulfate soluble in 0.5 mL water and practically insolusoble in ethanol.

Impurities and other requirements:

1. Insoluble matter: Not more than 1.0 mg of insoluble matter in 20.0 g of $Na_2S_2O_3$ (0.005%) (General rule 7001).
2. Acidity or alkalinity: Take 5.0 g of the test specimen, dissolve in 50 mL of freshly boiled and cooled water, and add 3 drops of phenolphthalein, there is no pink color in the solution. Add 0.05 mL of 0.1 N sodium hydroxide and the solution should be pink.
3. Sulfate and sulfite: Dissolve 1.0 g of the test specimen in 50 mL of water, add an appropriate amount of 0.1 N iodine solution until the slightly yellow is produced, dilute it to 100 mL, and mix well. To 10 mL of the solution add 0.5 mL of 1 N hydrochloric acid and 2 mL of barium chloride. If the turbidity is produced, the concentration should not be higher than the control solution added 0.1 mg of SO_4 (General rule 7001).
4. Sulfide: Dissolve 1.0 g of the test specimen in 10 mL of water, add 0.5 mL of alkaline lead acetate (prepare by adding an appropriate amount of sodium hydroxide (1 in 10) into lead acetate solution (1 in 10) until the precipitate which forms at first is completely dissolved), the dark color should not be produced within 1 minute.

Sulfuric Acid

H_2SO_4 molecular weight: 98.08

Sulfuric Acid contains 95%~ 98% of H_2SO_4 by weight.

Characteristics: Colorless and odorless oily liquid.

Impurities and other requirements:

1. Color: Shake the test specimen in the container. Place 10 mL of the test specimen in a 150 mm × 20 mm tube, compare with the other tube added with water, both liquids are clear and with no suspended matter. Compare the colors of two liquids under transmitted light, it should be no difference, carefully dilute the test solution to 2 N for comparison and it should be clear.
2. Residue on ignition: Place 55 mL of the test specimen in a platinum dish, evaporate to dryness, ignite for 5 minutes, cool and weigh, the weight of the residue should not exceed 0.5 mg (0.0005 %). Retain the residue for later use.
3. Chloride: Dilute 5 mL of test specimen carefully with water to 50 mL, cool, add 1 mL of dilute nitric acid and 1 mL of silver nitrate. If the turbidity is produced, the concentration should not be higher than the control solution added 0.005 mg of Cl (General rule 7001).

4. Nitrate: To 10 mL of test specimen, add to 5 mL of water containing 0.1 mL of indigo carmine TS solution, the blue color is not vanish within 5 minutes.
5. Ammonium salt: Place 1.6 mL (about 3.0 g) of the test specimen in a flask contained 30 mL of cold water, cool in ice, carefully add 20 mL of sodium hydroxide (1 in 10), keep at low temperature, cool in ice again, add 20 mL of sodium hydroxide. Connect the flask to the condenser, and immerse the outlet of the condenser in 10 mL of water contained 2 drops of dilute hydrochloric acid, heat and distill. Collect 35 mL of distillate, add 2 mL of sodium hydroxide (1 in 10), dilute it to 50 mL, add 2 mL of alkali mercuric potassium iodide, the color should not be darker than the control solution added with 0.01 mg of NH_3 (prepared with NH_4Cl).
6. Arsenic: To 55 mL of test specimen, add 3 mL of nitric acid, concentrate to 10 mL, cool. Carefully dilute with 20 mL of water, and concentrate to about 5 mL, cool, carefully dilute the residue with 20 mL of water. The limit of arsenic is 0.04 ppm (General rule 2211).
7. Total heavy metal: To 11 mL (20.0 g) of the test specimen, gradually add in a small quantity of water contained 10 mg of sodium carbonate, heat to dryness by a small flame, add 1 mL of nitric acid, evaporate to dryness in a boiler. Dissolve the residue in 20 mL of water, add phenolphthalein solution as an indicator, and neutralized with 0.1 N sodium hydroxide. Add 1 mL of dilute acetic acid, dilute to 40 mL. To other 0.02 mg of Pb (General rule 7001), add 1 mL of dilute acetic acid, dilute to 40 mL as a control solution. Add 10 mL of hydrogen sulfide in each of the test solution and the control solution, the color of test solution should not be darker than control solution (1 ppm).
8. Iron: To the residue of (2), add 2 mL of hydrochloric acid, cover with a watch glass, heat for 15 to 20 minutes in a boiler, then remove the watch glass and evaporate to dryness. Dissolve the residue in 20 mL of hydrochloric acid, dilute it to 100 mL, the limit of Fe should not exceed 0.02 mg (1 ppm) in 20 mL of the solution. (General rule 7001)
9. Readily oxidizable substance: To 20 mL of test specimen, carefully add in 60 mL of water, cool to 25 ℃, add 0.05 mL of 0.1 N potassium permanganate, the pink color is produced, the color should not vanish within 5 minutes (0.0005 % of SO_2).

Assay: Place about 1 mL of sulfuric acid in an accurately weighed glass-stopper flask. Dilute with 25 mL of water, cool, add methyl red as an indicator, and titrate with 1 N sodium hydroxide. Each mL of 1 N sodium hydroxide is equivalent to 49.04 mg of H_2SO_4.

Tetrahydrofuran

C_4H_8O molecular weight: 72.21

1. General Charateristics: Colorless liquid, with a special stimulative odor, miscible with water and organic solvent. When mix with water, it release small amount of heat and reduce volume slightly, when mix with chloroform a mass quantity of heat is produced. Adding some suitable preservatives reduces the production of peroxides, the quantity of the preservatives should not exceed 0.1%, and label the concentration and name. Store in a small air-tight container, avoid light.
2. Specific gravity: The specific gravity is 0.884 ~ 0.886.
3. Boiling point: The boiling point is 65 ~ 66℃.
4. Acidity: Mix 5.00 mL of test specimen with 10 mL of water, add 1 drop of methyl red, if the pink color is produced, titrate with 0.02 N sodium hydroxide, not more than 0.25 mL of alkali solution is used.

Impurities and other requirements:

1. Water: Determine by the Karl Fischer's method (General rule 1921), water content is not more than 0.1 %.
2. Residue on evaporation: Evaporate 10 mL (12.0 g) of the test specimen to dryness in a boiler, dry at 105 ℃ for 1 hour and weigh. The residue with preservative should not exceed 2 mg, without preservative should not exceed 1 mg.

Toluene

$C_6H_5CH_3$ molecular weight: 92.14

Characteristics: Colorless and flammable liquid, strong refractivity, insoluble in water, miscible with ethanol, chloroform, carbon disulfide, petroleum benzine, the specific gravity is about 0.865.

Impurities and other requirements:

1. Distillation range: To 100 mL of test specimen, distill it by determination of boiling point method Ⅱ (General rule 1003), the distillate should be 95 % or above at 110~111℃.
2. Residue on evaporation: Place 115 mL of the test specimen in a boiler, evaporate to dryness, dry at 120 ℃ for 30 minutes, the weight of the residue should not exceed 1.0 mg (0.001 %).
3. Sulfide: Determine it by test of benzene (General rule 7001), the weight of the residue should not exceed 1.2 mg (0.003 % of S).
4. Readily carbonizable substance: To 15 mL of test specimen, add 50 mL of sulfuric acid, shake for 15 to 20 seconds, stand for 15 minutes, the layer of the test specimen is colorless, the color of sulfuric acid should not be darker than the color of a mixture with colorimetric standard solution and water (1:2). Each 1000 mL of colorimetric standard solution contains 5.0 g of $CoCl_2 \cdot 6H_2O$, 40.0 g of $FeCl_3 \cdot 6H_2O$ and 20 mL of hydrochloric acid.
5. Water: Place a small quantity of test specimen (NOTE: Avoid absorb any moisture in the air) in a dried tube, stopper. Cool in ice, and the turbidity should not be produced after 3 minutes.

Triketohydrindene Hydrate (Ninhydrin)

$C_9H_4O_3 \cdot H_2O$ molecular weight: 178.15

Characteristics: White or brown-white crystals or crystalline powder, the powder is soluble in water or ethanol, slightly soluble in ether and chloroform. Heat it to 100℃, it changes to red.

Impurities and other requirements:
1. Melting point: The melting point is 240~245℃, the crystal structure decomposes immediately, before measuring, the heat-transfer fluid should heat to 220℃ (General rule1005).
2. Residue on ignition: Ignite 100 mg of the test specimen, no residue should be retained.
3. Sensitivity: Dissolve 10 mg of glycine in 25 mL of water, take 1 mL of the solution, add to a mixture solution of sodium acetate 50 mg and water 2 mL, then add 0.2 mL of a mixture of water 1 mL and test specimen 5 mg, boil for 1~2 minutes, violet color is produced, stand for several minutes and the color becomes deeper.

Vanillin

$C_8H_8O_3$ molecular weight: 152.15

Vanillin contains 97.0%~103.0% of $C_8H_8O_3$, calculate on the dry basis.

Characteristics:
1. General Characteristics: White and slightly yellow needle-like crystals or crystalline powder. Odor like vanillin. Deteriorated under light, the solution is acid to litmus papers.
2. Solubility: Slightly soluble in water; freely soluble in ethanol, chloroform, ether, and alkali metal hydroxides; soluble in glycerol and hot water.
3. Melting point: The melting point is 81~83 ℃. (General rule 1005)

Identification:
1. Determined the test specimen and standard solution by determination of spectrophotometry potassium bromide pallet method (General rule 1197)(NOTE: dry at silica gel desiccator for 4 hours before carry out the determination), both solutions should obtain the greatest absorption at the same wavelength by the same method.
2. Prepare vanillin methanol solution (1 in 125,000) as the test solution. Determine both standard and test solution by the determination of ultraviolet spectrophotometry (General rule 1197). For the test and standard solution, they respectively show the highest and the lowest absorption at the same wavelength.

Impurities and other requirements:
1. Loss on drying: Dry the test specimen in silica gel desiccator for 4 hours, the weight loss is not more than 1%.(General rule 1733)
2. Residue on ignition: After igniting, the residue is not more than 0.05%. (General rule 2281)

Assay:
1. Standard Solution: Dissolve an accurately weighed quantity of standard vanillin in methanol, and dilute with methanol to obtain a standard solution with the concentration of about 8 μg per mL.
2. Test solution: Place about 100 mg of accurately weighed vanillin to a 250-mL volumetric flask, add methanol to volume, and mix. Pipette 2.0 mL of this solution into a 100-mL volumetric flask, add methanol to volume, and mix.
3. Assay: Put both test and standard solutions in 1-cm cells. Determine the absorbance with a suitable spectrophotometer at the wavelength near 308 nm where has maximum absorbance, use methanol as the blank, test and get the absorbance. Calaulate the quantity of $C_8H_8O_3$ in mg, in the test specimen, taken by the formula:

$$12.5C\,(A_U/A_S)$$

C: is the concentration, in μg per mL, of vanillin in the standard solution.
A_U: the absorbance of the solution of test solution.
A_S: the absorbance of the solution of standard solution.

Aluminium Trichloride

$AlC1_3$ molecular weight: 133.34

White or slightly yellow crystals or a crystalline powder; odor likes hydrochloric acid, fuming in air; the sample is exothermal greatly or even explosion in contact with water, hygroscopic, corrosive. Soluble in water or ether.

Aluminium Nitrate

$Al(NO_3)_3 \cdot 9H_2O$ molecular weight: 375.13

White crystals, hygroscopic, induce combustion and explosion when heat with organic substances. Freely soluble in water and ethanol; very slightly soluble in acetone; insoluble in ethyl acetate or pyridine.

Ammonium Reineckate

$NH_4Cr(NH_3)_2(SCN)_4 \cdot H_2O$ molecular weight: 354.45

Red or dark red crystals; dissociate in water with formation of hydrogen cyanide which brings blue color. Soluble in hot water and ethanol; slightly soluble in water.

Citric Acid

$C_6H_8O_7 \cdot H_2O$ molecular weight: 210.14

White crystal or granule, easily lose the hydration water, hygroscopic. Freely soluble in water or ethanol.

Cupric Chloride

$CuCl_2 \cdot 2H_2O$ molecular weight: 170.48

Slightly blue-green crystal. Soluble in water, ethanol and methanol; slightly soluble in acetone or ethyl acetate.

3, 5-Dinitrobenzoic Acid

$C_7H_4N_2O_6$ molecular weight: 212.12

White or slightly yellow crystal, volatilize with water vapor. Freely soluble in ethanol and glacial acetic acid, slightly soluble in water, ether, benzene and carbon disulfide.

Ethyl Formate

$HCOOC_2H_5$ molecular weight: 74.08

Low viscosity, flammable liquid; stimulate skin and mucous; anesthetic in high concentration. Miscible with ether and ethanol, soluble in 10 times of water and gradually decomposes into formic acid and ethanol.

Ferric Chloride

$FeCl_3 \cdot 6H_2O$ molecular weight: 270.30

Brown-yellow or orange-yellow crystalline lumps, freely hygroscopic. Freely soluble in water, ethanol, acetone, ether or glycerol.

Methyl Ethyl Ketone

$CH_3COC_2H_5$ molecular weight: 72.11

Colorless liquid, freely soluble in water and ethanol.

Perchloric Acid

$HClO_4$ molecular weight: 100.46

Colorless clear liquid, strong oxidant, very hygroscopic, corrosive and volatile. Miscible with water.

Phenol

C_6H_5OH molecular weight: 94.11

Colorless or slightly red needle crystals or a crystalline lump; special odor; corrode to skin and mucous; gradually darken under light and on air; hygroscopic. Freely soluble in ethanol, choroform, ether, glycerol, fatty oil, and volatile oil, soluble in water.

Thymolphthalein (Indicator)

$C_8H_{30}O_4$ molecular weight: 430.55

This product is a white to slightly yellow crystalline powder, insoluble in water, soluble in ethanol or alkali metal hydroxide solution. The color change range is from pH 9.3~10.5 and from colorless to blue.

Trinitrophenol

$C_6H_3N_3O_7$ molecular weight: 229.11

Slightly yellow crystal; odorless; with a bitter taste. When the dry test specimen encounters strong heat, hit or friction, it will violently explode. Soluble in hot water, ethanol or benzene.

(7003) Test Solutions (TS)

For the preparation of test solutions, use reagents of the quality described under reagents. The symbol "*" in superscript form is used to provide a notice that the test solution also being used as an indicator solution.

Aluminium Trichloride TS

Dissolve 1.0 g of aluminium trichloride in alcohol to make 100 mL.

Ammonia TS (6N Ammonium hydroxide solution)

To 400.0 mL of concentrated ammonium solution add water to make 1000 mL. It contains between 9.5% and 10.5% of NH_3.

Ammonia TS, Stronger
(Concentrated ammonium solution)

Dissolve ammonia prepared by heating a mixture of calcium hydroxide and ammonium chloride or by Haber Process in water. It contains between 27.0% and 30.0% of NH_3.

NOTE: Use care in handling concentrated ammonium solution because of the caustic nature of the solution and the irritating properties of its vapor. Do not taste it, and avoid inhalation of its vapor. Cool the container well before opening, and cover the closure with a cloth or similar material while opening.

Description:

1. General description: Clear, colorless solution with characteristic ammonia odor. Upon exposure to air it loses ammonia rapidly. It is strongly basic.
2. Specific Gravity: 0.90 (General rule 1841).

Identification:

Dense white fumes are produced when holding a glass rod moistened with hydrochloric acid near the surface of the sample solution.

Impurities and other requirements:

Dilute 1 volume of the sample solution with 1.5 volume of water, perform the following tests using this solution as the test solution, and their compliance should meet the requirements.

1. Nonvolatile residue: Evaporate 10.0 mL of the sample solution in a tared platinum or porcelain dish to dryness, and dry the residue at 105℃ for 1 hour. The mass of the residue is not more than 2.0 mg.

2. Heavy metals: Evaporate 5.0 mL of the sample solution to dryness on a water bath, add 1.0 mL of dilute hydrochloric acid to the residue, and evaporate to dryness. Dissolve the residue in 2.0 mL of dilute acetic acid, add water to make 25 mL, and perform the test of method I of determination of total heavy metals in general rule 6301 by using this solution as the test solution. The heavy metals limit is 5.0 ppm.
3. Readily oxidizable substances: To 10.0 mL of the sample solution add a slightly excess of dilute sulfuric acid, and add 0.10 mL of 0.1 N potassium permanganate. The red color of the potassium permanganate does not disappear within 10 minutes.

Assay:
Weigh accurately a glass-stoppered flask containing about 15 mL of water, and transfer about 2 mL of the sample solution into the flask. Insert the stopper, mix, and again weigh to obtain the weight of the specimen. Adding methyl red TS as the indicator, titrate with 1 N sulfuric acid. Each mL of 1 N sulfuric acid is equivalent to 17.03 mg of NH_3.

Ammonium Molybdate TS

Dissolve 6.5 g of finely powdered molybdic acid in a mixture of 14 mL of water and 14.5 mL of concentrated ammonium solution. Cool the solution, and add slowly, with stirring, to a well-cooled mixture of 32 mL of nitric acid and 40 mL of water. Allow to stand for 48 hours, and filter through asbestos.

This solution deteriorates upon standing and is unsuitable for use if, upon the addition of 2 mL of dibasic sodium phosphate TS to 5 mL of the solution, an abundant yellow precipitate does not form at once or after slight warming. Store in the dark. If a precipitate forms during storage, use only the clear supernatant.

p-Anisaldehyde Sulfuric Acid TS
(4-Methoxy Benzaldehyde-Sulfuric acid TS)

To 0.5 mL of 4-methoxy benzaldehyde add 0.1 mL of glacial acetic acid, 0.5 mL of concentrated sulfuric acid and 9 ml of ethanol, and mix well. Prepare this solution fresh.

Antimony Trichloride TS

Dissolve 20.0 g of antimony trichloride in chloroform to make 100 mL, and filter if necessary.

Bromocresol Blue TS

Dissolve 50.0 mg of bromocresol green in 100 mL of alcohol, and filter if necessary. For use in pH measurement, dissolve 50.0 mg of bromocresol green in 1.4 mL of 0.05 N sodium hydroxide, and dilute with recently boiled and thoroughly cooled water to 100 mL.

Chloral Hydrate TS

Dissolve 50.0 g of chloral hydrate in a mixture of 15 mL of water and 10 mL of glycerin.

Cupric Tartrate TS, Alkaline
(Fehling's Solution)

For use, mix equal volumes of Solutions A and B at the time required.

Solutions A: Dissolve 34.66 g of carefully selected, small crystals of cupric sulfate, showing no trace of efflorescence of adhering moisture, in water to make 500 mL. Store in well-stoppered glass containers.
Solutions B: Dissolve 173.0 g of crystallized potassium sodium tartrate and 50.0 g of sodium hydroxide in water to make 500 mL. Store in glass containers with rubber stoppers.

Diazo TS

Dissolve 0.35 g of *p*-nitroaniline in 5 mL of hydrochloric acid, and dilute with water to 500 mL as Solution A. Disslove 5.0 g of sodium nitrite in 70 mL of water as Solutions B. For use, mix equal volumes of Solutions A and B, and store in the cold water at the time required.

p-Dimethylaminobenzaldehyde TS

Dissolve 125.0 mg of *p*-dimethylamino- benzaldehyde in a cooled mixture of 65 mL of sulfuric acid and 35 mL of water, and add 0.05 mL of ferric chloride TS. Use within 7 days

Dinitrophenylhydrazine TS

Dissolve 1.5 g of 2,4-dinitrophenylhydrazine in a cooled mixture of 10 mL of sulfuric acid and 10 mL of water, dilute with aldehyde-free ethanol to 100 mL, and filter if necessary.

2,4-Dinitrophenylhydrazine TS, Alcoholic

Dissolve 1.5 g of 2,4-dinitrophenylhydrazine in a cooled mixture of 10 mL of sulfuric acid and 10 mL of water, dilute with 1 volume of absolute ethanol and 3 volumes of water to 100 mL, and filter if necessary.

Dragendorff's TS
(Dragendorff's Reagent)

Dissolve 0.85 g of bismuth subnitrate in 10 mL of glacial acetic acid and 40 mL of water. Add 20 mL of potassium iodide solution (4 in 10), shake well.

Dragendorff's TS, Modified (Dragendorff's Reagent, Modified)

Solution A: Dissolve 1.7 g of bismuth subnitrate in 20 mL of glacial acetic acid and 80 mL of water, warning if necessary, and allow cool. Add 100 mL of potassium iodide solution (1 in 3), which can be stored in a refrigerator for several months in a dark bottle.
Dilute 10 mL of the stock solution with water to 100 mL, add 10 mL of glacial acetic acid, and dissolve 120 mg of iodine in with vigorous shaking.
Store in a refrigerator, and use within 2 weeks.

Dragendorff's Spray TS, Modified (Dragendorff's Spray Reagent, Modified)

Solution A: Dissolve 1.7 g of bismuth subnitrate and 20 g of tartaric acid in 80 mL of water.

Solution B: Dissolve 16.0 g of potassium iodide in 40 mL of water.

Mix equal portions of solution A and solution B to obtain a stock solution, and mix 5 mL of the stock solution with 50 mL of tartaric acid solution (1 in 5).

Ferric Chloride TS

Dissolve 9.0 g of ferric chloride in water and make to 100 mL.

Ferric Perchlorate TS

With the aid of heat, dissolve 0.8 g of iron powder slowly in 70% perchloric acid, Cool the solution and dilute with absolute ethanol to 100 mL. For use, to 20 mL of the supernatant add 6.0 mL of 70% perchloric acid, and dilute with absolute ethanol to 500 mL.

Ferrous Sulfate TS

Dissolve 8.0 g of clear crystals of ferrous sulfate in 100 mL of recently boiled and thoroughly cooled water. Prepare this solution fresh.

Fuchsin Solution

Add 100.0 mL of the solution (0.1% w/v) to a cooled mixture of 40 mL of sulfuric acid and 60 mL of water, dilute with water to 200 mL, and allow to stand until an orange-yellow color develops in the solution.

Fuchsin-Sulfurous Acid TS

Dissolve 200.0 mg of basic fuchsin in 120 mL of hot water, and allow the solution to cool. Add a solution of 2.0 g of anhydrous sodium sulfite in 20 mL of water, and then add 2 mL of hydrochloric acid. Dilute the solution with water to 200 mL, and allow to stand for at least 1 hour. Prepare this solution fresh.

Glycerin Base TS

To 200.0 g of glycerin add water to bring the total weight to 235 g. Add 140 mL of 1 N sodium hydroxide and 50 mL of water.

Hydroxylamine Hydrochloride TS

Dissolve 3.5 g of hydroxylamine hydrochloride in 95 mL of 60% alcohol, and add 0.5 mL of bromophenol blue solution (1 in 1000 of alcohol) and 0.5 N alcoholic potassium hydroxide until a greenish tint develops in the solution. Then add 60% alcohol to make 100 mL.

Hydroxylamine Hydrochloride-Ethanol TS

Dissolved 34.8 g of hydroxylammonium chloride in water to make 100 mL solution A. Dissolved 10.3 g of sodium acetate trihydrate and 86.5 g of sodium hydroxide in water to make 1000 mL solution B.

Mix 1 volume of Solution A, 1 volume of Solution B and 4 volumes of ethanol.

Iodine TS

Use 0.1 N Iodine (General rule 7013).

Lead Acetate TS

Dissolve 9.5 g of clear, transparent crystals of lead acetate in recently boiled water to make 100 mL. Store in well-stoppered glass containers.

Mercuric Nitrate TS

Dissolve 40.0 g of mercuric oxide (red or yellow) in a mixture of 32 mL of nitric acid and 15 mL of water. Store in glass containers, protected from light.

Millon's Reagent

To 2.0 mL of mercury in a conical flask add 20.0 mL of nitric acid. Shake the flask under a hood to break up the mercury into small globules. After about 10 minutes, add 35 mL of water, and, if a precipitate or crystals appear, add sufficient dilute nitric acid (1 in 5, prepared from nitric acid which the oxides have been removed by blowing air through it until it is colorless) to dissolve the separated solid. Add sodium hydroxide solution (1 in 10) dropwise, with thorough mixing, until the curdy precipitate that forms after the addition of each drop no longer redissolves but is dispersed to form a suspension. Add 5 mL more of the dilute nitric acid, and mix. Prepare this solution fresh.

Molisch TS (α-Naphthol TS)

Dissolve 1.0 g of α-naphthol in 25 mL of methanol. Prepare this solution fresh.

Phosphomolybdic Acid/EtOH TS

Dissolve 1.0 g of phosphomolybdic acid in 10 mL of ethanol.

Potassium and Mercuric Iodide TS

Dissolve 1.358 g of mercuric chloride in 60 mL of water. Dissolve 5.0 g of potassium iodide in 10 mL of water. Mix the two solutions, and dilute with water to 100 mL.

Potassium Ferrocyanide TS

Dissolve 1.0 g of potassium ferrocyanide in 10 mL of water. Prepare this solution fresh.

Potassium Permanganate TS

Use 0.1 N Potassium Permanganate (General rule 7013).

Potassium Hydroxide TS

Dissolve 6.5 g of potassium hydroxide in water to make 100 mL.

Potassium Hydroxide-Ethanol TS

Dissolve 10.0 g of potassium hydroxide in alcohol to make 100 mL. Prepare this solution fresh.

Starch-Potassium Iodide TS

Dissolve 500.0 mg of potassium iodide in 100 mL of freshly prepared starch TS. Use within 24 hours.

Silver Nitrate TS

Use 0.1 N Silver Nitrate (General rule 7013).

Silicotungstic Acid TS

Dissolve 10.0 g of silicotungstic acid in water to make 100 mL.

Simulated Gastric Fluid

Dissolve 2.0 g of sodium chloride and 3.2 g of pepsin in 7.0 mL of hydrochloric acid and the amount of water, added to 1000 mL. The pH of this solution is about 1.2.

Simulated Intestinal Fluid

Dissolve 6.8 g of potassium dihydrogen phosphate in 250 mL of water, add 190 mL of 0.2 N sodium hydroxide solution and 400 mL of water. Add 10.0 g trypsin, mix well, adjust the pH to 7.5 ± 0.1 with 0.2 N sodium hydroxide solution, and dilute to 1000 mL with water.

Sodium Fluoride TS

Dry about 500.0 mg of sodium fluoride at 200 ℃ for 4 hours. Accurately weigh 222 mg of the dried material, and dissolve in water to make 100 mL. Dilute 10.0 mL of this solution with water to 1000 mL. Each mL of this solution corresponds to 0.01 mg of fluorine (F).

Sodium Hydroxide TS

Dissolve 4.3 g of sodium hydroxide in water to make 100 mL.

Sodium Hydroxide Solution (10%)

Dissolve 20.0 g of sodium hydroxide in water to make 200 mL.

Sodium Hypochlorite TS

Passing chlorine into sodium hydroxide TS while cooling with ice. Prepare before use.
Clear, yellowish-green solution with an odor of chlorine. Gradually deteriorates if affected by light. Preserve in light-resistant containers, at a temperature not exceeding 25℃. It contains between 4.0% and 6.0% of NaClO.

Assay:
Weigh accurately, in a tared glass-stoppered flask, about 3 mL of the sample solution, and dilute with 50 mL of water. Add 2.0 g of potassium iodide and 10 mL of 6 N acetic acid, and titrate the liberated iodine with 0.1 N sodium thiosulfate VS, adding 3 mL of starch TS as the indicator. Each mL of 0.1 N sodium thiosulfate is equivalent to 3.723 mg of NaClO.

Sodium Nitrite-Ethanol TS

Dissolve 5.0 g of sodium nitrite in 60% ethanol to make 1000 mL.

Thioacetamide TS

Dissolve 4.0 g of thioacetamide in 100 mL of water.

Thioacetamide-Glycerin Base TS

Mix 0.2 mL of thioacetamide TS and 1 mL of glycerin base TS, and heat in a boiling water bath for 20 seconds. Use the mixture immediately.

Thymolphthalein TS

Dissolve 100.0 mg of thymolphthalein in 100 mL of alcohol, and filter if necessary.

Triketohydrindene Hydrate TS (Ninhydrin TS)

Dissolve 200.0 mg of triketohydrindene hydrate in water to make 10 mL. Prepare this solution fresh.

Trinitrophenol TS (Picric acid TS)

Dissolve the equivalent of 1.0 g of anhydrous trinitrophenol in 100 mL of hot water. Cool the solution, and filter if necessary.

Vanillin-Sulfuric Acid TS

Dissolve 0.5 g vanillin in 100 mL mixture of concentrated sulfuric acid and ethanol (4: 1).

(7005) Indicators

Indicators are reagents used to indicate the completion of a chemical reaction in volumetric analysis or to indicate the hydrogen-ion concentration (pH) of solutions by specific color changing reactions. Indicators are usually prepared as solutions or test papers. All indicators required in this pharmacopeia are listed below except the necessary solutions of indicators listed among the section of test solutions.

Methyl Orange

$C_{14}H_{14}N_3NaO_3S$ MW: 327.33

Orange-yellow powder or crystalline scales. Slightly soluble in cold water; readily soluble in hot water; insoluble in alcohol. Transition interval: from pH 3.1 to 4.4. Color change: from red to yellow.

Methyl Red

$2\text{-}[4\text{-}(CH_3)_2NC_6H_4N{:}N]C_6H_4COOH{\bullet}HCl$ MW: 305.76

Dark-red powder or violet crystals. Sparingly soluble in water; soluble in alcohol. Transition interval: from pH 4.2 to 6.2. Color change: from red to yellow.

Phenolphthalein TS

Dissolve 1.0 g of phenolphthalein in 100 mL of ethanol.

Starch Indicator TS

Triturate 0.5 g of soluble starch with 5 mL of cold water. Add to 100 mL of boiling water, and boil for 2 minutes with continuous stirring. Cool, and use only the clear solution.

(7007) Test Paper

Treat strong, white filter paper with hydrochloric acid, and wash with water until the last washing no longer shows an acid reaction to methyl red. Then treat with ammonia TS, and wash again with water until the last washing is not alkaline to phenolphthalein. After thorough drying, saturate the paper with the proper strength of indicator solutions, and carefully dry in still air, unless otherwise specified, by suspending it in a space free from acid, alkali, and other fumes. Store the papers in well-closed containers, protected from moisture and light.

(7009) Colorimetric Solutions (CS)

These solutions are used in the preparation of the colorimetric standards for certain drugs. Store the solutions in corrosion resistant containers with glass stopper.

Comparison of colors as directed in the tests preferably is made in matched color-comparison tubes or in a suitable colorimeter under conditions that ensure that the colorimetric reference solution and that of the specimen under test are treated alike in all respects. The comparison of colors is best made in layers of equal depth, and viewed transversely against a white background. It is particularly important that the solutions be compared at the same temperature, preferably 25℃.

(7013) Volumetric Solutions (VS)

Normal Solutions: Normal solutions which also known as equivalent solutions are solutions that contain 1 gram of the active substance in each 1000 mL of solution; that is an amount equivalent to 1.0079 g of hydrogen or 7.9997 g of oxygen.

Normal solutions or other special normal solutions are marked as follows: normal, 1 N; double-normal, 2 N; half-normal, 0.5 N; tenth-normal, 0.1 N; fiftieth-normal, 0.02 N; hundredth-normal, 0.01 N; two hundredth-normal, 0.005 N, thousandth-normal, 0.001 N.

Molar Solutions: Molar solutions are solutions that contain 1 gram-molecule of the reagent in 1000 mL. For example, a molar solution of sulfuric acid contains 98.07 g of H_2SO_4 each liter and a molar solution of potassium dichromate contains 294.22 g of $K_2Cr_2O_7$ each liter.

Molar solutions are designated as M, a gram-molecule of the reagent is designated as 1M, one-tenth of a gram-molecule of the reagent is designated as 0.1 M; and other molarities are similarly indicated.

It is more difficult to prepare standard solutions with a desired theoretical normality, and this is not essential. A solution which concentration is approximated to the desired normality is prepared and standardized the concentration, titrate the titer of the solution, and prepare for use.

All volumetric solution, whether made by direct dissolved procedure or by dilution from a stronger solution, must be completely mixed by shaking before standardization. As the strength of a standard solution may change by long

time standing, the factor should be calibrated by determining again frequently.

Dilute solutions that are not stable, for instance, dilute potassium permanganate 0.01 N and dilute sodium thiosulfate 0.01 N, should be prepared by exactly diluting the higher normality of solutions with freshly boiled and cooled water on the same day.
When solutions with several normalities are prepared by only one reagent, the details of the preparation and standardization are usually given for the normality solution which is most frequently required. Stronger or weaker solutions are prepared and standardized in the same general manner as described, the weaker solution can be diluted from the higher solution, and determine the normality again.

Preparation and Standardization of Volumetric Solutions: The following directions give only one method for standardization, but other methods of standardization which has the same degree of accuracy is capable, may be used. All volumetric solutions are be prepared, standardized, and used at the standard temperature of 25 ℃. If a titration is carried out with the volumetric solution at a markedly different temperature, standardize the volumetric solution used as the titrant at the different temperature, or make a suitable temperature correction.

1 N Hydrochloric Acid

HCl: 36.46 36.46 g in 1000 mL

Take 85 mL of hydrochloric acid in a 1000 mL volumetric flask, dilute to 1000 mL with water, mix well, and then determine the titer by any method below:

1. Weigh accurately about 1.5 g of anhydrous sodium carbonate primary standard, previously dried at 270 ℃ for 1 hour, and dissolve it in 100 mL of water, add 2 drops of methyl red as an indicator, titrate slowly, stirring constantly, until the pink color occurs in the solution, boil, cool, continue titrate until the pink color do not disappear by heating. According to the results of titrations, calculate the normality: Each mL of 1 N hydrochloric acid is equivalent to 52.99 mg of anhydrous sodium carbonate. If necessary, adjust the normality to 1 N.
2. Accurately pipet 20 mL of the specimen, place it in 300-mL flask, dilute with 130 mL of water, add 5 drops of nitric acid, then slowly add 40 mL of silver nitrate (1 in 10), stirring constantly, until the precipitates of silver chloride is totally produced (if necessary, add a small quantity of silver nitrate solution). Boil the mixture carefully for 5 minutes, then stand in the dark, until the precipitates are sink in the bottom of the beaker, and the layer of the liquid is totally clear, and then filter by tared filtering crucible, wash the precipitates with water, add nitric acid to acidify water, until wash liquid has no silver salt reaction, dry at 110℃ to constant, according to the weight of silver chloride, calculate the normality of hydrochloric acid, protect silver chloride from light in the test, avoid deteriorated and effect the result.

The equivalent solutions in various normalities and the weight of HCl in each 1000 mL of solution as follows:

Equivalent solution	The weight of HCl in each 1000 mL of solution
1 N	36.46 g
0.5 N	18.23 g
0.2 N	7.292 g
0.1 N	3.646 g
0.05 N	1.823 g
0.02 N	0.7292 g
0.01 N	0.3646 g
0.005 N	0.1823 g
0.001 N	0.03646 g

0.1 N Iodine

I: 126.91 12.69 g in 1000 mL

1. Dissolve 36.0 g of potassium iodide in 100 mL of water, then accurately weighed 12.75 g of sublimation of iodine, rapidly added, add 3 drops of hydrochloric acid and dilute with water to 1000 mL, according the weight of iodine to calculate the normality.
2. Dissolve 36.0 g of potassium iodide in 100 mL of water, then accurately weighed 14.0 g of iodine, rapidly added, add 3 drops of hydrochloric acid and dilute with water to 1000 mL, and calculate the normality by the method below.
   Weigh accurately about 150 mg of arsenic trioxide primary standard, previously grinding and dried to constant weight at 100℃, and dissolve it in 20 mL of 1 N sodium hydroxide by heating gently. Add 40 mL of water, 2 drops of methyl orange, and dilute hydrochloric acid until the color turns from yellow to pink, then add 2.0 g of sodium bicarbonate, dilute with 50 mL of water and 3 mL of starch TS as an indicator, titrate with 1N iodine VS until the solution is blue, according the result of titration and calculate the normality. Each mL of 0.1 N iodine is equivalent to 4.946 mg of arsenic trioxide. Preserve in well closed amber color glass stopper bottle and protected from light, the normality is usually adjusted.

0.1 N Potassium Permanganate

$KMnO_4$: 158.04 3.161g in 1000 mL

Take about 3.3 g of potassium permanganate in a flask, dissolve in 1000 mL of water and boil the solution for

about 15 minutes, stopper, stand at least 2 days, and filter through an asbestos filter which in the bottom of a glass crucible. Standardize the filtrate as follows.

Weigh accurately about 200 mg of sodium oxalate primary standard, previously dried to constant weight at 110℃, dissolve it in 250 mL of water and add 7 mL of sulfuric acid, heat to about 70 ℃, then slowly add the permanganate solution by a burette, with constant stirring, until a pale pink color persists for 15 seconds. The temperature of the solution should not be lower than 60℃ at the end of titration, according to the result of titration calculate the normality. Each mL of 0.1 N potassium permanganate is equivalent to 6.700 mg of sodium oxalate.

Preserve in well closed amber color glass stopper bottle, the normality is usually adjusted

The equivalent solutions in various normalities and the weight of $KMnO_4$ in each 1000 mL of solution as follows:

Equivalent solution	The weight of $KMnO_4$ in each 1000 mL of solution
1 N	31.61 g
0.1 N	3.161 g
0.02 N	0.6321 g
0.01 N	0.3161 g

1 N Sodium Hydroxide

NaOH: 40.00 40.00 g in 1000 mL

Dissolve 45.0 g of sodium hydroxide in 950 mL of water, add freshly prepared saturated barium hydroxide until the precipitate is not produced, mix well, tightly stoppered, stand for overnight. Pour out or filter the upper layer of liquid, determine the normality as follows:

1. Pipet accurately 30 mL of 1 N hydrochloric acid or 1 N sulfuric acid, dilute it with 50 mL of freshly boiled and cooled water, add 2 drops of phenolphthalein as an indicator, titrate with the specimen until the pink color is produced lastingly, according the result of titration to calculate the normality.
2. Weigh accurately about 6 g of potassium hydrogen phthalate primary standard(if the specimen is bid crystals, need to be crushed), previously dried at 105 ℃ for 3 hours, and dissolve it in 75 mL of freshly boiled and cooled water, add 2 drops of phenolphthalein as an indicator, titrate with 1N Sodium Hydroxide until the pink color is produced lastingly, and calculate the normality. Each mL of 1 N sodium hydroxide is equivalent to 204.2 mg of potassium hydrogen phthalate. It freely absorbs carbon dioxide when exposing to air, so the solution places in a glass-stopper bottle, the glass bottle has two-hole rubber stoppers, one hole insert in a tube with mixture of sodium hydroxide and calcium oxide, another hole is inserted with a glass tube to suck out the sodium hydroxide solution. Measured the normalities of the solution frequently.

The equivalent solutions in various normalities and the weight of NaOH in each 1000 mL of solution as follows:

Equivalent solution	The weight of NaOH in each 1000 mL of solution
0.1 N	40.00 g
0.5 N	20.00 g
0.2 N	8.00 g
0.1 N	4.00 g
0.05 N	2.00 g
0.02 N	0.80 g
0.01 N	0.40 g
0.005 N	0.20 g
0.001 N	0.040 g

1 N Sulfuric Acid

H_2SO_4: 98.08 49.04 g in 1000 mL

Take 27 mL of sulfuric acid, add slowly in about 1000 mL of water with stirring, cool to 25℃, determine the normality as follows.

1. Determine the normality of the sulfuric acid by the method of determination the normality of 1N hydrochloric acid with sodium carbonate (general rule 7013).
2. Weigh accurately 20 mL of the sample, put in a 500-mL beaker, and add 25 mL of water and 1 mL of hydrochloric acid, boiling, slowly add hot barium chloride solution with stirring until the precipitate of barium sulfate is produced completely. Heat on a hot plate for 1 hour, filter by a tared filter crucible, wash the residue with hot water, until the washed liquid has no chloride reaction, dried, ignite to constant weight, calculated the normality by the weight of barium sulfate.

The equivalent solutions in various normalities and the weight of H_2SO_4 in each 1000 mL of solution as followst

Equivalent solution	The weight of H_2SO_4 in each 1000 mL of solution
1 N	49.04 g
0.5 N	24.52 g
0.2 N	9.808 g
0.1 N	4.904 g
0.05 N	2.452 g
0.02 N	0.980 g
0.01 N	0.4904 g

VIII Others

(8001) Relative Density of Ethanol

Ethanol		Relative density with air		Ethanol		Relative density with air	
Concentration (v/v) % at 15.56℃	Concentration (w/w) %	$d\frac{25°C}{25°C}$	$d\frac{15.56°C}{15.56°C}$	Concentration (w/w) %	Concentration (v/v) % at 15.56℃	$d\frac{25°C}{25°C}$	$d\frac{15.56°C}{15.56°C}$
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
0	0.00	1.0000	1.0000	0	0.00	1.0000	1.0000
1	0.80	0.9985	0.9985	1	1.26	0.9981	0.9981
2	1.59	0.9970	0.9970	2	2.51	0.9963	0.9963
3	2.39	0.9956	0.9956	3	3.76	0.9945	0.9945
4	3.19	0.9941	0.9942	4	5.00	0.9927	0.9928
5	4.00	0.9927	0.9928	5	6.24	0.9911	0.9912
6	4.80	0.9914	0.9915	6	7.48	0.9894	0.9896
7	5.61	0.9901	0.9902	7	8.71	0.9879	0.9881
8	6.42	0.9888	0.9890	8	9.94	0.9863	0.9867
9	7.23	0.9875	0.9878	9	11.17	0.9848	0.9852
10	8.05	0.9862	0.9866	10	12.39	0.9833	0.9839
11	8.86	0.9850	0.9854	11	13.61	0.9818	0.9825
12	9.68	0.9838	0.9843	12	14.83	0.9804	0.9812
13	10.50	0.9826	0.9832	13	16.05	0.9789	0.9799
14	11.32	0.9814	0.9821	14	17.26	0.9776	0.9787
15	12.14	0.9802	0.9810	15	18.47	0.9762	0.9774
16	12.96	0.9790	0.9800	16	19.68	0.9748	0.9763
17	13.79	0.9778	0.9789	17	20.88	0.9734	0.9751
18	14.61	0.9767	0.9779	18	22.08	0.9720	0.9738
19	15.44	0.9756	0.9769	19	23.28	0.9706	0.9726
20	16.27	0.9744	0.9759	20	24.47	0.9692	0.9714
21	17.10	0.9733	0.9749	21	25.66	0.9677	0.9701
22	17.93	0.9721	0.9739	22	26.85	0.9663	0.9688
23	18.77	0.9710	0.9729	23	28.03	0.9648	0.9675
24	19.60	0.9698	0.9719	24	29.21	0.9633	0.9662
25	20.44	0.9685	0.9708	25	30.39	0.9617	0.9648
26	21.29	0.9673	0.9697	26	31.56	0.9601	0.9635
27	22.13	0.9661	0.9687	27	32.72	0.9585	0.9620

Ethanol		Relative density with air		Ethanol		Relative density with air	
Concentration (v/v) % at 15.56℃	Concentration (w/w) %	$d\frac{25°C}{25°C}$	$d\frac{15.56°C}{15.56°C}$	Concentration (w/w) %	Concentration (v/v) % at 15.56℃	$d\frac{25°C}{25°C}$	$d\frac{15.56°C}{15.56°C}$
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
28	22.97	0.9648	0.9676	28	33.88	0.9568	0.9605
29	23.82	0.9635	0.9664	29	35.03	0.9551	0.9590
30	24.67	0.9622	0.9653	30	36.18	0.9534	0.9574
31	25.52	0.9609	0.9641	31	37.32	0.9516	0.9558
32	26.38	0.9595	0.9629	32	38.46	0.9498	0.9541
33	27.24	0.9581	0.9617	33	39.59	0.9480	0.9524
34	28.10	0.9567	0.9604	34	40.72	0.9461	0.9506
35	28.97	0.9552	0.9590	35	41.83	0.9442	0.9488
36	29.84	0.9537	0.9576	36	42.94	0.9422	0.9470
37	30.72	0.9521	0.9562	37	44.05	0.9402	0.9451
38	31.60	0.9506	0.9548	38	45.15	0.9382	0.9432
39	32.48	0.9489	0.9533	39	46.24	0.9362	0.9412
40	33.36	0.9473	0.9517	40	47.33	0.9341	0.9392
41	34.25	0.9456	0.9501	41	48.41	0.9320	0.9372
42	35.15	0.9439	0.9485	42	49.48	0.9299	0.9352
43	36.05	0.9421	0.9469	43	50.55	0.9278	0.9331
44	36.96	0.9403	0.9452	44	51.61	0.9256	0.9310
45	37.87	0.9385	0.9434	45	52.66	0.9235	0.9289
46	38.78	0.9366	0.9417	46	53.71	0.9213	0.9268
47	39.70	0.9348	0.9399	47	54.75	0.9191	0.9246
48	40.62	0.9328	0.9380	48	55.78	0.9169	0.9225
49	41.55	0.9309	0.9361	49	56.81	0.9147	0.9203
50	42.94	0.9289	0.9342	50	57.83	0.9124	0.9181
51	43.43	0.9269	0.9322	51	58.84	0.9102	0.9159
52	44.37	0.9248	0.9302	52	59.85	0.9079	0.9137
53	45.33	0.9228	0.9282	53	60.85	0.9056	0.9114
54	46.28	0.9207	0.9262	54	61.85	0.9033	0.9092
55	47.25	0.9185	0.9241	55	62.84	0.9010	0.9069
56	48.21	0.9164	0.9220	56	63.82	0.8987	0.9046
57	49.19	0.9142	0.9199	57	64.80	0.8964	0.9024
58	50.17	0.9120	0.9177	58	65.77	0.8941	0.9001

Ethanol		Relative density with air		Ethanol		Relative density with air	
Concentration (v/v) % at 15.56℃	Concentration (w/w) %	$d\frac{25°C}{25°C}$	$d\frac{15.56°C}{15.56°C}$	Concentration (w/w) %	Concentration (v/v) % at 15.56℃	$d\frac{25°C}{25°C}$	$d\frac{15.56°C}{15.56°C}$
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
59	51.15	0.9098	0.9155	59	66.73	0.8918	0.8978
60	52.15	0.9076	0.9133	60	67.79	0.8895	0.8955
61	53.15	0.9053	0.9111	61	68.64	0.8871	0.8932
62	54.15	0.9030	0.9088	62	69.59	0.8848	0.8909
63	55.17	0.9006	0.9065	63	70.52	0.8824	0.8886
64	56.18	0.8983	0.9042	64	71.46	0.8801	0.8862
65	57.21	0.8959	0.9019	65	72.38	0.8777	0.8839
66	58.24	0.8936	0.8995	66	73.30	0.8753	0.8815
67	59.28	0.8911	0.8972	67	74.21	0.8729	0.8792
68	60.33	0.8887	0.8948	68	75.12	0.8706	0.8768
69	61.38	0.8862	0.8923	69	76.02	0.8682	0.8745
70	62.44	0.8837	0.8899	70	76.91	0.8658	0.8721
71	63.51	0.8812	0.8874	71	77.79	0.8634	0.8697
72	64.59	0.8787	0.8848	72	78.67	0.8609	0.8673
73	65.67	0.8761	0.8823	73	79.54	0.8585	0.8649
74	66.77	0.8735	0.8797	74	80.41	0.8561	0.8625
75	67.87	0.8709	0.8771	75	81.27	0.8537	0.8601
76	68.98	0.8682	0.8745	76	82.12	0.8512	0.8576
77	70.10	0.8655	0.8718	77	82.97	0.8488	0.8552
78	71.23	0.8628	0.8691	78	83.81	0.8463	0.8528
79	72.38	0.8600	0.8664	79	84.64	0.8439	0.8503
80	73.53	0.8572	0.8636	80	85.46	0.8414	0.8479
81	74.69	0.8544	0.8608	81	86.28	0.8389	0.8454
82	75.86	0.8516	0.8580	82	87.08	0.8364	0.8429
83	77.04	0.8487	0.8551	83	87.89	0.8339	0.8404
84	78.23	0.8458	0.8522	84	88.68	0.8314	0.8379
85	79.44	0.8428	0.8493	85	89.46	0.8288	0.8354
86	80.66	0.8397	0.8462	86	90.24	0.8263	0.8328
87	81.90	0.8367	0.8432	87	91.01	0.8237	0.8303
88	83.14	0.8335	0.8401	88	91.77	0.8211	0.8276
89	84.41	0.8303	0.8369	89	92.52	0.8184	0.8250

Ethanol		Relative density with air		Ethanol		Relative density with air	
Concentration (v/v) % at 15.56℃	Concentration (w/w) %	$d\frac{25°C}{25°C}$	$d\frac{15.56°C}{15.56°C}$	Concentration (w/w) %	Concentration (v/v) % at 15.56℃	$d\frac{25°C}{25°C}$	$d\frac{15.56°C}{15.56°C}$
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
90	85.69	0.8271	0.8336	90	93.25	0.8158	0.8224
91	86.99	0.8237	0.8303	91	93.98	0.8131	0.8197
92	88.31	0.8202	0.8268	92	94.70	0.8104	0.8170
93	89.65	0.8167	0.8233	93	95.41	0.8076	0.8142
94	91.03	0.8130	0.8196	94	96.10	0.8048	0.8114
95	92.42	0.8092	0.8158	95	96.79	0.8020	0.8086
96	93.85	0.8053	0.8118	96	97.64	0.7992	0.8057
97	95.32	0.8011	0.8077	97	98.12	0.7962	0.8028
98	96.82	0.7968	0.8033	98	98.76	0.7932	0.7998
99	98.83	0.7921	0.7986	99	99.39	0.7902	0.7967
100	100.00	0.7871	0.7936	100	100.00	0.7871	0.7936

(8999) Code Number of Chromatographic Column Packings

Table 1. Table of stationary phase of liquid chromatographic columns with code number

Code	Packings
L1	Octadecyl silane chemically bonded to porous or nonporous silica or ceramic microparticles, 1.5 to 10 μm in diameter, or a monolithic silica rod.
L3	Porous silica particles, 1.5 to 10 μm in diameter, or a monolithic silica rod.
L7	Octyl silane chemically bonded to totally porous or superficially porous silica particles, 1.5–10 μm in diameter, or a monolithic silica rod.
L9	Irregular or spherical, totally porous silica gel having a chemically bonded, strongly acidic cation-exchange coating, 3 to 10 μm in diameter.
L11	Phenyl groups chemically bonded to porous silica particles, 1.5–10 μm in diameter, or a monolithic silica rod.
L18	Amino and cyano groups chemically bonded to porous silica particles, 3 to 10 μm in diameter.
L20	Dihydroxypropane groups chemically bonded to porous silica or hybrid particles, 1.5–10 μm in diameter, or a monolithic silica rod.
L42	Octyl silane and octadecyl silane groups chemically bonded to porous silica particles, 5 μm in diameter.

Table 2. Table of stationary phase of gas chromatographic columns with code number

Code	Packings
G1	Dimethylpolysiloxane oil.
G2	Dimethylpolysiloxane gum.
G16	Polyethylene glycol compound (av. mol. wt. about 15,000). A high molecular weight compound of polyethylene glycol with a diepoxide linker. [NOTE—Available commercially as Polyethylene Glycol Compound 20M, or as Carbowax 20M, from suppliers of chromatographic reagents.]
G27	5% Phenyl-95% methylpolysiloxane.
G43	6% Cyanopropylphenyl-94% dimethylpolysiloxane

IX. A List of Poisonous Chinese Materia Medica

Item	Official Name
Shengcianjinzih 生千金子	Euphorbiae Semen (Raw)
Shengchuanwu 生川烏	Aconiti Radix (Raw)
Shengtiansianzih 生天仙子	Hyoscyami Semen (Raw)
Shengbadou 生巴豆	Crotonis Semen (Raw)
Shengbansia 生半夏	Pinelliae Rhizoma (Raw)
Shenggansuei 生甘遂	Kansui Radix (Raw)
Shengbaifuzih 生白附子	Typhonii Rhizoma (Raw)
Shengfuzih 生附子	Aconiti Lateralis Radix (Raw)
Shengnansing 生南星	Arisaematis Rhizoma (Raw)
Shenglangdu 生狼毒	Euphorbiae Ebracteolatae Radix (Raw)
Shengcaowu 生草烏	Aconiti Kusnezoffii Radix (Raw)
Shengmacianzih 生馬錢子	Strychni Semen (Raw)
Shengtenghuang 生藤黃	Garciniae Resina (Raw)
Baijiangdan 白降丹	Hydrargyrum Chloratum Compositum
Yuanhua 芫花	Daphnis Genkwae Flos
Yangjinhua 洋金花	Daturae Flos
Pishih 砒石	Arsenolite
Pishuang 砒霜	Arsenicum
Hongshengdan 紅升丹	Hydrargyri Oxydum Rubrum
Banmao 斑蝥	Mylabris
Syonghuang 雄黃	Realgar
Ciandan 鉛丹(外用)	Plumbum Rubrum (external use)
Chansu 蟾酥	Bufonis Venenum

Note: Plumbum Rubrum (forbid to be taken orally).

X. 200 Standard TCM Formulas

No.	Formula Name
1	Liou-Wei-Di-Huang-Wan (Liu-Wei-Di-Huang-Wan)《Wan》
	六味地黃丸《丸》
2	Ba-Wei-Di-Huang-Wan (Ba-Wei-Di-Huang-Wan) 《Wan》
	八味地黃丸《丸》
3	Jhih-Bo-Di-Huang-Wan (Zhi-Bo-Di-Huang-Wan)《Wan》
	知柏地黃丸《丸》
4	Ci-Jyu-Di-Huang-Wan (Qi-Ju-Di-Huang-Wan)《Wan》
	杞菊地黃丸《丸》
5	Shen-Líng-Bai-Jhu-San (Shen-Ling-Bai-Zhu-San)《San》
	參苓白朮散《散》
6	Sih-Jyun-Zih-Tang (Si-Jun-Zi-Tang)
	四君子湯
7	Sih-Wu-Tang (Si-Wu-Tang)
	四物湯
8	Bu-Jhong-Yi-Ci-Tang (Bu-Zhong-Yi-Qi-Tang) (Wan)《Wan》
	補中益氣湯（丸）《丸》
9	Liou-Jyun-Zih-Tang (Liu-Jun-Zi-Tang)(Wan)《Wan》
	六君子湯（丸）《丸》
10	Guei-Pi-Tang (Gui-Pi-Tang)
	歸脾湯
11	Yang-Sin-Tang (Yang-Xin-Tang)
	養心湯
12	Ren-Shen-Yang-Rong- Tang (Ren-Shen-Yang- Rong-Tang) (Wan)《Wan》
	人參養榮湯（丸）《丸》
13	Bai-He-Gu-Jin-Tang (Bai-He-Gu-Jin-Tang) (Wan)《Wan》
	百合固金湯（丸）《丸》
14	Zih-Wan-Tang (Zi-Wan-Tang)
	紫菀湯
15	Cin-Ciou-Bie-Jia-San (Qin-Qiu-Bie-Jia-San)
	秦艽鱉甲散
16	Yi-Ci-Cong-Ming-Tang (Yi-Qi-Cong-Ming-Tang)
	益氣聰明湯
17	Ba-Jhen-Tang (Ba-Zhen-Tang) (Wan)《Wan》
	八珍湯（丸）《丸》
18	Ji-Sheng-Shen-Ci-Wan (Ji-Sheng-Shen-Qi-Wan) (Wan)《Wan》
	濟生腎氣丸《丸》
19	Shih-Cyuan-Da-Bu-Tang (Shi-Quan-Da-Bu-Tang) (Wan)《Wan》
	十全大補湯（丸）《丸》
20	Huan-Shao-Dan (Huan-Shao-Dan)《Wan》
	還少丹《丸》
21	Huang-Ci-Wu-Wu-Tang (Huang-Qi-Wu-Wu-Tang)
	黃耆五物湯
22	Ma-Huang-Tang (Ma-Huang-Tang)
	麻黃湯
23	Guei-Jhih-Tang (Gui-Zhi-Tang)
	桂枝湯
24	Siao-Cing-Long-Tang (Xiao-Qing-Long-Tang)

No.	Formula Name
	小青龍湯
25	Ge-Gen-Tang (Ge-Gen-Tang)
	葛根湯
26	Chai-Ge-Jie-Ji-Tang (Chai-Ge-Jie-Ji-Tang)
	柴葛解肌湯
27	Jiou-Wei-Ciang-Huo-Tang (Jiu-Wei-Qiang-Huo-Tang) 《Wan》
	九味羌活湯《丸》
28	Ren-Shen-Bai-Du-San (Ren-Shen-Bai-Du-San)
	人參敗毒散
29	Chuan-Cyong-Cha-Tiao- San (Chuan-Qiong-Cha-Tiao-San) 《San》
	川芎茶調散《散》
30	Jing-Fang-Bai-Du-San (Jing-Fang-Bai-Du-San)
	荊防敗毒散
31	Ma-Sing-Gan-Shih-Tang (Ma-Xing-Gan-Shi-Tang)
	麻杏甘石湯
32	Ma-Sing-Yi-Gan-Tang (Ma-Xing-Yi-Gan-Tang)
	麻杏薏甘湯
33	Ma-Huang-Fu-Zih-Si-Sin-Tang (Ma-Huang-Fu-Zi- Xi-Xin-Tang)
	麻黃附子細辛湯
34	Da-Cheng-Ci-Tang (Da-Cheng-Qi-Tang)
	大承氣湯
35	Siao-Sian-Syong-Tang (Xiao-Xian-Xiong-Tang)
	小陷胸湯
36	Wu-Ji-San (Wu-Ji-San)
	五積散

No.	Formula Name
37	Shen-Su-Yin (Shen-Su-Yin)
	參蘇飲
38	Siang-Su-San (Xiang-Su-San)
	香蘇散
39	Siao-Yao-San (Xiao-Yao-San)
	逍遙散
40	Jia-Wei-Siao-Yao-San (Jia-Wei-Xiao-Yao-San)
	加味逍遙散
41	Huo-Siang-Jheng-Ci-San (Huo-Xiang-Zheng-Qi-San) (Wan)《Wan》
	藿香正氣散（丸）《丸》
42	Wu-Yao-Shun-Ci-San (Wu-Yao-Shun-Qi-San)
	烏藥順氣散
43	Su-Zih-Jiang-Ci-Tang (Su-Zi-Jiang-Qi-Tang)
	蘇子降氣湯
44	Ding-Chuan-Tang (Ding-Chuan-Tang)
	定喘湯
45	Yue-Jyu-Wan (Yue-Ju-Wan)《Wan》
	越鞠丸《丸》
46	Huai-Hua-San (Huai-Hua-San)
	槐花散
47	Shu-Jing-Huo-Sie-Tang (Shu-Jing-Huo-Xie-Tang)
	疏經活血湯
48	Di-Dang-Tang (Di-Dang-Tang)
	抵當湯
49	Sie-Fu-Jhu-Yu-Tang

No.	Formula Name
	(Xie-Fu-Zhu-Yu-Tang)
	血府逐瘀湯
50	Bu-Yang-Huan-Wu-Tang (Bu-Yang-Huan-Wu-Tang)
	補陽還五湯
51	Jheng-Gu-Zih-Jin-Dan (Zheng-Gu-Zi-Jin-Dan)《Dan》
	正骨紫金丹《丹》
52	Tao-Hong-Sih-Wu-Tang (Tao-Hong-Si-Wu-Tang)
	桃紅四物湯
53	Siao-Fong-San (Xiao-Feng-San)
	消風散
54	Shang-Jhong-Sia-Tong-Yong-Tong-Fong-Wan (Shang-Zhong-Xia-Tong-Yong-Tong-Feng-Wan)《Wan》
	上中下通用痛風丸《丸》
55	Jyuan-Bi-Tang (Juan-Bi-Tang)
	蠲痹湯
56	San-Bi-Tang (San-Bi-Tang)
	三痺湯
57	Du-Huo-Ji-Sheng-Tang (Du-Huo-Ji-Sheng-Tang)
	獨活寄生湯
58	Gou-Teng-San (Gou-Teng-San)
	鉤藤散
59	Siao-Syu-Ming-Tang (Xiao-Xu-Ming-Tang)
	小續命湯
60	Wu-Jhu-Yu-Tang (Wu-Zhu-Yu-Tang)
	吳茱萸湯
61	Fu-Zih-Li-Jhong-Tang (Fu-Zi-Li-Zhong-Tang)(Wan)《Wan》
	附子理中湯（丸）《丸》
62	Cing-Shu-Yi-Ci-Tang (Qing-Shu-Yi-Qi-Tang)
	清暑益氣湯
63	Jhu-Ye-Shih-Gao-Tang (Zhu-Ye-Shi-Gao-Tang)
	竹葉石膏湯
64	Siang-Ru-Yin (Xiang-Ru-Yin)
	香薷飲
65	Wu-Pi-Yin (Wu-Pi-Yin)
	五皮飲
66	Ba-Jheng-San (Ba-Zheng-San)
	八正散
67	Bi-Sie-Fen-Cing-Yin (Bi-Xie-Fen-Qing-Yin)
	萆薢分清飲
68	Yin-Chen-Wu-Ling-San (Yin-Chen-Wu-Ling-San)《San》
	茵陳五苓散《散》
69	Wu-Lin-San (Wu-Lin-San)
	五淋散
70	Dao-Shuei-Fu-Ling-Tang (Dao-Shui-Fu-Ling-Tang)
	導水茯苓湯
71	Mu-Fang-Ji-Tang (Mu-Fang-Ji-Tang)
	木防己湯
72	Ji-Ming-San (Ji-Ming-San)
	雞鳴散
73	Jhih-Gan-Cao-Tang (Zhi-Gan-Cao-Tang)
	炙甘草湯
74	Cing-Zao-Jiou-Fei-Tang

No.	Formula Name
	(Qing-Zao-Jiu-Fei-Tang)
	清燥救肺湯
75	Gan-Lu-Yin (Gan-Lu-Yin)
	甘露飲
76	Huang-Lian-Jie-Du-Tang (Huang-Lian-Jie-Du-Tang)
	黃連解毒湯
77	Bai-Hu-Tang (Bai-Hu-Tang)
	白虎湯
78	Liang-Ge-San (Liang-Ge-San0
	涼膈散
79	Long-Dan-Sie-Gan-Tang (Long-Dan-Xie-Gan-Tang) (Wan)《Wan》
	龍膽瀉肝湯（丸）《丸》
80	Cing-Wei-San (Qing-Wei-San)
	清胃散
81	Gan-Lu-Siao-Du-Dan (Gan-Lu-Xiao-Du-Dan) 《Dan》
	甘露消毒丹《丹》
82	Cing-Sin-Lian-Zih-Yin (Qing-Xin-Lian-Zi-Yin)
	清心蓮子飲
83	Dao-Chih-San (Dao-Chi-San)
	導赤散
84	Yu-Nyu-Jian (Yu-Nu-Jian)
	玉女煎
85	Jing-Jie-Lian-Ciao-Tang (Jing-Jie-Lian-Qiao-Tang)
	荊芥連翹湯
86	Zih-Yin-Jiang-Huo-Tang (Zi-Yin-Jiang-Huo-Tang)
	滋陰降火湯

No.	Formula Name
87	Dang-Guei-Long-Huei-Wan-Cyu-She-Siang (Dang-Gui-Long-Hui-Wan-Qu-She-Xian) 《Wan》
	當歸龍薈丸去麝香《丸》
88	Sin-Yi-Cing-Fei-Tang (Xin-Yi-Qing-Fei-Tang)
	辛夷清肺湯
89	Hua-Gai-San (Hua-Gai-San)
	華蓋散
90	Cing-Fei-Tang (Qing-Fei-Tang)
	清肺湯
91	Jhih-Sou-San (Zhi-Sou-San) 《San》
	止嗽散《散》
92	Jin-Fei-Cao-San (Jin-Fei-Cao-San)
	金沸草散
93	Siang-Sha-Liou-Jyun-Zih- Tang (Xiang-Sha-Liu-Jun-Zi-Tang)
	香砂六君子湯
94	Jhih-Jhuo-Gu-Ben-Wan (Zhi-Zhuo-Gu-Ben-Wan) 《Wan》
	治濁固本丸《丸》
95	Dang-Guei-Liou-Huang- Tang (Dang-Gui-Liu-Huang-Tang)
	當歸六黃湯
96	San-Jhong-Kuei-Jian-Tang (San-Zhong-Kui-Jian-Tang)
	散腫潰堅湯
97	Pai-Nong-San (Pai-Nong-San)《San》
	排膿散《散》
98	Ru-Yi-Jin-Huang-San (Ru-Yi-Jin-Huang-San)
	如意金黃散(Only for traditional formula.)
99	Wan-Dai-Tang (Wan-Dai-Tang)

No.	Formula Name
	完帶湯
100	Tiao-Jing-Wan (Tiao-Jing-Wan) 《Wan》
	調經丸《丸》
101	Sheng-Yu-Tang (Sheng-Yu-Tang)
	聖愈湯
102	Shih-Shen-Tang (Shi-Shen-Tang)
	十神湯
103	Sheng-Ma-Ge-Gen-Tang (Sheng-Ma-Ge-Gen-Tang) 《San》
	升麻葛根湯《散》
104	Sin-Yi-San (Xin-Yi-San) 《San》
	辛夷散《散》
105	Siao-Cheng-Ci-Tang (Xiao-Cheng-Qi-Tang)
	小承氣湯
106	Tiao-Wei-Cheng-Ci-Tang (Tiao-Wei-Cheng-Qi-Tang)
	調胃承氣湯
107	Tao-Ren-Cheng-Ci-Tang (Tao-Ren-Cheng-Qi-Tang) Tao-He-Cheng-Ci-Tang (Tao-He-Cheng-Qi-Tang)
	桃仁承氣湯 (桃核承氣湯)
108	Da-Chai-Hu-Tang (Da-Chai-Hu-Tang)
	大柴胡湯
109	Fang-Fong-Tong-Sheng-San (Fang-Feng-Tong-Sheng-San)《San》
	防風通聖散《散》
110	Ge-Gen-Huang-Cin-Huang-Lian-Tang (Ge-Gen-Huang-Qin-Huang-Lian-Tang)
	葛根黃芩黃連湯
111	Sang-Jyu-Yin (Sang-Ju-Yin)
	桑菊飲

No.	Formula Name
112	Sing-Su-San (Xing-Su-San)
	杏蘇散
113	Yin-Ciao-San (Yin-Qiao-San)
	銀翹散
114	Chai-Hu-Guei-Jhih-Tang (Chai-Hu-Gui-Zhi-Tang)
	柴胡桂枝湯
115	Siao-Chai-Hu-Tang (Xiao-Chai-Hu-Tang)
	小柴胡湯
116	Shao-Yao-Gan-Cao-Tang (Shao-Yao-Gan-Cao-Tang)
	芍藥甘草湯
117	Chai-Sian-Tang (Chai-Xian-Tang)
	柴陷湯
118	Huang-Lian-Tang (Huang-Lian-Tang)
	黃連湯
119	Sih-Ni-San (Si-Ni-San)《San》
	四逆散《散》
120	Syuan-Fu-Dai-Jhe-Shih-Tang (Xuan-Fu-Dai-Zhe-Shi-Tang)
	旋覆代赭石湯
121	Ban-Sia-Hou-Pu-Tang (Ban-Xia-Hou-Pu-Tang)
	半夏厚朴湯
122	Jyu-Pi-Jhu-Ru-Tang (Ju-Pi-Zhu-Ru-Tang)
	橘皮竹茹湯
123	Jyu-He-Wan (Ju-He-Wan) 《Wan》
	橘核丸《丸》
124	

No.	Formula Name
	Fu-Yuan-Huo-Sie-Tang-Cyu-Chuan-Shan-Jia (Fu-Yuan-Huo-Xie-Tang-Qu-Chuan-Shan-Jia)
	復元活血湯去穿山甲
125	Da-Huang-Mu-Dan-Pi-Tang (Da-Huang-Mu-Dan-Pi-Tang)
	大黃牡丹皮湯
126	Shao-Yao-Tang (Shao-Yao-Tang)
	芍藥湯
127	Guei-Jhih-Fu-Ling-Wan (Gui-Zhi-Fu-Ling-Wan)《Wan》
	桂枝茯苓丸《丸》
128	Dang-Guei-Nian-Tong-Tang (Dang-Gui-Nian-Tong-Tang)
	當歸拈痛湯
129	Sih-Ni-Tang (Si-Ni-Tang)
	四逆湯
130	Dang-Guei-Sih-Ni-Tang (Dang-Gui-Si-Ni-Tang)
	當歸四逆湯
131	Jhen-Wu-Tang (Zhen-Wu-Tang)
	真武湯
132	Siao-Jian-Jhong-Tang (Xiao-Jian-Zhong-Tang)
	小建中湯
133	Da-Jian-Jhong-Tang (Da-Jian-Zhong-Tang)
	大建中湯
134	Huang-Ci-Jian-Jhong-Tang (Huang-Qi-Jian-Zhong-Tang)
	黃耆建中湯
135	Liou-Yi-San (Liu-Yi-San)《San》
	六一散《散》
136	Wu-Ling-San (Wu-Ling-San)《San》
	五苓散《散》

No.	Formula Name
137	Jhu-Ling-Tang (Zhu-Ling-Tang)
	豬苓湯
138	Yue-Bi-Jia-Jhu-Tang (Yue-Bi-Jia-Zhu-Tang)
	越婢加朮湯
139	Ciang-Huo-Sheng-Shih-Tang (Qiang-Huo-Sheng-Shi-Tang)
	羌活勝濕湯
140	Yin-Chen-Hao-Tang (Yin-Chen-Hao-Tang)
	茵陳蒿湯
141	Yi-Yi-Ren-Tang (Yi-Yi-Ren-Tang)
	薏苡仁湯
142	Ling-Guei-Jhu-Gan-Tang (Ling-Gui-Zhu-Gan-Tang)
	苓桂朮甘湯
143	Siao-Ban-Sia-Jia-Fu-Ling-Tang (Xiao-Ban-Xia-Jia-Fu-Ling-Tang)
	小半夏加茯苓湯
144	Shen-Jhu-Tang (Shen-Zhu-Tang)
	腎著湯
145	Run-Chang-Tang (Run-Chang-Tang)
	潤腸湯
146	Siang-Sheng-Po-Di-Wan (Xiang-Sheng-Po-Di-Wan)《Wan》
	響聲破笛丸《丸》
147	Ban-Sia-Sie-Sin-Tang (Ban-Xia-Xie-Xin-Tang)
	半夏瀉心湯
148	Sie-Bai-San (Xie-Bai-San)
	瀉白散
149	Pu-Ji-Siao-Du-Yin (Pu-Ji-Xiao-Du-Yin)《San》

No.	Formula Name
	普濟消毒飲《散》
150	San-Huang-Sie-Sin-Tang (San-Huang-Xie-Xin-Tang) 《Wan》
	三黃瀉心湯《丸》
151	Cing-Sin-Li-Ge-Tang (Qing-Xin-Li-Ge-Tang)
	清心利膈湯
152	Ban-Sia-Tian-Ma-Bai-Jhu-Tang (Ban-Xia-Tian-Ma-Bai-Zhu-Tang)
	半夏天麻白朮湯
153	An-Jhong-San (An-Zhong-San)《San》
	安中散《散》
154	Yu-Ping-Fong-San (Yu-Ping-Feng-San)《San》
	玉屏風散《散》
155	Yi-Zih-Tang (Yi-Zi-Tang)
	乙字湯
156	Siao-Jhih-Wan (Xiao-Zhi-Wan)《Wan》
	消痞丸《丸》
157	Zih-Yun-Gao (Zi-Yun-Gao)
	紫雲膏(Only for traditional formula.)
158	Ba-Wei-Dai-Sia-Fang (Ba-Wei-Dai-Xia-Fang)
	八味帶下方
159	Wun-Jing-Tang (Wen-Jing-Tang)
	溫經湯
160	Cyong-Guei-Jiao-Ai-Tang (Qiong-Gui-Jiao-Ai-Tang)
	芎歸膠艾湯
161	Dang-Guei-Shao-Yao- San (Dang-Gui-Shao-Yao-San) 《San》
	當歸芍藥散《散》

No.	Formula Name
162	Sheng-Hua-Tang (Sheng-Hua-Tang)
	生化湯
163	Yu-Cyuan-Wan (Yu-Quan-Wan)《Wan》
	玉泉丸《丸》
164	Huang-Lian-Shang-Cing-Wan (Huang-lian-Shang-Qing-Wan)《Wan》
	黃連上清丸《丸》
165	Jhih-Zih-Shih-Tang (Zhi-Zi-Shi-Tang)
	梔子豉湯
166	Jie-Geng-Tang (Jie-Geng-Tang)
	桔梗湯
167	Cing-Fei-Yin (Qing-Fei-Yin)
	清肺飲
168	Gua-Lou-Jhih-Shih-Tang (Gua-Lou-Zhi-Shi-Tang)
	瓜蔞枳實湯
169	Bu-Huan-Jin-Jheng-Ci-San (Bu-Huan-Jin-Zheng-Qi-San)
	不換金正氣散
170	Jian-Pi-Wan (Jian-Pi-Wan)《Wan》
	健脾丸《丸》
171	Lian-Ciao-Bai-Du-San (Lian-Qiao-Bai-Du-San)
	連翹敗毒散
172	Bu-Yin-Tang (Bu-Yin-Tang)
	補陰湯
173	Mai-Wei-Di-Huang-Wan (Mai-Wei-Di-Huang-Wan) 《Wan》
	麥味地黃丸《丸》
174	Zih-Yin-Di-Huang-Wan (Zi-Yin-Di-Huang-Wan) Shou-Gan-Di-Huang-Wan

No.	Formula Name
	(Shou-Gan-Di-Huang-Wan)《Wan》
	滋陰地黃丸(熟乾地黃丸)《丸》
175	Dang-Guei-Bu-Sie-Tang (Dang-Gui-Bu-Xie-Tang)
	當歸補血湯
176	Da-Bu-Yin-Wan (Da-Bu-Yin-Wan) 《Wan》
	大補陰丸《丸》
177	Ci-Bao-Mei-Ran-Dan (Qi-Bao-Mei-Ran-Dan)《Wan》
	七寶美髯丹《丸》
178	Ban-Long-Wan (Ban-Long-Wan)《Wan》
	斑龍丸《丸》
179	Zai-Zao-San (Zai-Zao-San)
	再造散
180	Yang-Gan-Wan (Yang-Gan-Wan)《Wan》
	養肝丸《丸》
181	Cing-Liang-San (Qing-Liang-San)
	清涼散
182	Gan-Mai-Da-Zao-Tang (Gan-Mai-Da-Zao-Tang) Gan-Cao-Siao-Mai-Da-Zao-Tang (Gan-Cao-Xiao-Mai-Da-Zao-Tang)
	甘麥大棗湯(甘草小麥大棗湯)
183	Chai-Hu-Jia-Long-Gu-Mu-Li-Tang (Chai-Hu-Jia-Long-Gu-Mu-Li-Tang)
	柴胡加龍骨牡蠣湯
184	Bao-Chan-Wu-You-Fang (Bao-Chan-Wu-You-Fang)
	保產無憂方
185	Dang-Guei-Yin-Zih (Dang-Gui-Yin-Zi)
	當歸飲子
186	Ning-Sou-Wan (Ning-Sou-Wan)《Wan》
	寧嗽丸《丸》
187	Er-Chen-Tang (Er-chen-Tang) (Wan)《Wan》
	二陳湯(丸)《丸》
188	Guei-Jhih-Shao-Yao-Jhih-Mu-Tang (Gui-Zhi-Shao-Yao-Zhi-Mu-Tang)
	桂枝芍藥知母湯
189	Cang-Er-San (Cang-Er-San)《San》
	蒼耳散《散》
190	Chai-Hu-Cing-Gan-Tang (Chai-Hu-Qing-Gan-Tang)
	柴胡清肝湯
191	Tuo-Li-Siao-Du-Yin (Tuo-Li-Xiao-Du-Yin)
	托裏消毒飲
192	Sang-Piao-Siao-San (Sang-Piao-Xiao-San)《San》
	桑螵蛸散《散》
193	Wun-Cing-Yin (Wen-Qing-Yin) Jie-Du-Sih-Wu-Tang (Jie-Du-Si-Wu-Tang)
	溫清飲(解毒四物湯)
194	Jin-Suo-Gu-Jing-Wan (Jin-Suo-Gu-Jing-Wan)《Wan》
	金鎖固精丸《丸》
195	Bao-He-Wan (Bao-He-Wan) 《Wan》
	保和丸《丸》
196	Wei-Ling-Tang (Wei-Ling-Tang)《San》
	胃苓湯《散》
197	Ping-Wei-San (Ping-Wei-San) 《Wan》
	平胃散《丸》
198	Bai-Hu-Jia-Ren-Shen-Tang (Bai-Hu-Jia-Ren-Shen-Tang)
	白虎加人參湯

No.	Formula Name
199	Yi-Gan-San (Yi-Gan-San)
	抑肝散
200	Wun-Dan-Tang (Wen-Dan-Tang)
	溫膽湯

The list is based on announcement of 100 Standard TCM Formulas including Liu-Wei-Di-Huang-Wan from Department of Health, Executive Yuan on August, 31,1995 with document serial Wei-Shu-Yao-Jhih-Zih NO.84056272 and announcement of another 100 Standard TCM Formulas including Sheng-Yu-Tang on June, 29, 2000 with document serial Wei- Shu-Yao-Jhih-Zih NO. 89037929, a total of 200 Standard TCM Formulas.

No.	Formula Name	Reference	Composition	Effects	Indications
1	Liou-Wei-Di-Huang-Wan (Liu-Wei-Di-Huang-Wan) 《Wan》	Siao-Er-Yao-Jheng-Jhih-Jyue (Xiao-Er-Yao-Zheng-Zhi-Jue) Key to Therapeutics of Childen's Diseases	Rehmanniae Radix Praeparata 8, Corni Sarcocarpium 4, Dioscoreae Rhizoma 4, Alismatis Rhizoma 3, Moutan Radicis Cortex 3, Poria 3. (Daily dosage 25 g)	Nourish yin to tonify the kidney.	Deficiency of the liver and kidney, lumbago and sore feet, dizziness and blurred vision, wasting-thirst, dry tongue and sore throat, heel pain.
	六味地黃丸《丸》	小兒藥證直訣	Add honey q.s. to make pills in traditional formula.		
2	Ba-Wei-Di-Huang-Wan (Ba-Wei-Di-Huang-Wan) 《Wan》	Yi-Fang-Ji-Jie (Yi-Fang-Ji-Jie) Collected Explanation on Prescriptions	Poria 3, Moutan Radicis Cortex 3, Alismatis Rhizoma 3, Rehmanniae Radix Praeparata 8, Corni Sarcocarpium 4, Dioscoreae Rhizoma 4, Aconiti Lateralis Radix Preparata 1, Cinnamomi Cortex 1. (Daily dosage 27 g)	Warm and tonify kidney yang.	Kidney yang deficiency, debilitation of the life gate fire, nocturia, spontaneous sweating and tinnitus.
	八味地黃丸《丸》	醫方集解	Add honey q.s. to make pills in traditional formula.		
3	Jhih-Bo-Di-Huang-Wan (Zhi-Bo-Di-Huang-Wan) 《Wan》	Yi-Fang-Ji-Jie (Yi-Fang-Ji-Jie) Collected Explanation on Prescriptions	Rehmanniae Radix Praeparata 8, Corni Sarcocarpium 4, Poria 3, Dioscoreae Rhizoma 4, Moutan Radicis Cortex 3, Alismatis Rhizoma 3, Anemarrhenae Rhizoma 2, Phellodendri Cortex 2. (Daily dosage 29 g)	Nourish yin to downbear fire.	Dizziness, tinnitus, dry tongue and sore throat, lumbar vertebrae pain.
	知柏地黃丸《丸》	醫方集解	Add honey q.s. to make pills in traditional formula.		
4	Ci-Jyu-Di-Huang-Wan (Qi-Ju-Di-Huang-Wan) 《Wan》	Jhong-Guo-Yi-Syue-Da-Cih-Dian (Zhong-Guo-Yi-Xue-Da-Ci-Dian) Chinese Medical Science Dictionary	Lycii Fructus 2, Chrysanthemi Flos 2, Rehmanniae Radix Praeparata 8, Corni Sarcocarpium 4, Dioscoreae Rhizoma 4, Poria 3, Moutan Radicis Cortex 3, Alismatis Rhizoma 3. (Daily dosage 29 g)	Enrich the kidney and nourish the liver.	Liver-kidney yin deficiency, dizziness and blurred vision, dry and painful eye, windward tears.

No.	Formula Name	Reference	Composition	Effects	Indications
	杞菊地黃丸《丸》	中國醫學大辭典	Add honey q.s. to make pills in traditional formula.		
5	Shen-Líng-Bai-Jhu-San (Shen-Ling-Bai-Zhu-San) 《San》	Tai-Ping-Huei-Min-He-Ji-Jyu-Fang (Tai-Ping-Hui-Min-He-Ji-Ju-Fang)	Lablab Semen Album 2.3, Ginseng Radix et Rhizoma 3, Poria 3, Atractylodis Macrocephalae Rhizoma 3, Glycyrrhizae Radix et Rhizoma 3, Dioscoreae Rhizoma 3, Nelumbinis Sarcocarpium 1.5, Platycodonis Radix 1.5, Coicis Semen 1.5, Amomi Fructus 1.5, Jujubae Fructus 1.5. (Daily dosage 24.8 g)	Tonify qi and fortify the spleen, drain dampness and harmonize the stomach.	Spleen-stomach weakness, poor appetite and sloppy stool.
		Prescription of Peaceful Benevolent Dispensary			
	參苓白朮散《散》	太平惠民和劑局方	Without Jujubae Fructus in traditional formula.		
6	Sih-Jyun-Zih-Tang (Si-Jun-Zi-Tang)	Yi-Fang-Ji-Jie (Yi-Fang-Ji-Jie)	Ginseng Radix et Rhizoma 6, Poria 6, Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 3, Atractylodis Macrocephalae Rhizoma 6, Zingiberis Rhizoma Recens 3, Jujubae Fructus 2. (Daily dosage 26 g)	Replenish qi and fortify the spleen.	Spleen-stomach qi deficiency, indigestion, pale complexion, poor appetite and sloppy stool.
		Collected Explanation on Prescriptions			
	四君子湯	醫方集解			
7	Sih-Wu-Tang (Si-Wu-Tang)	Tai-Ping-Huei-Min-He-Ji-Jyu-Fang (Tai-Ping-Hui-Min-He-Ji-Ju-Fang)	Rehmanniae Radix Praeparata 7.5, Paeoniae Radix Alba 7.5, Angelicae Sinensis Radix 7.5, Chuanxiong Rhizoma 7.5. (Daily dosage 30 g)	Tonify and harmonize blood.	Dual deficiency of qi and blood, fatigue and debility.
		Prescription of Peaceful Benevolent Dispensary			
	四物湯	太平惠民和劑局方			
8	Bu-Jhong-Yi-Ci-Tang (Bu-Zhong-Yi-Qi-Tang)	Pi-Wei-Lun (Pi-Wei-Lun)	Astragali Radix 6, Ginseng Radix et Rhizoma 4, Atractylodis Macrocephalae Rhizoma 2, Glycyrrhizae		Overexertion and fatigue, poor appetite and tasteless, spleen-

No.	Formula Name	Reference	Composition	Effects	Indications
	(Wan)《Wan》	Treatise on the Spleen and stomach	Radix et Rhizoma Praeparatum cum Melle 4, Angelicae Sinensis Radix 2, Citri Reticulatae Pericarpium 2, Cimicifugae Rhizoma 1, Bupleuri Radix 1, Zingiberis Rhizoma Recens 3, Jujubae Fructus 2. (Daily dosage 27 g)	Tonify the middle and replenish qi, harmonize and tonify the spleen and stomach.	stomach weakness and deficiency of original qi.
	補中益氣湯（丸）《丸》	脾胃論			
9	Liou-Jyun-Zih-Tang (Liu-Jun-Zi-Tang) (Wan)《Wan》	Tai-Ping-Huei-Min-He-Ji-Jyu-Fang (Tai-Ping-Hui-Min-He-Ji-Ju-Fang) Prescription of Peaceful Benevolent Dispensary	Ginseng Radix et Rhizoma 5, Atractylodis Macrocephalae Rhizoma 5, Poria 5, Pinelliae Rhizoma Praeparatum 5, Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 2.5, Citri Reticulatae Pericarpium 2.5, Zingiberis Rhizoma Recens 2.5, Jujubae Fructus 2.5. (Daily dosage 30 g)	Tonify qi and harmonize the middle.	Spleen-stomach weakness, poor appetite, indigestion, sloppy stool and qi deficiency with phlegm.
	六君子湯（丸）《丸》	太平惠民和劑局方			
10	Guei-Pi-Tang (Gui-Pi-Tang)	Jiao-Jhu-Fu-Ren-Lian-Fang (Jiao-Zhu-Fu-Ren-Liang-Fang) Corrected Effective Prescriptions for Women	Ginseng Radix et Rhizoma 3, Longan Arillus 3, Astragali Radix 3, Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 1.5, Atractylodis Macrocephalae Rhizoma 3, Poria 3, Aucklandiae Radix 1.5, Angelicae Sinensis Radix 3, Ziziphi Spinosae Semen 3, Polygalae Radix 3, Zingiberis Rhizoma Recens 2, Jujubae Fructus 2. (Daily dosage 31 g)	Fortify the spleen and calm the heart, replenish qi and tonify blood.	Dual deficiency of the heart and spleen, deficiency of qi and blood, palpitations, insomnia, poor appetite, fatigue and menstrual irregularities.
	歸脾湯	校註婦人良方			
11	Yang-Sin-Tang (Yang-Xin-Tang)	Jheng-Jhih-Jhun-Sheng (Zheng-Zhi-Zhun-Sheng) Standards for Diagnosis and Treatment	Astragali Radix Praeparata cum Melle 3, Poria cum Pini Radix 3, Poria 3, Pinelliae Rhizoma Fermentatum 3, Angelicae Sinensis Radix 3, Chuanxiong Rhizoma 3, Polygalae Radix 2, Ziziphi Spinosae Semen 2, Cinnamomi Cortex 2, Platycladi Semen 2, Schisandrae Chinensis Fructus 2, Ginseng Radix et Rhizoma 2,	Tonify blood and nourish the heart, tranquilize and stabilize the mind.	Heart blood deficiency, disquieted heart spirit, insomnia and profuse dreaming.
	養心湯	證治準繩			

No.	Formula Name	Reference	Composition	Effects	Indications
			Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 1, Zingiberis Rhizoma Recens 1, Jujubae Fructus 1. (Daily dosage 33 g)		
12	Ren-Shen-Yang-Rong-Tang (Ren-Shen-Yang-Rong-Tang) (Wan)《Wan》	Tai-Ping-Huei-Min-He-Ji-Jyu-Fang (Tai-Ping-Hui-Min-He-Ji-Ju-Fang)	Paeoniae Radix Alba 4, Angelicae Sinensis Radix 2.5, Cinnamomi Cortex Centralis 2.5, Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 2.5, Citri Reticulatae Pericarpium 2.5, Ginseng Radix et Rhizoma 2.5, Atractylodis Macrocephalae Rhizoma 2.5, Astragali Radix 2.5, Rehmanniae Radix Praeparata 2, Schisandrae Chinensis Fructus 2, Poria 2, Polygalae Radix 1.5, Zingiberis Rhizoma Recens 3, Jujubae Fructus 1. (Daily dosage 33 g)	Tonify qi and blood.	Spleen-lung qi deficiency, deficiency of nutrient and blood, poor appetite and tasteless, fatigue and emaciation.
		Prescription of Peaceful Benevolent Dispensary			
	人參養榮湯（丸）《丸》	太平惠民和劑局方			
13	Bai-He-Gu-Jin-Tang (Bai-He-Gu-Jin-Tang) (Wan)《Wan》	Yi-Fang-Ji-Jie (Yi-Fang-Ji-Jie)	Rehmanniae Radix Recens 4, Rehmanniae Radix Praeparata 6, Ophiopogonis Radix 3, Lilii Bulbus 2, Paeoniae Radix Alba 2, Angelicae Sinensis Radix 2, Fritillariae Cirrhosae Bulbus 2, Glycyrrhizae Radix et Rhizoma 2, Scrophulariae Radix 1.6, Platycodonis Radix 1.6. (Daily dosage 26.2 g)	Nourish yin and clear heat, moisten the lung to resolve phlegm.	Lung-kidney yin deficiency, deficiency fire flaming upward, dry and painful throat, cough and panting.
		Collected Explanation on Prescriptions			
	百合固金湯（丸）《丸》	醫方集解	Add honey q.s. to make pills in traditional formula.		
14	Zih-Wan-Tang (Zi-Wan-Tang)	Yi-Fang-Ji-Jie (Yi-Fang-Ji-Jie)	Asteris Radix et Rhizoma 4, Asini Corii Colla 4, Anemarrhenae Rhizoma 4, Fritillariae Cirrhosae Bulbus 4, Platycodonis Radix 2, Ginseng Radix et Rhizoma 2, Poria 2, Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 2, Schisandrae Chinensis Fructus 1.5. (Daily dosage 25.5 g)	Tonify the lung to suppress cough, clear heat to resolve phlegm.	Fatigue heat and chronic cough, phlegm with blood, lung atrophy and lung abscess.
		Collected Explanation on Prescriptions			
	紫菀湯	醫方集解			

No.	Formula Name	Reference	Composition	Effects	Indications
15	Cin-Ciou-Bie-Jia-San (Qin-Qiu-Bie-Jia-San)	Wei-Sheng-Bao-Jian (Wei-Sheng-Bao-Jian)	Trionycis Carapax 5, Gentianae Macrophyllae Radix 2.5, Anemarrhenae Rhizoma 2.5, Angelicae Sinensis Radix 2.5, Bupleuri Radix 5, Lycii Radicis Cortex 5, Mume Fructus 2, Artemisiae Annuae Herba 1.5. (Daily dosage 26 g)	Nourish yin and blood, clear heat to relieve bone-steaming fever.	Bone-steaming tidal fever, reddened lips and cheeks, night sweating and cough.
		Detailed of Analysis of Seasonal Febrile Diseases			
	秦艽鱉甲散	衛生寶鑑			
16	Yi-Ci-Cong-Ming-Tang (Yi-Qi-Cong-Ming-Tang)	Yi-Fang-Ji-Jie (Yi-Fang-Ji-Jie)	Astragali Radix 6, Glycyrrhizae Radix et Rhizoma 1.2, Ginseng Radix et Rhizoma 6, Cimicifugae Rhizoma 1.8, Puerariae Radix 3.6, Viticis Simplicifoliae Fructus 3.6, Paeoniae Radix Alba 2.4, Phellodendri Cortex 2.4. (Daily dosage 27 g)	Replenish qi and upraise yang, disperse wind and clear heat.	Wind-heat harassing upward, headache and dizziness, the initial stage of cataract, tinnitus and deafness.
		Collected Explanation on Prescriptions			
	益氣聰明湯	醫方集解			
17	Ba-Jhen-Tang (Ba-Zhen-Tang) (Wan)《Wan》	Jheng-Jhih-Jhun-Sheng (Zheng-Zhi-Zhun-Sheng)	Angelicae Sinensis Radix 3, Chuanxiong Rhizoma 3, Paeoniae Radix Alba 3, Rehmanniae Radix Praeparata 3, Ginseng Radix et Rhizoma 3, Atractylodis Macrocephalae Rhizoma 3, Poria 3, Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 1.5, Zingiberis Rhizoma Recens 3, Jujubae Fructus 2. (Daily dosage 27.5 g)	Tonify both qi and blood.	Dual deficiency of qi and blood, lassitude of spirit and fatigue of limbs, poor appetite, yellow complexion and emaciation.
		Standards for Diagnosis and Treatment			
	八珍湯（丸）《丸》	證治準繩			
18	Ji-Sheng-Shen-Ci-Wan (Ji-Sheng-Shen-Qi-Wan) (Wan)《Wan》	Ji-Sheng-Fang (Ji-Sheng-Fang)	Rehmanniae Radix Praeparata 8, Corni Sarcocarpium 4, Dioscoreae Rhizoma 4, Poria 6, Moutan Radicis Cortex 3, Alismatis Rhizoma 3, Aconiti Lateralis Radix Preparata 1, Cinnamomi Cortex 1, Achyranthis Bidentatae Radix 2, Plantaginis Semen 2. (Daily dosage 34 g)	Warm the kidney and resolve qi, induce diuresis to alleviate edema.	Kidney yang deficiency, heavy aching lumbar and knees, inhibited urination.
		Recipes for Saving Lives			
	濟生腎氣丸《丸》	濟生方	Add honey q.s. to make pills in traditional formula.		

No.	Formula Name	Reference	Composition	Effects	Indications
19	Shih-Cyuan-Da-Bu-Tang (Shi-Quan-Da-Bu-Tang) (Wan)《Wan》	Tai-Ping-Huei-Min-He-Ji-Jyu-Fang (Tai-Ping-Hui-Min-He-Ji-Ju-Fang) Prescription of Peaceful Benevolent Dispensary	Poria 3, Atractylodis Macrocephalae Rhizoma 3, Ginseng Radix et Rhizoma 3, Rehmanniae Radix Praeparata 3, Paeoniae Radix Alba 3, Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 3, Astragali Radix 3, Cinnamomi Cortex 3, Angelicae Sinensis Radix 3, Chuanxiong Rhizoma 3, Zingiberis Rhizoma Recens 3, Jujubae Fructus 2. (Daily dosage 35 g)	Tonify blood and replenish qi.	Dual deficiency of qi and blood, fatigued limbs.
	十全大補湯（丸）《丸》	太平惠民和劑局方	Without Zingiberis Rhizoma Recens and Jujubae Fructus, add honey q.s. to make pills in traditional formula.		
20	Huan-Shao-Dan (Huan-Shao-Dan) 《Wan》	Yang-Shih-Jia-Cang-Fang (Yang-Shi-Jia-Cang-Fang) Yang's Family Prescriptions	Dioscoreae Rhizoma 3, Achyranthis Bidentatae Radix 3, Poria 2, Corni Sarcocarpium 2, Broussonetiae Fructus 2, Eucommiae Cortex 2, Schisandrae Chinensis Fructus 2, Morindae Officinalis Radix 2, Cistanchis Herba 2, Polygalae Radix 2, Foeniculi Fructus 2, Acori Graminei Rhizoma 1, Rehmanniae Radix Praeparata 1, Lycii Fructus 1, Jujubae Fructus 1. (Daily dosage 28 g)	Tonify the heart, kidney, spleen and stomach deficiency.	Spleen-kidney deficiency cold, blood and qi deficiency, weakness and night sweating, seminal emission and turbid urine.
	還少丹《丸》	楊氏家藏方	Add honey q.s. to make pills in traditional formula.		
21	Huang-Ci-Wu-Wu-Tang (Huang-Qi-Wu-Wu-Tang)	Shan-Bu-Ming-Yi-Fang-Lun (Shan-Bu-Ming-Yi-Fang-Lun) Revised Famous Doctor's Prescription	Astragali Radix 10, Paeoniae Radix Alba 5, Cinnamomi Ramulus 5, Zingiberis Rhizoma Recens 5, Jujubae Fructus 3. (Daily dosage 28 g)	Tonify qi and blood, harmonize the nutrient and defense.	Nutrient-defense qi and blood deficiency, invade wind pathogen, nutrient-blood obstruction, numbness of muscle and fatigued limbs.
	黃耆五物湯	刪補名醫方論			
22	Ma-Huang-Tang (Ma-Huang-Tang)	Shang-Han-Lun (Shang-Han-Lun)	Ephedrae Herba 9, Cinnamomi Ramulus 6, Glycyrrhizae Radix et Rhizoma Praeparatum cum		Wind-cold induced by exopathogen, aversion to cold

No.	Formula Name	Reference	Composition	Effects	Indications
		Treatise on Febrile Diseases	Melle 3, Armeniacae Semen Amarum 5. (Daily dosage 23 g)	Promote sweating to release the exterior, diffuse the lung to calm panting.	with fever, headache and generalized pain, panting without sweating.
	麻黃湯	傷寒論			
23	Guei-Jhih-Tang (Gui-Zhi-Tang)	Shang-Han-Lun (Shang-Han-Lun)	Cinnamomi Ramulus 6, Paeoniae Radix Alba 6, Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 4, Zingiberis Rhizoma Recens 6, Jujubae Fructus 5. (Daily dosage 27 g)	Release the flesh to effuse the exterior, harmonize the nutrient and defense.	Wind-cold induced by exopathogen, headache and fever, sweating and aversion to wind, noisy nose and dry retching.
		Treatise on Febrile Diseases			
	桂枝湯	傷寒論			
24	Siao-Cing-Long-Tang (Xiao-Qing-Long-Tang)	Shang-Han-Lun (Shang-Han-Lun)	Ephedrae Herba 4, Paeoniae Radix Alba 4, Schisandrae Chinensis Fructus 1.5, Zingiberis Rhizoma 4, Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 4, Cinnamomi Ramulus 4, Pinelliae Rhizoma Praeparatum 4, Asari Radix et Rhizoma 1.5. (Daily dosage 27 g)	Release the exterior to dissipate cold, warm the lung and resolve fluid retention.	Wind-cold induced by exopathogen, internal stagnation of fluid-dampness, aversion to cold with fever, absence of sweating, cough and panting, white and watery phlegm.
		Treatise on Febrile Diseases			
	小青龍湯	傷寒論			
25	Ge-Gen-Tang (Ge-Gen-Tang)	Shang-Han-Lun (Shang-Han-Lun)	Puerariae Radix 6, Ephedrae Herba 4.5, Cinnamomi Ramulus 3, Paeoniae Radix Alba 3, Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 3, Zingiberis Rhizoma Recens 4.5, Jujubae Fructus 4. (Daily dosage 28 g)	Promote sweating to release the flesh.	Wind-cold induced by exopathogen, headache and fever, aversion to cold without sweating, contracture of the nape and neck.
		Treatise on Febrile Diseases			
	葛根湯	傷寒論			
26	Chai-Ge-Jie-Ji-Tang (Chai-Ge-Jie-Ji-Tang)	Jhong-Guo-Yi-Syue-Da-Cih-Dian (Zhong-Guo-Yi-Xue-Da-Ci-Dian)	Bupleuri Radix 2.5, Puerariae Radix 2.5, Notopterygii Rhizoma et Radix 2.5, Angelicae Dahuricae Radix 2.5, Scutellariae Radix 2.5, Paeoniae Radix Alba 2.5,	Release the flesh and clear heat.	Headache and fever, vexation and insomnia, painful eye socket and dry nose, dry throat

No.	Formula Name	Reference	Composition	Effects	Indications
		Chinese Medical Science Dictionary	Platycodonis Radix 2.5, Glycyrrhizae Radix et Rhizoma 1.5, Gypsum Fibrosum 2.5, Zingiberis Rhizoma Recens 2, Jujubae Fructus 2. (Daily dosage 25.5 g)		and deafness, aversion to cold without sweating.
	柴葛解肌湯	中國醫學大辭典			
27	Jiou-Wei-Ciang-Huo-Tang (Jiu-Wei-Qiang-Huo-Tang) 《Wan》	Cih-Shih-Nan-Jhih (Ci-Shi-Nan-Zhi)	Notopterygii Rhizoma et Radix 3, Saposhnikoviae Radix 3, Atractylodis Rhizoma 3, Asari Radix et Rhizoma 1, Chuanxiong Rhizoma 2, Angelicae Dahuricae Radix 2, Rehmanniae Radix Recens 2, Scutellariae Radix 2, Glycyrrhizae Radix et Rhizoma 2, Zingiberis Rhizoma Recens 3, Allii Fistulosi Bulbus Recens 3. (Daily dosage 26 g)	Release the exterior, dispel dampness and clear interior heat.	Wind-cold and dampness induced by exopathogen, headache, contracture of neck and limb pain.
		Medical Problems			
	九味羌活湯《丸》	此事難知			
28	Ren-Shen-Bai-Du-San (Ren-Shen-Bai-Du-San)	Tai-Ping-Huei-Min-He-Ji-Jyu-Fang (Tai-Ping-Hui-Min-He-Ji-Ju-Fang)	Ginseng Radix et Rhizoma 3, Poria 3, Glycyrrhizae Radix et Rhizoma 1.5, Peucedani Radix 3, Chuanxiong Rhizoma 3, Notopterygii Rhizoma et Radix 3, Angelicae Pubescentis Radix 3, Platycodonis Radix 3, Bupleuri Radix 3, Citri Fructus Immaturus 3, Zingiberis Rhizoma Recens 3, Menthae Herba 0.5. (Daily dosage 32 g)	Replenish qi and release the exterior, disperse wind and dispel dampness.	Wind-cold and dampness induced by exopathogen, aversion to cold with fever without sweating, contracture of the head and neck, limb and body pain, stuffiness and oppression in the chest and diaphragm, nasal congestion, cough with phlegm.
		Prescription of Peaceful Benevolent Dispensary			
	人參敗毒散	太平惠民和劑局方			
29	Chuan-Cyong-Cha-Tiao-San (Chuan-Qiong-Cha-Tiao-San)	Tai-Ping-Huei-Min-He-Ji-Jyu-Fang (Tai-Ping-Hui-Min-He-Ji-Ju-Fang)	Angelicae Dahuricae Radix 2, Glycyrrhizae Radix et Rhizoma 2, Notopterygii Rhizoma et Radix 2, Nepetae Herba 4, Chuanxiong Rhizoma 4, Asari Radix et	Dispel wind and relieve pain.	Migraine and aching all over the head.

No.	Formula Name	Reference	Composition	Effects	Indications
	《San》	Prescription of Peaceful Benevolent Dispensary	Rhizoma 1, Saposhnikoviae Radix 1.5, Menthae Herba 8. (Daily dosage 24.5 g)		
	川芎茶調散《散》	太平惠民和劑局方			
30	Jing-Fang-Bai-Du-San (Jing-Fang-Bai-Du-San)	Ci-Siao-Liang-Fang (Qi-Xiao-Liang-Fang)	Nepetae Herba 3, Saposhnikoviae Radix 3, Notopterygii Rhizoma et Radix 3, Angelicae Pubescentis Radix 3, Bupleuri Radix 3, Peucedani Radix 3, Chuanxiong Rhizoma 3, Citri Fructus Immaturus 3, Platycodonis Radix 3, Poria 3, Glycyrrhizae Radix et Rhizoma 1.5, Zingiberis Rhizoma Recens 3, Menthae Herba 1. (Daily dosage 35.5 g)	Promote sweating to release the exterior, disperse wind and dispel dampness.	Wind-cold and dampness induced by exopathogen, aversion to cold with fever, contracture of the head and neck, limb and body pain, mumps.
		Effective Prescriptions			
	荊防敗毒散	奇效良方			
31	Ma-Sing-Gan-Shih-Tang (Ma-Xing-Gan-Shi-Tang)	Shang-Han-Lun (Shang-Han-Lun)	Ephedrae Herba 8, Armeniacae Semen Amarum 6, Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 4, Gypsum Fibrosum 16. (Daily dosage 34 g)	Diffusion with pungent-cool, clear the lung to calm panting.	Pathogenic heat congesting the lung, fever, cough and panting.
		Treatise on Febrile Diseases			
	麻杏甘石湯	傷寒論			
32	Ma-Sing-Yi-Gan-Tang (Ma-Xing-Yi-Gan-Tang)	Jin-Kuei-Yao-Lyue (Jin-Kui-Yao-Lue)	Ephedrae Herba 5, Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 10, Coicis Semen 5, Armeniacae Semen Amarum 4. (Daily dosage 24 g)	Promote sweating to release the exterior, dispel wind-dampness.	Wind-dampness, generalized pain and fever, which worse in the late afternoon.
		Synopsis of Golden Cabinet			
	麻杏薏甘湯	金匱要略			
33	Ma-Huang-Fu-Zih-Si-Sin-Tang (Ma-Huang-Fu-Zi-Xi-Xin-Tang)	Shang-Han-Lun (Shang-Han-Lun)	Ephedrae Herba 8, Aconiti Lateralis Radix Preparata 5, Asari Radix et Rhizoma 8. (Daily dosage 21 g)	Disperse exterior pathogen, warm the meridian to dissipate cold.	Get lesser yin disease, but fever and sunken pulse.
		Treatise on Febrile Diseases			
	麻黃附子細辛湯	傷寒論			

No.	Formula Name	Reference	Composition	Effects	Indications
34	Da-Cheng-Ci-Tang (Da-Cheng-Qi-Tang)	Shang-Han-Lun (Shang-Han-Lun)	Rhei Radix et Rhizoma 8, Magnoliae Cortex 16, Aurantii Fructus Immaturus 3, Natrii Sulfas 6. (Daily dosage 33 g)	Drastic (purgative) heat-accumulation, eliminate stuffiness and remove food stagnation.	Yang brightness excess heat, intestinal dryness and stool bind, abdominal stuffiness and fullness.
		Treatise on Febrile Diseases			
	大承氣湯	傷寒論			
35	Siao-Sian-Syong-Tang (Xiao-Xian-Xiong-Tang)	Shang-Han-Lun (Shang-Han-Lun)	Coptidis Rhizoma 3, Pinelliae Rhizoma 12, Trichosanthis Fructus 12. (Daily dosage 27 g)	Clear heat to resolve phlegm, disperse nodules to soothe the chest.	Phlegm-heat block the chest, stuffiness and painful below the heart.
		Treatise on Febrile Diseases			
	小陷胸湯	傷寒論			
36	Wu-Ji-San (Wu-Ji-San)	Tai-Ping-Huei-Min-He-Ji-Jyu-Fang (Tai-Ping-Hui-Min-He-Ji-Ju-Fang)	Citri Reticulatae Pericarpium 2, Citri Fructus Immaturus 2, Ephedrae Herba 2, Paeoniae Radix Alba 1, Chuanxiong Rhizoma 1, Angelicae Sinensis Radix 1, Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 1, Poria 1, Pinelliae Rhizoma Praeparatum 1, Cinnamomi Cortex 1, Angelicae Dahuricae Radix 1, Magnoliae Cortex 1.5, Zingiberis Rhizoma Praeparatum 1.5, Platycodonis Radix 4, Atractylodis Rhizoma 8, Zingiberis Rhizoma Recens 2. (Daily dosage 31 g)	Release the exterior to dissipate cold, warm the middle and resolve accumulation.	Pathogenic cold induced by exopathogen, internal damage engendering cold and painful limb joints.
		Prescription of Peaceful Benevolent Dispensary			
	五積散	太平惠民和劑局方			
37	Shen-Su-Yin (Shen-Su-Yin)	Tai-Ping-Huei-Min-He-Ji-Jyu-Fang (Tai-Ping-Hui-Min-He-Ji-Ju-Fang)	Citri Reticulatae Pericarpium 2, Citri Fructus Immaturus 2, Platycodonis Radix 2, Glycyrrhizae Radix et Rhizoma 2, Aucklandiae Radix 2, Pinelliae Rhizoma Praeparatum 3, Perillae Folium 3, Puerariae Radix 3, Peucedani Radix 3, Ginseng Radix et Rhizoma	Replenish qi and release the exterior, diffuse the lung to resolve phlegm.	Weakness, common cold, aversion to cold with fever, headache and nasal congestion, cough with copious phlegm.
		Prescription of Peaceful Benevolent Dispensary			
	參蘇飲	太平惠民和劑局方			

No.	Formula Name	Reference	Composition	Effects	Indications
			3, Poria 3, Zingiberis Rhizoma Recens 2, Jujubae Fructus 1. (Daily dosage 31 g)		
38	Siang-Su-San (Xiang-Su-San)	Tai-Ping-Huei-Min-He-Ji-Jyu-Fang (Tai-Ping-Hui-Min-He-Ji-Ju-Fang)	Citri Reticulatae Pericarpium 4, Cyperi Rhizoma 8, Perillae Folium 8, Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 2, Zingiberis Rhizoma Recens 3, Allii Fistulosi Bulbus Recens 3. (Daily dosage 28 g)	Regulate qi and harmonize the middle, release the exterior to dissipate cold.	Wind-cold induced by exopathogen, internal qi stagnation, physical cold and generalized heat, headache without sweating, stuffiness and oppression in the chest and stomach.
		Prescription of Peaceful Benevolent Dispensary			
	香蘇散	太平惠民和劑局方			
39	Siao-Yao-San (Xiao-Yao-San)	Tai-Ping-Huei-Min-He-Ji-Jyu-Fang (Tai-Ping-Hui-Min-He-Ji-Ju-Fang)	Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 2, Paeoniae Radix Alba 4, Angelicae Sinensis Radix 4, Poria 4, Atractylodis Macrocephalae Rhizoma 4, Bupleuri Radix 4, Zingiberis Rhizoma Tostum 4, Menthae Herba 2. (Daily dosage 28 g)	Soothe the liver and release depression, nourish blood and fortify the spleen.	Blood deficiency, overexertion and fatigue, heavy head and blurred vision, menstrual irregularities, lassitude of spirit, poor appetite, nutrient-defense disharmony.
		Prescription of Peaceful Benevolent Dispensary			
	逍遙散	太平惠民和劑局方			
40	Jia-Wei-Siao-Yao-San (Jia-Wei-Xiao-Yao-San)	Jheng-Jhih-Jhun-Sheng (Zheng-Zhi-Zhun-Sheng)	Angelicae Sinensis Radix 4, Atractylodis Macrocephalae Rhizoma 4, Paeoniae Radix Alba 4, Bupleuri Radix 4, Poria 4, Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 2, Moutan Radicis Cortex 2.5, Gardeniae Fructus 2.5, Zingiberis Rhizoma Tostum 4, Menthae Herba 2. (Daily dosage 33 g)	Soothe the liver and release depression, clear heat to cool the blood.	Liver depression, blood deficiency and fever, menstrual irregularities, disquieted fearful throbbing.
		Standards for Diagnosis and Treatment			
	加味逍遙散	證治準繩			

No.	Formula Name	Reference	Composition	Effects	Indications
41	Huo-Siang-Jheng-Ci-San (Huo-Xiang-Zheng-Qi-San) (Wan)《Wan》	Tai-Ping-Huei-Min-He-Ji-Jyu-Fang (Tai-Ping-Hui-Min-He-Ji-Ju-Fang)	Arecae Pericarpium 3, Poria 3, Angelicae Dahuricae Radix 3, Perillae Folium 3, Citri Reticulatae Pericarpium 2, Platycodonis Radix 2, Atractylodis Macrocephalae Rhizoma 2, Magnoliae Cortex 2, Pinelliae Rhizoma Fermentatum 2, Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 1, Agastachis Herba 3, Zingiberis Rhizoma Recens 3, Jujubae Fructus 1. (Daily dosage 30 g)	Release the exterior and resolve dampness, regulate qi and harmonize the middle.	Wind-cold induced by exopathogen, gastrointestinal discomfort, indigestion, vomiting and diarrhea, food stagnation, summerheat stroke and failure to acclimatize to a new environment.
		Prescription of Peaceful Benevolent Dispensary			
	藿香正氣散（丸）《丸》	太平惠民和劑局方	Traditional formula: grind into powder, add Zingiberis Rhizoma Recens and Jujubae Fructus q.s., and then decoct into water pills. Take 1/3 portion of the pills in warm orally, three times a day.		
42	Wu-Yao-Shun-Ci-San (Wu-Yao-Shun-Qi-San)	Tai-Ping-Huei-Min-He-Ji-Jyu-Fang (Tai-Ping-Hui-Min-He-Ji-Ju-Fang)	Ephedrae Herba 4, Citri Reticulatae Pericarpium 4, Linderae Radix 4, Chuanxiong Rhizoma 2, Bombyx Batryticatus 2, Citri Fructus Immaturus 2, Angelicae Dahuricae Radix 2, Glycyrrhizae Radix et Rhizoma 2, Platycodonis Radix 2, Zingiberis Rhizoma 1, Zingiberis Rhizoma Recens 3, Jujubae Fructus 1. (Daily dosage 29 g)	Regulate qi and diffusion, dispel wind and resolve phlegm.	Numbness of the whole body, joint pain, difficulty in walking, sluggish speech, deviated eye and mouth, spastic sinews.
		Prescription of Peaceful Benevolent Dispensary			
	烏藥順氣散	太平惠民和劑局方			
43	Su-Zih-Jiang-Ci-Tang (Su-Zi-Jiang-Qi-Tang)	Tai-Ping-Huei-Min-He-Ji-Jyu-Fang (Tai-Ping-Hui-Min-He-Ji-Ju-Fang)	Angelicae Sinensis Radix 2, Glycyrrhizae Radix et Rhizoma 2, Magnoliae Cortex 2, Peucedani Radix 2, Citri Reticulatae Pericarpium 3, Cinnamomi Cortex 3, Pinelliae Rhizoma Praeparatum 5, Pinelliae Rhizoma 5, Zingiberis Rhizoma Recens 2, Jujubae Fructus 1. (Daily dosage 27 g)	Direct qi downward to calm panting, warm and resolve phlegm-dampness.	Phlegm-drool congestion, cough and panting, shortness of breath, fullness and oppression in the chest and diaphragm, discomfort in the throat.
		Prescription of Peaceful Benevolent Dispensary			
	蘇子降氣湯	太平惠民和劑局方			

No.	Formula Name	Reference	Composition	Effects	Indications
44	Ding-Chuan-Tang (Ding-Chuan-Tang)	Jheng-Jhih-Jhun-Sheng (Zheng-Zhi-Zhun-Sheng) Standards for Diagnosis and Treatment	Ginkgo Semen 6, Ephedrae Herba 4, Farfarae Flos 4, Mori Radicis Cortex 4, Pinelliae Rhizoma Praeparatum 4, Perillae Fructus 2.5, Armeniacae Semen Amarum 2, Scutellariae Radix 2, Glycyrrhizae Radix et Rhizoma 1.5. (Daily dosage 30 g)	Diffuse the lung to calm panting, clear heat to resolve phlegm.	Heat symptom, panting and cough.
	定喘湯	證治準繩			
45	Yue-Jyu-Wan (Yue-Ju-Wan) 《Wan》	Dan-Si-Sin-Fa (Dan-Xi-Xin-Fa) Danxi`s Experiential Therapy	Atractylodis Rhizoma 5, Cyperi Rhizoma 5, Chuanxiong Rhizoma 5, Massa Medicata Fermentata 5, Gardeniae Fructus Praeparatus 5. (Daily dosage 25 g)	Move qi to release depression.	Fullness and oppression in the chest and diaphragm, stomach duct and abdomen pain, gastric upset and acid regurgitation, indigestion, belching and vomiting induced by qi, blood, phlegm, fire, dampness and food depression.
	越鞠丸《丸》	丹溪心法			
46	Huai-Hua-San (Huai-Hua-San)	Pu-Ji-Ben-Shih-Fang (Pu-Ji-Ben-Shi-Fang) Experiential Prescriptions for Curing All People	Sophorae Flos Praeparatus 6, Platycladi Ramulus et Folium 6, Schizonepetae Spica 6, Citri Fructus Immaturus 6. (Daily dosage 24 g)	Clear intestinal heat, disperse wind, move qi and stop bleeding.	Intestinal wind and visceral toxin, hemorrhoid fistula and hematochezia.
	槐花散	普濟本事方			
47	Shu-Jing-Huo-Sie-Tang (Shu-Jing-Huo-Xie-Tang)	Wan-Bing-Huei-Chun (Wan-Bing-Hui-Chun)	Glycyrrhizae Radix et Rhizoma 1, Angelicae Sinensis Radix 2, Paeoniae Radix Alba 2.5, Rehmanniae Radix Recens 2, Atractylodis Rhizoma 2, Cyathulae Radix 2, Citri Reticulatae Pericarpium 2, Persicae Semen 2,	Soothe menstruation, activate blood and dispel wind.	Joint pain, lumbago, intramuscular pain or whole body pains.

No.	Formula Name	Reference	Composition	Effects	Indications
		Recovery from All Ailments	Clematidis Radix et Rhizoma 2, Chuanxiong Rhizoma 1, Stephaniae Tetrandrae Radix 1, Notopterygii Rhizoma et Radix 1, Saposhnikoviae Radix 1, Angelicae Dahuricae Radix 1, Gentianae Radix et Rhizoma 1, Poria 1, Zingiberis Rhizoma Recens 3. (Daily dosage 27.5 g)		
	疏經活血湯	萬病回春			
48	Di-Dang-Tang (Di-Dang-Tang)	Shang-Han-Lun (Shang-Han-Lun)	Hirudo 10, Tabanus 1, Persicae Semen 2, Rhei Radix et Rhizoma cum Vino Preparati 10. (Daily dosage 23 g)	Attack and expel static blood.	Blood amass in lower energizer, hardness and fullness in lower abdomen and inhibited menstruation.
		Treatise on Febrile Diseases			
	抵當湯	傷寒論			
49	Sie-Fu-Jhu-Yu-Tang (Xie-Fu-Zhu-Yu-Tang)	Yi-Lin-Gai-Cuo (Yi-Lin-Gai-Cuo)	Angelicae Sinensis Radix 4.5, Rehmanniae Radix Recens 4.5, Persicae Semen 6, Carthami Flos 4.5, Citri Fructus Immaturus 3, Paeoniae Radix Rubra 3, Bupleuri Radix 1.5, Glycyrrhizae Radix et Rhizoma 1.5, Platycodonis Radix 2.3, Chuanxiong Rhizoma 2.3, Cyathulae Radix 4.5. (Daily dosage 37.6 g)	Activate blood and resolve stasis, move qi to relieve pain.	Blood stasis in the chest, late afternoon tidal fever, chest pain for years, headache, persistent hiccup, internal heat, vexation and oppression, palpitations and insomnia.
		Correction on Errors of Medical Works			
	血府逐瘀湯	醫林改錯			
50	Bu-Yang-Huan-Wu-Tang (Bu-Yang-Huan-Wu-Tang)	Yi-Lin-Gai-Cuo (Yi-Lin-Gai-Cuo)	Astragali Radix 20, Rootlet of Angelicae Sinensis Radix 1, Paeoniae Radix Rubra 1, Pheretima 0.5, Chuanxiong Rhizoma 0.5, Persicae Semen 0.5, Carthami Flos 0.5. (Daily dosage 24 g)	Tonify qi, activate blood to free the collateral vessels.	Hemiplegia, deviated eye and mouth, sluggish speech and sequela of wind stroke.
		Correction on Errors of Medical Works			
	補陽還五湯	醫林改錯			
51	Jheng-Gu-Zih-Jin-Dan (Zheng-Gu-Zi-Jin-Dan) 《Dan》	Yi-Zong-Jin-Jian (Yi-Zong-Jin-Jian)	Caryophylli Flos 2, Aucklandiae Radix 2, Draconis Sanguis 2, Catechu 2, Rhei Radix et Rhizoma Praeparatum 2, Carthami Flos 2, Angelicae Sinensis	Activate blood to resolve stasis and relieve pain.	Knocks and falls, static blood stagnation.

No.	Formula Name	Reference	Composition	Effects	Indications
		Golden Mirror of Medicine	Radix 4, Nelumbinis Sarcocarpium 4, Poria 4, Paeoniae Radix Alba 4, Moutan Radicis Cortex 1, Glycyrrhizae Radix et Rhizoma 0.6. (Daily dosage 29.6 g)		
	正骨紫金丹《丹》	醫宗金鑑	Add honey q.s. to make pills in traditional formula.		
52	Tao-Hong-Sih-Wu-Tang (Tao-Hong-Si-Wu-Tang)	Yi-Zong-Jin-Jian (Yi-Zong-Jin-Jian)	Persicae Semen 5, Carthami Flos 2.5, Angelicae Sinensis Radix 5, Chuanxiong Rhizoma 2.5, Paeoniae Radix Alba 5, Rehmanniae Radix Praeparata 5. (Daily dosage 25 g)	Activate blood to resolve stasis.	Menstrual irregularities, dysmenorrhea and inhibited menstruation with clots.
		Golden Mirror of Medicine			
	桃紅四物湯	醫宗金鑑			
53	Siao-Fong-San (Xiao-Feng-San)	Wai-Ke-Jheng-Zong (Wai-Ke-Zheng-Zong)	Angelicae Sinensis Radix 2.5, Rehmanniae Radix Recens 2.5, Saposhnikoviae Radix 2.5, Cicadae Periostracum 2.5, Anemarrhenae Rhizoma 2.5, Sophorae Flavescentis Radix 2.5, Sesami Semen Nigrum 2.5, Nepetae Herba 2.5, Atractylodis Rhizoma 2.5, Arctii Fructus 2.5, Gypsum Fibrosum 2.5, Glycyrrhizae Radix et Rhizoma 1.25, Akebiae Caulis 1.25. (Daily dosage 30 g)	Moisten blood and dispel wind, eliminate dampness and clear heat.	Itchy scabies induced by wind-dampness spreading blood vessels and wind-heat latent syndrome.
		Orthodox Manual of External Disease			
	消風散	外科正宗			
54	Shang-Jhong-Sia-Tong-Yong-Tong-Fong-Wan (Shang-Zhong-Xia-Tong-Yong-Tong-Feng-Wan) 《Wan》	Dan-Si-Sin-Fa (Dan-Xi-Xin-Fa)	Arisaematis Rhizoma Preparatum 4, Atractylodis Rhizoma 4, Phellodendri Cortex 4, Chuanxiong Rhizoma 2, Angelicae Dahuricae Radix 2, Massa Medicata Fermentata 2, Persicae Semen 2, Clematidis Radix et Rhizoma 1, Notopterygii Rhizoma et Radix 1, Stephaniae Tetrandrae Radix 2, Cinnamomi Ramulus 1, Carthami Flos 0.5, Gentianae Radix et Rhizoma 2. (Daily dosage 27.5 g)	Disperse wind and dispel phlegm, clear heat and dry dampness, activate blood to relieve pain.	Wind-cold and dampness induced by exopathogen with phlegm-heat, inhibited blood vessels, joint pain.
		Danxi`s Experiential Therapy			
	上中下通用痛風丸《丸》	丹溪心法			

No.	Formula Name	Reference	Composition	Effects	Indications
55	Jyuan-Bi-Tang (Juan-Bi-Tang)	Jhong-Guo-Yi-Syue-Da-Cih-Dian (Zhong-Guo-Yi-Xue-Da-Ci-Dian)	Angelicae Sinensis Radix 4, Paeoniae Radix Rubra 4, Astragali Radix 4, Curcumae Longae Rhizoma 4, Notopterygii Rhizoma et Radix 4, Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 1.5, Zingiberis Rhizoma Recens 3, Jujubae Fructus 2, Saposhnikoviae Radix 4. (Daily dosage 30.5 g)	Replenish qi and harmonize the nutrient, dispel wind and eliminate dampness.	Moving impediment, body pain, contracture of the nape and neck, heavy pain of shoulder and elbow, difficulty in moving, cold-impediment of the extremities.
		Chinese Medical Science Dictionary			
	蠲痹湯	中國醫學大辭典			
56	San-Bi-Tang (San-Bi-Tang)	Fu-Ren-Liang-Fang (Fu-Ren-Liang-Fang)	Dipsaci Radix 1.5, Eucommiae Cortex 1.5, Saposhnikoviae Radix 1.5, Cinnamomi Cortex 1.5, Asari Radix et Rhizoma 1.5, Ginseng Radix et Rhizoma 1.5, Poria 1.5, Angelicae Sinensis Radix 1.5, Paeoniae Radix Alba 1.5, Astragali Radix 1.5, Cyathulae Radix 1.5, Glycyrrhizae Radix et Rhizoma 1.5, Gentianae Macrophyllae Radix 1.5, Rehmanniae Radix Recens 1.5, Chuanxiong Rhizoma 1.5, Angelicae Pubescentis Radix 1.5, Zingiberis Rhizoma Recnes 1.5, Jujubae Fructus 1.5. (Daily dosage 27 g)	Tonify qi and blood, dispel wind-dampness and resolve painful impediment.	Qi and blood stagnation, spastic extremities and wind-cold dampness impediment.
		Compendium of Effective Prescriptions for Women			
	三痹湯	婦人良方			
57	Du-Huo-Ji-Sheng-Tang (Du-Huo-Ji-Sheng-Tang)	Cian-Jin-Fang (Qian-Jin-Fang)	Angelicae Pubescentis Radix 3, Taxilli Herba 2, Eucommiae Cortex 2, Cyathulae Radix 2, Asari Radix et Rhizoma 2, Gentianae Macrophyllae Radix 2, Poria 2, Cinnamomi Cortex Centralis 2, Saposhnikoviae Radix 2, Chuanxiong Rhizoma 2, Ginseng Radix et Rhizoma 2, Glycyrrhizae Radix et Rhizoma 2, Angelicae Sinensis Radix 2, Paeoniae Radix Alba 2, Rehmanniae Radix Recens 2. (Daily dosage 31 g)	Dispel wind-dampness, resolve painful impediment, tonify qi and blood.	Wind-cold dampness impediment, cold pain of lumbar and knees, inhibited bending and stretching of the legs.
		Thousand Gold Prescriptions			
	獨活寄生湯	千金方			

No.	Formula Name	Reference	Composition	Effects	Indications
58	Gou-Teng-San (Gou-Teng-San)	Pu-Ji-Ben-Shih-Fang (Pu-Ji-Ben-Shi-Fang)	Uncariae Ramulus Cum Uncis 2, Citri Reticulatae Pericarpium 2, Pinelliae Rhizoma Praeparatum 2, Ophiopogonis Radix 2, Poria 2, Poria cum Pini Radix 2, Ginseng Radix et Rhizoma 2, Chrysanthemi Flos 2, Saposhnikoviae Radix 2, Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 1, Gypsum Fibrosum 4, Zingiberis Rhizoma Recens 3. (Daily dosage 26 g)	Dispel wind-phlegm, clear the head and eyes.	Liver syncope, vomiting and dizziness.
		Experiential Prescriptions for Curing All People			
	鉤藤散	普濟本事方			
59	Siao-Syu-Ming-Tang (Xiao-Xu-Ming-Tang)	Yi-Fang-Ji-Jie (Yi-Fang-Ji-Jie)	Ephedrae Herba 2, Cinnamomi Ramulus 2, Glycyrrhizae Radix et Rhizoma 2, Zingiberis Rhizoma Recens 6, Ginseng Radix et Rhizoma 2, Chuanxiong Rhizoma 2, Armeniacae Semen Amarum 2, Aconiti Lateralis Radix Preparata 1, Stephaniae Tetrandrae Radix 2, Paeoniae Radix Alba 2, Scutellariae Radix 2, Saposhnikoviae Radix 3, Jujubae Fructus 1. (Daily dosage 29 g)	Tonify qi and dissipate cold, disperse wind and dispel dampness.	Wind stroke, deviated eye and mouth, contracture of sinews, hemiplegia, stiff tongue inhibits speech or depressed expression.
		Collected Explanation on Prescriptions			
	小續命湯	醫方集解			
60	Wu-Jhu-Yu-Tang (Wu-Zhu-Yu-Tang)	Shang-Han-Lun (Shang-Han-Lun)	Evodiae Fructus 7.5, Ginseng Radix et Rhizoma 4.5, Zingiberis Rhizoma Recens 9, Jujubae Fructus 6. (Daily dosage 27 g)	Warm the middle to tonify deficiency, direct qi downward to stop vomiting.	Spleen-stomach deficiency cold, feel nauseated after meals, vomiting and diarrhea, agitation, reversal cold of the extremities, dry retching, salivation and headache.
		Treatise on Febrile Diseases			
	吳茱萸湯	傷寒論			
61	Fu-Zih-Li-Jhong-Tang (Fu-Zi-Li-Zhong-Tang) (Wan)《Wan》	Tai-Ping-Huei-Min-He-Ji-Jyu-Fang (Tai-Ping-Hui-Min-He-Ji-Ju-Fang)	Ginseng Radix et Rhizoma 5, Aconiti Lateralis Radix Preparata 5, Zingiberis Rhizoma Praeparatum 5, Glycyrrhizae Radix et Rhizoma Praeparatum cum	Warm the middle to dissipate cold.	Spleen-stomach deficiency cold, indigestion, reversal cold of the limbs, borborygmus and

No.	Formula Name	Reference	Composition	Effects	Indications
		Prescription of Peaceful Benevolent Dispensary	Melle 5, Atractylodis Macrocephalae Rhizoma 5, (Daily dosage 25 g)		abdominal pain, vomiting and diarrhea.
	附子理中湯（丸）《丸》	太平惠民和劑局方	Add honey q.s. to make pills in traditional formula.		
62	Cing-Shu-Yi-Ci-Tang (Qing-Shu-Yi-Qi-Tang)	Pi-Wei-Lun (Pi-Wei-Lun)	Astragali Radix 3, Atractylodis Rhizoma 3, Cimicifugae Rhizoma 3, Ginseng Radix et Rhizoma 1.5, Alismatis Rhizoma 1.5, Massa Medicata Fermentata 1.5, Citri Reticulatae Pericarpium 1.5, Atractylodis Macrocephalae Rhizoma 1.5, Ophiopogonis Radix 1, Angelicae Sinensis Radix 1, Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 1, Citri Reticulatae Pericarpium Viride 1, Phellodendri Cortex 1, Puerariae Radix 1, Schisandrae Chinensis Fructus 0.5, Zingiberis Rhizoma Recens 3, Jujubae Fructus 2. (Daily dosage 28 g)	Clear summerheat and eliminate dampness, tonify qi to engender fluid.	Dampness-heat steaming due to the long summer, fatigued limbs, fever and vexation, spontaneous sweating and thirst, yellow stool, hematuria and vacuous pulse.
		Treatise on the Spleen and stomach			
	清暑益氣湯	脾胃論			
63	Jhu-Ye-Shih-Gao-Tang (Zhu-Ye-Shi-Gao-Tang)	Shang-Han-Lun (Shang-Han-Lun)	Lophatheri Caulis et Folium 2, Gypsum Fibrosum 16, Pinelliae Rhizoma Praeparatum 4, Ginseng Radix et Rhizoma 3, Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 2, Oryzae Semen 6, Ophiopogonis Radix 6. (Daily dosage 39 g)	Clear heat to engender fluid, tonify qi and harmonize the stomach.	Late stage of febrile disease, dual damage of qi and ying, dry retching, shortage of qi, thirst, vacuous, large and feeble pulse.
		Treatise on Febrile Diseases			
	竹葉石膏湯	傷寒論			
64	Siang-Ru-Yin (Xiang-Ru-Yin)	Tai-Ping-Huei-Min-He-Ji-Jyu-Fang (Tai-Ping-Hui-Min-He-Ji-Ju-Fang)	Moslae Herba 12, Lablab Semen Album 6, Magnoliae Cortex 6. (Daily dosage 24 g)	Dispel summerheat to release the exterior, resolve dampness and harmonize the middle.	Overconsumption of cold foods and drinks in summer, cold induced by exopathogen,

No.	Formula Name	Reference	Composition	Effects	Indications
		Prescription of Peaceful Benevolent Dispensary			dampness induced by internal damage, aversion to cold with fever, heavy-headedness and headache, abdominal pain, vomiting and diarrhea.
	香薷飲	太平惠民和劑局方			
65	Wu-Pi-Yin (Wu-Pi-Yin)	Tai-Ping-Huei-Min-He-Ji-Jyu-Fang (Tai-Ping-Hui-Min-He-Ji-Ju-Fang)	Acanthopanacis Cortex 6, Lycii Radicis Cortex 6, Peel of Zingiberis Cortex Recens 6, Arecae Pericarpium 6, Poriae Cutis 6. (Daily dosage 30 g)	Fortify the spleen and resolve dampness, regulate qi and disperse swelling.	Swelling and fullness due to water disease, panting with dyspnea and inhibited urination.
		Prescription of Peaceful Benevolent Dispensary			
	五皮飲	太平惠民和劑局方			
66	Ba-Jheng-San (Ba-Zheng-San)	Tai-Ping-Huei-Min-He-Ji-Jyu-Fang (Tai-Ping-Hui-Min-He-Ji-Ju-Fang)	Plantaginis Semen 3, Dianthi Herba 3, Talcum 3, Rhei Radix et Rhizoma 3, Gardeniae Fructus 3, Polygoni Avicularis Herba 3, Akebiae Caulis 3, Glycyrrhizae Radix Tenuis or Glycyrrhizae Radix et Rhizoma 3, Junci Medulla 2. (Daily dosage 26 g)	Clear heat and purge fire, induce diuresis and relieve strangury.	Heat accumulating in the bladder and difficult painful urination.
		Prescription of Peaceful Benevolent Dispensary			
	八正散	太平惠民和劑局方			
67	Bi-Sie-Fen-Cing-Yin (Bi-Xie-Fen-Qing-Yin)	Dan-Si-Sin-Fa (Dan-Xi-Xin-Fa)	Alpiniae Oxyphyllae Semen with Shell Removed 6, Dioscoreae Hypoglaucae Rhizoma 6, Acori Graminei Rhizoma 6, Linderae Radix 6, Glycyrrhizae Radix Tenuis or Glycyrrhizae Radix et Rhizoma 3, Poria 3. (Daily dosage 30 g)	Warm the kidney and drain dampness, separate clear and excrete turbid.	Unctuous strangury and white turbidity, frequent urination.
		Danxi`s Experiential Therapy			
	萆薢分清飲	丹溪心法			

No.	Formula Name	Reference	Composition	Effects	Indications
68	Yin-Chen-Wu-Ling-San (Yin-Chen-Wu-Ling-San) 《San》	Jin-Kuei-Yao-Lyue (Jin-Kui-Yao-Lue) Synopsis of Golden Cabinet	Artemisiae Scopariae Herba 16, Alismatis Rhizoma 2.5, Polyporus 1.5, Poria 1.5, Atractylodis Macrocephalae Rhizoma 1.5, Cinnamomi Ramulus 1. (Daily dosage 24 g)	Drain dampness and clear heat.	Jaundice, inhibited urination and polydipsia.
	茵陳五苓散《散》	金匱要略			
69	Wu-Lin-San (Wu-Lin-San)	Tai-Ping-Huei-Min-He-Ji-Jyu-Fang (Tai-Ping-Hui-Min-He-Ji-Ju-Fang) Prescription of Peaceful Benevolent Dispensary	Poria Rubra 6, Angelicae Sinensis Radix 4.8, Glycyrrhizae Radix et Rhizoma 4.8, Gardeniae Fructus 4, Paeoniae Radix Rubra 4, Junci Medulla 2. (Daily dosage 25.6 g)	Clear heat and drain dampness, relieve strangury and harmonize the blood.	Five stranguries, deficiency of kidney qi, bladder heat, congesting and dribbling urination, acute pain of umbilicus and abdomen.
	五淋散	太平惠民和劑局方			
70	Dao-Shuei-Fu-Ling-Tang (Dao-Shui-Fu-Ling-Tang)	Ci-Siao-Liang-Fang (Qi-Xiao-Liang-Fang) Effective Prescriptions	Poria Rubra 4.8, Ophiopogonis Radix 4.8, Alismatis Rhizoma 4.8, Atractylodis Macrocephalae Rhizoma 4.8, Mori Radicis Cortex 1.6, Perillae Folium 1.6, Arecae Semen 1.6, Chaenomelis Fructus 1.6, Arecae Pericarpium 1.2, Citri Reticulatae Pericarpium 1.2, Amomi Fructus 1.2, Aucklandiae Radix 1.2, Junci Medulla 1. (Daily dosage 31.4 g)	Move qi and resolve dampness, induce diuresis to alleviate edema.	Edema of the whole body, panting in semireclining position, inability to lay flat, poor appetite, astringentl urination.
	導水茯苓湯	奇效良方			
71	Mu-Fang-Ji-Tang (Mu-Fang-Ji-Tang)	Jin-Kuei-Yao-Lyue (Jin-Kui-Yao-Lue) Synopsis of Golden Cabinet	Cocculi Orbiculati Radix 6, Gypsum Fibrosum 12, Cinnamomi Ramulus 4, Ginseng Radix et Rhizoma 8. (Daily dosage 30 g)	Settle the inverse-asthenia, disperse thoracic fluid retention.	Tthoracic fluid retention in diaphragm, panting, stuffiness and rigidity below the heart.
	木防己湯	金匱要略			
72	Ji-Ming-San (Ji-Ming-San)	Jheng-Jhih-Jhun-Sheng (Zheng-Zhi-Zhun-Sheng)	Arecae Semen 8, Citri Reticulatae Pericarpium 5, Chaenomelis Fructus 5, Evodiae Fructus 1.5, Perillae	Warm diffusion and downbearing the turbid.	

No.	Formula Name	Reference	Composition	Effects	Indications
		Standards for Diagnosis and Treatment	Folium 1.5, Platycodonis Radix 2.5, Zingiberis Rhizoma Recens 2.5. (Daily dosage 26 g)		Beriberi pain, deep multiple abscess with wind-dampnes, foot pain and sinews edema.
	雞鳴散	證治準繩			
73	Jhih-Gan-Cao-Tang (Zhi-Gan-Cao-Tang)	Shang-Han-Lun (Shang-Han-Lun)	Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 3, Zingiberis Rhizoma Recens 2.5, Cinnamomi Ramulus 2.5, Ginseng Radix et Rhizoma 1.5, Rehmanniae Radix Recens 12, Asini Corii Colla 1.5, Ophiopogonis Radix 2.5, Cannabis Fructus 3, Jujubae Fructus 3. (Daily dosage 31.5 g)	Tonify qi and blood, enrich yin and rehabilitate vessel.	Deficiency of qi and blood, bound pulse, palpitations, shortness of breath, oppression in the chest, consumptive disease and lung atrophy.
		Treatise on Febrile Diseases			
	炙甘草湯	傷寒論			
74	Cing-Zao-Jiou-Fei-Tang (Qing-Zao-Jiu-Fei-Tang)	Yi-Zong-Jin-Jian (Yi-Zong-Jin-Jian)	Mori Folium 7.5, Gypsum Fibrosum 6.5, Glycyrrhizae Radix et Rhizoma 2.5, Sesami Semen Nigrum 2.5, Asini Corii Colla 2, Ginseng Radix et Rhizoma 2, Ophiopogonis Radix 3, Armeniacae Semen Amarum 2, Eriobotryae Folium 2. (Daily dosage 30 g)	Clear dryness to moisten the lung.	Dryness invading the lung, headache and fever, dry cough without phlegm, qi counterflow and panting, thirst and vexation.
		Golden Mirror of Medicine			
	清燥救肺湯	醫宗金鑑			
75	Gan-Lu-Yin (Gan-Lu-Yin)	Tai-Ping-Huei-Min-He-Ji-Jyu-Fang (Tai-Ping-Hui-Min-He-Ji-Ju-Fang)	Rehmanniae Radix Praeparata 2.5, Ophiopogonis Radix 2.5, Citri Fructus Immaturus 2.5, Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 2.5, Artemisiae Scopariae Herba 2.5, Eriobotryae Folium 2.5, Dendrobii Caulis 2.5, Scutellariae Radix 2.5, Rehmanniae Radix Recens 2.5, Asparagi Radix 2.5. (Daily dosage 25 g)	Nourish yin and clear dampness-heat.	Dampness-heat of stomach meridian, fetid mouth odor and sore throat, mouth and tongue sores, gum atrophy and swollen gums.
		Prescription of Peaceful Benevolent Dispensary			
	甘露飲	太平惠民和劑局方			
76	Huang-Lian-Jie-Du-Tang (Huang-Lian-Jie-Du-Tang)	Wai-Tai-Mi-Yao (Wai-Tai-Mi-Yao)	Coptidis Rhizoma 6, Scutellariae Radix 6, Phellodendri Cortex 6, Gardeniae Fructus 6. (Daily dosage 24 g)	Clear heat and detoxicate.	Dry mouth and throat, reddish painful urination, constipation and all the fire-heat syndrome.
		The Medical Secrets of an Official			

No.	Formula Name	Reference	Composition	Effects	Indications
	黃連解毒湯	外台秘要			
77	Bai-Hu-Tang (Bai-Hu-Tang)	Shang-Han-Lun (Shang-Han-Lun)	Anemarrhenae Rhizoma 6, Gypsum Fibrosum 16, Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 2, Oryzae Semen 8. (Daily dosage 32 g)	Clear heat to engender fluid.	Yang brightness meridian syndrome or qi aspect heat of warm disease, manifested as thrist, fever, large and surging pulse, great sweating.
		Treatise on Febrile Diseases			
	白虎湯	傷寒論			
78	Liang-Ge-San (Liang-Ge-San0	Tai-Ping-Huei-Min-He-Ji-Jyu-Fang (Tai-Ping-Hui-Min-He-Ji-Ju-Fang)	Rhei Radix et Rhizoma 4, Natrii Sulfas 4, Glycyrrhizae Radix et Rhizoma 4, Forsythiae Fructus 8, Gardeniae Fructus 2, Scutellariae Radix 2, Menthae Herba 2, Lophatheri Caulis et Folium 2. (Daily dosage 28 g)	Clear heat and detoxicate, purge fire to relax the bowels.	Accumulated heat in viscera and bowels, agitation and thirst, mouth and tongue sores, swelling and painful throat, constipation and reddish urine.
		Prescription of Peaceful Benevolent Dispensary			
	涼膈散	太平惠民和劑局方			
79	Long-Dan-Sie-Gan-Tang (Long-Dan-Xie-Gan-Tang) (Wan)《Wan》	Li-Dong-Yuan-Fang (Li-Dong-Yuan-Fang)	Gentianae Radix et Rhizoma 4, Scutellariae Radix 2, Gardeniae Fructus 2, Alismatis Rhizoma 4, Akebiae Caulis 2, Plantaginis Semen 2, Angelicae Sinensis Radix 2, Rehmanniae Radix Recens 2, Bupleuri Radix 4, Glycyrrhizae Radix et Rhizoma 2. (Daily dosage 26 g)	Purge liver fire and drain dampness-heat.	Accumulated heat in viscera and bowels, tinnitus and deafness, ear swelling and pain, inhibited urination.
		Dong-Yuan Li's Prescriptions			
	龍膽瀉肝湯（丸）《丸》	李東垣方			
80	Cing-Wei-San (Qing-Wei-San)	Lan-Shih-Mi-Cang (Lan-Shi-Mi-Cang)	Angelicae Sinensis Radix 3.6, Coptidis Rhizoma 3.6, Rehmanniae Radix Recens 3.6, Moutan Radicis Cortex 6, Cimicifugae Rhizoma 12. (Daily dosage 28.8 g)	Clear stomach fire and cool blood-heat.	Toothache, facial heat, swelling and painful lips, mouth and cheeks with sores, bleeding gum atrophy and ulcerating sore gums induced by stomach fire.
		Medical Works Secretly Kept in Imperial Library			
	清胃散	蘭室秘藏			

No.	Formula Name	Reference	Composition	Effects	Indications
81	Gan-Lu-Siao-Du-Dan (Gan-Lu-Xiao-Du-Dan) 《Dan》	Yi-Siao-Mi-Chuan (Yi-Xiao-Mi-Chuan)	Talcum 6, Scutellariae Radix 4, Artemisiae Scopariae Herba 4.4, Pogostemonis Herba 1.6, Forsythiae Fructus 1.6, Acori Graminei Rhizoma 2.4, Amomi Rotundus Fructus 1.6, Menthae Herba 1.6, Akebiae Caulis 2, Belamcandae Rhizoma 1.6, Fritillariae Cirrhosae Bulbus 2. (Daily dosage 28.8 g)	Resolve turbidity and drain dampness, Clear heat and detoxicate.	Summerheat-dampness, seasonal epidemic and heat fatigue, oppression in the chest and abdominal distention, swelling throat and thirst, hematuria and difficult urination.
		Effective Secret Formula			
	甘露消毒丹《丹》	醫效秘傳			
82	Cing-Sin-Lian-Zih-Yin (Qing-Xin-Lian-Zi-Yin)	Tai-Ping-Huei-Min-He-Ji-Jyu-Fang (Tai-Ping-Hui-Min-He-Ji-Ju-Fang)	Nelumbinis Fructus 4.5, Poria 4.5, Astragali Radix 4.5, Ginseng Radix et Rhizoma 4.5, Ophiopogonis Radix 3, Lycii Radicis Cortex 3, Scutellariae Radix 3, Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 3, Plantaginis Semen 3. (Daily dosage 33 g)	Clear heart fire, tonify qi and yin.	Upper excess and lower deficiency, heart fire flaming upward, bitter taste in the mouth and dry throat, bladder dampness-heat, seminal emission turbid and dripping.
		Prescription of Peaceful Benevolent Dispensary			
	清心蓮子飲	太平惠民和劑局方			
83	Dao-Chih-San (Dao-Chi-San)	Siao-Er-Yao-Jheng-Jhih-Jyue (Xiao-Er-Yao-Zheng-Zhi-Jue)	Rehmanniae Radix Recens 6, Glycyrrhizae Radix et Rhizoma 6, Akebiae Caulis 6, Lophatheri Caulis et Folium 6. (Daily dosage 24 g)	Clear heart fire and drain urination.	Oral erosion and tongue sore, reddish painful urination, inhibited heat strangury.
		Key to Therapeutics of Childen’s Diseases			
	導赤散	小兒藥證直訣			
84	Yu-Nyu-Jian (Yu-Nu-Jian)	Jing-Yue-Cyuan-Shu (Jing-Yue-Quan-Shu)	Gypsum Fibrosum Crudum 10, Rehmanniae Radix Praeparata 10, Ophiopogonis Radix 5, Anemarrhenae Rhizoma 4, Achyranthis Bidentatae Radix 4. (Daily dosage 33 g)	Clear stomach and nourish yin.	Yin deficiency and stomach heat, vexing heat and thirst, headache and toothache.
		Complete Works of Jingyue			
	玉女煎	景岳全書			

No.	Formula Name	Reference	Composition	Effects	Indications
85	Jing-Jie-Lian-Ciao-Tang (Jing-Jie-Lian-Qiao-Tang)	Shen-Shih-Zun-Sheng-Shu (Shen-Shi-Zun-Sheng-Shu)	Angelicae Sinensis Radix 2, Paeoniae Radix Alba 2, Chuanxiong Rhizoma 2, Scutellariae Radix 2, Gardeniae Fructus 2, Forsythiae Fructus 2, Nepetae Herba 2, Saposhnikoviae Radix 2, Citri Fructus Immaturus 2, Glycyrrhizae Radix et Rhizoma 1.5, Angelicae Dahuricae Radix 2, Platycodonis Radix 2, Bupleuri Radix 2. (Daily dosage 25.5 g)	Clear heat and detoxicate.	Wind-heat, ear swelling and pain.
		Shen's Health Keeping			
	荊芥連翹湯	沈氏尊生書			
86	Zih-Yin-Jiang-Huo-Tang (Zi-Yin-Jiang-Huo-Tang)	Shen-Shih-Zun-Sheng-Shu (Shen-Shi-Zun-Sheng-Shu)	Paeoniae Radix Alba 2.5, Angelicae Sinensis Radix 2.5, Rehmanniae Radix Praeparata 2, Atractylodis Macrocephalae Rhizoma 2, Asparagi Radix 2, Ophiopogonis Radix 2, Rehmanniae Radix Recens 1.5, Citri Reticulatae Pericarpium 1.5, Anemarrhenae Rhizoma 1, Phellodendri Cortex 1, Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 1, Zingiberis Rhizoma Recens 3, Jujubae Fructus 2. (Daily dosage 24 g)	Nourish yin and downbear fire.	Yin deficiency with fever, cough with phlegm, rapid panting, night weating and dry mouth.
		Shen's Health Keeping			
	滋陰降火湯	沈氏尊生書			
87	Dang-Guei-Long-Huei-Wan-Cyu-She-Siang (Dang-Gui-Long-Hui-Wan-Qu-She-Xian) 《Wan》	Dan-Si-Sin-Fa (Dan-Xi-Xin-Fa)	Angelicae Sinensis Radix 3, Gentianae Radix et Rhizoma 3, Aloe 1.5, Gardeniae Fructus 3, Coptidis Rhizoma 3, Scutellariae Radix 3, Phellodendri Cortex 3, Rhei Radix et Rhizoma 1.5, Aucklandiae Radix 0.75, Indigo Naturalis 1.5,~~ Moschus 0.15~~. (Daily dosage 23.25 g)	Purge excess liver and spleen fire, relax the bowels.	Liver-gallbladder with fire effulgence, disquieted fright palpitations and constipation.
		Danxi`s Experiential Therapy			
	當歸龍薈丸去麝香《丸》	丹溪心法			
88	Sin-Yi-Cing-Fei-Tang (Xin-Yi-Qing-Fei-Tang)	Wai-Ke-Jheng-Zong (Wai-Ke-Zheng-Zong)	Magnoliae Flos 2, Scutellariae Radix 3, Gardeniae Fructus 3, Ophiopogonis Radix 3, Lilii Bulbus 3,	Clear lung heat.	Nasal congestion and nasal polyp.

No.	Formula Name	Reference	Composition	Effects	Indications
		Orthodox Manual of External Disease	Gypsum Fibrosum 3, Anemarrhenae Rhizoma 3, Glycyrrhizae Radix et Rhizoma 1.5, Eriobotryae Folium 3, Cimicifugae Rhizoma 1. (Daily dosage 25.5 g)		
	辛夷清肺湯	外科正宗			
89	Hua-Gai-San (Hua-Gai-San)	Tai-Ping-Huei-Min-He-Ji-Jyu-Fang (Tai-Ping-Hui-Min-He-Ji-Ju-Fang)	Ephedrae Herba 4, Perillae Fructus 4, Mori Radicis Cortex 4, Armeniacae Semen Amarum 4, Poria Rubra 4, Citri Reticulatae Pericarpium 4, Glycyrrhizae Radix et Rhizoma 2. (Daily dosage 26 g)	Diffuse the lung to calm panting, suppress cough and resolve phlegm.	Lung with pathogenic cold, cough with dyspnea, vexation and stuffiness in the chest and diaphragm, dizzy vision.
		Prescription of Peaceful Benevolent Dispensary			
	華蓋散	太平惠民和劑局方			
90	Cing-Fei-Tang (Qing-Fei-Tang)	Zeng-Bu-Wan-Bing-Huei-Chun (Zeng-Bu-Wan-Bing-Hui-Chun)	Glycyrrhizae Radix et Rhizoma 0.6, Scutellariae Radix 3, Platycodonis Radix 2, Poria 2, Citri Reticulatae Pericarpium 2, Angelicae Sinensis Radix 2, Fritillariae Cirrhosae Bulbus 2, Mori Radicis Cortex 2, Asparagi Radix 1.5, Gardeniae Fructus 1.5, Armeniacae Semen Amarum 1.5, Ophiopogonis Radix 1.5, Schisandrae Chinensis Fructus 0.4, Zingiberis Rhizoma Recens 3, Jujubae Fructus 2, Bambusae Caulis in Taenias 2. (Daily dosage 29 g)	Clear liver, resolve phlegm and suppress cough.	Cough and upper energizer with copious phlegm.
		Supplement of Recovery from All Ailments			
	清肺湯	增補萬病回春			
91	Jhih-Sou-San (Zhi-Sou-San) 《San》	Yi-Syue-Sin-Wu (Yi-Xue-Xin-Wu)	Platycodonis Radix 5, Nepetae Herba 5, Asteris Radix et Rhizoma 5, Stemonae Radix 5, Cynanchi Stauntonii Rhizoma et Radix 5, Glycyrrhizae Radix et Rhizoma 2, Citri Reticulatae Pericarpium 2.5. (Daily dosage 29.5 g)	Disperse wind to release the exterior, resolve phlegm and suppress cough.	Cough induced by exopathogen and inhibited expectoration.
		Medicine Comprehended			
	止嗽散《散》	醫學心悟			

No.	Formula Name	Reference	Composition	Effects	Indications
92	Jin-Fei-Cao-San (Jin-Fei-Cao-San)	Tai-Ping-Huei-Min-He-Ji-Jyu-Fang (Tai-Ping-Hui-Min-He-Ji-Ju-Fang)	Nepetae Herba 6, Peucedani Radix 4.5, Ephedrae Herba 4.5, Inulae Flos 4.5, Glycyrrhizae Radix et Rhizoma 1.5, Pinelliae Rhizoma Praeparatum 1.5, Paeoniae Radix Rubra 1.5, Zingiberis Rhizoma Recens 3, Jujubae Fructus 1. (Daily dosage 28 g)	Release the exterior to dissipate cold, dispel wind and resolve phlegm.	Lung with wind-cold and cough with copious phlegm.
		Prescription of Peaceful Benevolent Dispensary			
	金沸草散	太平惠民和劑局方			
93	Siang-Sha-Liou-Jyun-Zih-Tang (Xiang-Sha-Liu-Jun-Zi-Tang)	Shan-Bu-Ming-Yi-Fang-Lun (Shan-Bu-Ming-Yi-Fang-Lun)	Ginseng Radix et Rhizoma 2.5, Atractylodis Macrocephalae Rhizoma 5, Poria 5, Glycyrrhizae Radix et Rhizoma 2, Citri Reticulatae Pericarpium 2, Pinelliae Rhizoma Praeparatum 2.5, Amomi Fructus 2, Aucklandiae Radix 2, Zingiberis Rhizoma Recens 5. (Daily dosage 28 g)	Fortify the spleen and nourish the stomach.	Qi deficiency and phlegm-retained fluid, stuffiness and oppression in vomiting, abdominal distention.
		Revised Famous Doctor's Prescription			
	香砂六君子湯	刪補名醫方論			
94	Jhih-Jhuo-Gu-Ben-Wan (Zhi-Zhuo-Gu-Ben-Wan) 《Wan》	Yi-Syue-Jheng-Jhuan (Yi-Xue-Zheng-Zhuan)	Nelumbinis Stamen 4, Coptidis Rhizoma 4, Poria 2, Amomi Fructus 2, Alpiniae Oxyphyllae Semen with Shell Removed 2, Pinelliae Rhizoma Praeparatum 2, Phellodendri Cortex 2, Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 6, Polyporus 5. (Daily dosage 29 g)	Clear heat and drain dampness.	Lower energizer dampness-heat, frequent urination and white turbidity.
		Orthodox Transmission of Medicine			
	治濁固本丸《丸》	醫學正傳			
95	Dang-Guei-Liou-Huang-Tang (Dang-Gui-Liu-Huang-Tang)	Lan-Shih-Mi-Cang (Lan-Shi-Mi-Cang)	Angelicae Sinensis Radix 3.5, Rehmanniae Radix Recens 3.5, Rehmanniae Radix Praeparata 3.5, Phellodendri Cortex 3.5, Scutellariae Radix 3.5, Coptidis Rhizoma 3.5, Astragali Radix 7. (Daily dosage 28 g)	Nourish yin and clear heat, secure the exterior to stop sweating.	Yin deficiency with fire, night sweating and fever.
		Medical Works Secretly Kept in Imperial Library			
	當歸六黃湯	蘭室秘藏			

No.	Formula Name	Reference	Composition	Effects	Indications
96	San-Jhong-Kuei-Jian-Tang (San-Zhong-Kui-Jian-Tang)	Lan-Shih-Mi-Cang (Lan-Shi-Mi-Cang)	Scutellariae Radix 4, Gentianae Radix et Rhizoma 2.5, Trichosanthis Radix 2.5, Phellodendri Cortex 4, Anemarrhenae Rhizoma 2.5, Platycodonis Radix 2.5, Eckloniae Thallus 2.5, Bupleuri Radix 2.5, Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 1.5, Sparganii Rhizoma 1.5, Curcumae Rhizoma 1.5, Forsythiae Fructus 1.5, Puerariae Radix 1.5, Paeoniae Radix Alba 1, Rootlet of Angelicae Sinensis Radix 1, Coptidis Rhizoma 1, Cimicifugae Rhizoma 0.5. (Daily dosage 34 g)	Clear heat and detoxicate, break accumulation and promote rupture.	Scrofula and subcutaneous node.
		Medical Works Secretly Kept in Imperial Library			
	散腫潰堅湯	蘭室秘藏			
97	Pai-Nong-San (Pai-Nong-San) 《San》	Jin-Kuei-Yao-Lyue (Jin-Kui-Yao-Lue)	Aurantii Fructus Immaturus 18, Paeoniae Radix Alba 6, Platycodonis Radix 2. (Daily dosage 26 g)	Expel pus to relieve pain.	Stool with internal abscess and pus.
		Synopsis of Golden Cabinet			
	排膿散《散》	金匱要略			
98	Ru-Yi-Jin-Huang-San (Ru-Yi-Jin-Huang-San)	Wai-Ke-Jheng-Zong (Wai-Ke-Zheng-Zong)	Trichosanthis Radix 25, Phellodendri Cortex 12.5, Rhei Radix et Rhizoma 12.5, Curcumae Longae Rhizoma 12.5, Angelicae Dahuricae Radix 12.5, Magnoliae Cortex 5, Citri Reticulatae Pericarpium 5, Glycyrrhizae Radix et Rhizoma 5, Atractylodis Rhizoma 5, Arisaematis Rhizoma Recens 5 (Apply adequately.)	Disperse swelling, detoxicate and relieve pain.	Abscess and ulcer, swelling boil, acute mastitis, erysipelas, lacquer dermatitis, scald, knocks and falls.
		Orthodox Manual of External Disease			
	如意金黃散(Only for traditional formula.)	外科正宗			
99	Wan-Dai-Tang (Wan-Dai-Tang)	Fu-Cing-Jhu-Nyu-Ke (Fu-Qing-Zhu-Nu-Ke)	Atractylodis Macrocephalae Rhizoma 10, Dioscoreae Rhizoma 10, Ginseng Radix et Rhizoma 2, Paeoniae		White vaginal discharge.

No.	Formula Name	Reference	Composition	Effects	Indications
		Fu Qingzhu's Gynecology and Obstetrics	Radix Alba 5, Plantaginis Semen 3, Atractylodis Rhizoma 3, Glycyrrhizae Radix et Rhizoma 1, Citri Reticulatae Pericarpium 0.5, Nepetae Herba Carbonisata 0.5, Bupleuri Radix 0.6. (Daily dosage 35.6 g)	Dry dampness to fortify the spleen, soothe the liver and regulate qi.	
	完帶湯	傅青主女科			
100	Tiao-Jing-Wan (Tiao-Jing-Wan) 《Wan》	Liou-Ke-Jhun-Sheng (Liu-Ke-Zhun-Sheng)	Cyperi Rhizoma 4, Eucommiae Cortex 4, Chuanxiong Rhizoma 2, Paeoniae Radix Alba 2, Angelicae Sinensis Radix 2, Rehmanniae Radix Recens 2, Citri Reticulatae Pericarpium 2, Foeniculi Fructus 2, Corydalis Rhizoma 2, Cistanchis Herba 2, Citri Reticulatae Pericarpium Viride 2, Linderae Radix 2, Scutellariae Radix 2, Sepiae Endoconcha 2. (Daily dosage 32 g)	Activate blood to regulate menstruation, move qi to relieve pain.	Menstrual irregularities, dysmenorrhea, postpartum static blood and abdominal pain.
		Standards for Diagnosis and Treatment			
	調經丸《丸》	六科準繩	Add vinegar and flour q.s. to make pills in traditional formula.		
101	Sheng-Yu-Tang (Sheng-Yu-Tang)	Yi-Zong-Jin-Jian (Yi-Zong-Jin-Jian)	Rehmanniae Radix Praeparata 5, Chuanxiong Rhizoma 2.5, Ginseng Radix et Rhizoma 5, Angelicae Sinensis Radix 2.5, Astragali Radix 5, Paeoniae Radix Alba 5. (Daily dosage 25 g)	Tonify qi and blood.	Dual deficiency of qi and blood, polydipsia and dryness-heat, insomnia, fatigue and poor appetite.
		Golden Mirror of Medicine			
	聖愈湯	醫宗金鑑			
102	Shih-Shen-Tang (Shi-Shen-Tang)	Tai-Ping-Huei-Min-He-Ji-Jyu-Fang (Tai-Ping-Hui-Min-He-Ji-Ju-Fang)	Citri Reticulatae Pericarpium 2, Ephedrae Herba 2, Chuanxiong Rhizoma 2, Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 2, Cyperi Rhizoma 2, Perillae Folium 2, Angelicae Dahuricae Radix 2, Cimicifugae Rhizoma 2, Puerariae Radix 7, Paeoniae Radix Rubra 2, Zingiberis Rhizoma Recens 3. (Daily dosage 28 g)	Release the flesh to effuse exterior, regulate qi and free yang.	Common cold and wind-cold, aversion to cold with fever, headache without sweating, cough and nasal congestion.
		Prescription of Peaceful Benevolent Dispensary			
	十神湯	太平惠民和劑局方			

No.	Formula Name	Reference	Composition	Effects	Indications
103	Sheng-Ma-Ge-Gen-Tang (Sheng-Ma-Ge-Gen-Tang) 《San》	Yi-Fang-Ji-Jie (Yi-Fang-Ji-Jie) / Collected Explanation on Prescriptions	Puerariae Radix 6, Cimicifugae Rhizoma 9, Paeoniae Radix Alba 6, Glycyrrhizae Radix et Rhizoma 3, Zingiberis Rhizoma Recens 3. (Daily dosage 27 g)	Release the flesh to outthrust rashes, release smallpox heat toxin.	The initial stage or onset but not thorough of measles, aversion to wind with fever, sneezing and cough.
	升麻葛根湯《散》	醫方集解	Without Zingiberis Rhizoma Recens in traditional formula.		
104	Sin-Yi-San (Xin-Yi-San) 《San》	Yi-Fang-Ji-Jie (Yi-Fang-Ji-Jie) / Collected Explanation on Prescriptions	Magnoliae Flos 2.5, Asari Radix et Rhizoma 2.5, Ligustici Rhizoma et Radix 2.5, Cimicifugae Rhizoma 2.5, Chuanxiong Rhizoma 2.5, Akebiae Caulis 2.5, Saposhnikoviae Radix 2.5, Glycyrrhizae Radix et Rhizoma 2.5, Angelicae Dahuricae Radix 2.5, Camelliae Sinensis Folium 2.5. (Daily dosage 25 g)	Disperse wind-cold, dispel dampness pathogen and relieve the stuffy nose.	Nasal congestion induced by the initial stage of common cold, watery nasal mucus.
	辛夷散《散》	醫方集解			
105	Siao-Cheng-Ci-Tang (Xiao-Cheng-Qi-Tang)	Shang-Han-Lun (Shang-Han-Lun) / Treatise on Febrile Diseases	Rhei Radix et Rhizoma 14, Magnoliae Cortex 7, Aurantii Fructus Immaturus 7. (Daily dosage 28 g)	Discharge heat to relax the bowels, eliminate stuffiness and remove food stagnations.	Yang brightness excess heat, abdominal fullness and constipation.
	小承氣湯	傷寒論			
106	Tiao-Wei-Cheng-Ci-Tang (Tiao-Wei-Cheng-Qi-Tang)	Shang-Han-Lun (Shang-Han-Lun) / Treatise on Febrile Diseases	Rhei Radix et Rhizoma 8, Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 4, Natrii Sulfas 16. (Daily dosage 28 g)	Soften hardness to relax the bowels, harmonize the stomach and discharge heat.	Yang brightness heat bind, thirst and vexation, abdominal fullness and constipation.
	調胃承氣湯	傷寒論			
107	Tao-Ren-Cheng-Ci-Tang (Tao-Ren-Cheng-Qi-Tang) Tao-He-Cheng-Ci-Tang (Tao-He-Cheng-Qi-Tang)	Shang-Han-Lun (Shang-Han-Lun) / Treatise on Febrile Diseases	Persicae Semen Praeparatum 5, Cinnamomi Ramulus 5, Rhei Radix et Rhizoma 10, Natrii Sulfas 5, Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 5. (Daily dosage 30 g)	Relax the bowels and dissipate stasis.	Blood amass in lower energizer, lower abdomen cramp, spontaneous urination, blood stasis and amenorrhea.

No.	Formula Name	Reference	Composition	Effects	Indications
	桃仁承氣湯 (桃核承氣湯)	傷寒論			
108	Da-Chai-Hu-Tang (Da-Chai-Hu-Tang)	Shang-Han-Lun (Shang-Han-Lun)	Bupleuri Radix 8, Scutellariae Radix 3, Paeoniae Radix Alba 3, Pinelliae Rhizoma Praeparatum 5, Zingiberis Rhizoma Recens 5, Aurantii Fructus Immaturus 2, Jujubae Fructus 2, Rhei Radix et Rhizoma 2. (Daily dosage 30 g)	Harmonize and release the lesser yang, Drastic (purgative) heat-accumulation.	Cold damage entering yang brightness, incompletely release the lesser yang disease, alternating chills and fever, stuffiness and fullness below the heart, persistent vomiting, vexation and constipation.
		Treatise on Febrile Diseases			
	大柴胡湯	傷寒論			
109	Fang-Fong-Tong-Sheng-San (Fang-Feng-Tong-Sheng-San) 《San》	Yi-Fang-Ji-Jie (Yi-Fang-Ji-Jie)	Saposhnikoviae Radix 1, Nepetae Herba 1, Forsythiae Fructus 1, Ephedrae Herba 1, Menthae Herba 1, Chuanxiong Rhizoma 1, Angelicae Sinensis Radix 1, Paeoniae Radix Alba 1, Atractylodis Macrocephalae Rhizoma 1, Gardeniae Fructus 1, Rhei Radix et Rhizoma 1, Natrii Sulfas 1, Scutellariae Radix 2, Gypsum Fibrosum 2, Platycodonis Radix 2, Glycyrrhizae Radix et Rhizoma 4, Talcum 6, Zingiberis Rhizoma Recens 2, Allii Fistulosi Bulbus Recens 2. (Daily dosage 32 g)	Release the exterior and relieve interior, disperse wind to clear heat.	All excess of the exterior, interior and triple energizers, constipation, short and reddish urine, sore and ulcer, swelling toxin.
		Collected Explanation on Prescriptions			
	防風通聖散《散》	醫方集解	Without Zingiberis Rhizoma Recens and Allii Fistulosi Bulbus Recens to make fine powder in traditional formula.		
110	Ge-Gen-Huang-Cin-Huang-Lian-Tang (Ge-Gen-Huang-	Shang-Han-Lun (Shang-Han-Lun)		Clear heat to release the exterior.	Exterior syndrome unsolved, heat pathogen entering the

No.	Formula Name	Reference	Composition	Effects	Indications
	Qin-Huang-Lian-Tang)	Treatise on Febrile Diseases	Puerariae Radix 12, Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 3, Scutellariae Radix 4.5, Coptidis Rhizoma 4.5. (Daily dosage 24 g)		interior, fever and diarrhea, vexing heat in the chest and stomach, panting with sweating.
	葛根黃芩黃連湯	傷寒論			
111	Sang-Jyu-Yin (Sang-Ju-Yin)	Wun-Bing-Tiao-Bian (Wen-Bing-Tiao-Bian) Differentiation and Treatment of Epidemic Febrile Diseases	Armeniacae Semen Amarum Praeparatum 5, Forsythiae Fructus 4, Menthae Herba 2, Mori Folium 6, Chrysanthemi Flos 2.5, Platycodonis Radix 5, Glycyrrhizae Radix et Rhizoma 2, Phragmitis Rhizoma 5. (Daily dosage 31.5 g)	Disperse wind to clear heat, diffuse the lung to suppress cough.	The initial stage of wind-warmth, cough, fever and thirst.
	桑菊飲	溫病條辨			
112	Sing-Su-San (Xing-Su-San)	Wun-Bing-Tiao-Bian (Wen-Bing-Tiao-Bian) Differentiation and Treatment of Epidemic Febrile Diseases	Perillae Folium 3, Pinelliae Rhizoma Praeparatum 3, Poria 3, Peucedani Radix 2, Platycodonis Radix 2, Citri Fructus Immaturus 2 Glycyrrhizae Radix et Rhizoma 1, Zingiberis Rhizoma Recens 2, Jujubae Fructus 2, Citri Reticulatae Pericarpium recens 1, Armeniacae Semen Amarum Praeparatum 3. (Daily dosage 24 g)	Warm and disperse wind-cold, diffuse the lung to resolve phlegm.	Common cold, fever, headache and cough with phlegm.
	杏蘇散	溫病條辨			
113	Yin-Ciao-San (Yin-Qiao-San)	Wun-Bing-Tiao-Bian (Wen-Bing-Tiao-Bian) Differentiation and Treatment of Epidemic Febrile Diseases	Forsythiae Fructus 5, Lonicerae Flos 5, Platycodonis Radix 3, Menthae Herba 3, Lophatheri Caulis et Folium 2, Glycyrrhizae Radix et Rhizoma 2.5, Nepetae Herba 2, Sojae Semen Preparatum 2.5, Arctii Fructus 3, Phragmitis Rhizoma 2. (Daily dosage 30 g)	Outthrust through the exterior with pungent-cool, clear heat and detoxicate.	The initial stage of warm disease, slight aversion to wind-cold with fever, headache and thirst, cough and sore throat.
	銀翹散	溫病條辨			
114	Chai-Hu-Guei-Jhih-Tang (Chai-Hu-Gui-Zhi-Tang)	Shang-Han-Lun (Shang-Han-Lun)	Cinnamomi Ramulus 3, Scutellariae Radix 3, Ginseng Radix et Rhizoma 3, Glycyrrhizae Radix et Rhizoma	Release both the exterior and interior.	Both lesser yang syndrome and greater yang exterior

No.	Formula Name	Reference	Composition	Effects	Indications
		Treatise on Febrile Diseases	Praeparatum cum Melle 2, Pinelliae Rhizoma Praeparatum 5, Paeoniae Radix Alba 3, Jujubae Fructus 2, Zingiberis Rhizoma Recens 3, Bupleuri Radix 8. (Daily dosage 32 g)		syndrome, fever, slight aversion to cold, painful limb joints, slight vomiting, tightness below the heart.
	柴胡桂枝湯	傷寒論			
115	Siao-Chai-Hu-Tang (Xiao-Chai-Hu-Tang)	Shang-Han-Lun (Shang-Han-Lun)	Bupleuri Radix 8, Scutellariae Radix 3, Ginseng Radix et Rhizoma 3, Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 3, Pinelliae Rhizoma Praeparatum 5, Zingiberis Rhizoma Recens 3, Jujubae Fructus 2. (Daily dosage 27 g)	Harmonize and release the lesser yang.	Lesser yang syndrome, alternating chills and fever, fullness in the chest and hypochondrium, poor appetite, vexation and feel nauseated, bitter taste in the mouth, dry throat and dizzy vision.
		Treatise on Febrile Diseases			
	小柴胡湯	傷寒論			
116	Shao-Yao-Gan-Cao-Tang (Shao-Yao-Gan-Cao-Tang)	Shang-Han-Lun (Shang-Han-Lun)	Paeoniae Radix Alba 12, Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 12. (Daily dosage 24 g)	Relax tension to relieve pain.	Abdominal pain and foot spasm.
		Treatise on Febrile Diseases			
	芍藥甘草湯	傷寒論			
117	Chai-Sian-Tang (Chai-Xian-Tang)	Shen-Shih-Zun-Sheng-Shu (Shen-Shi-Zun-Sheng-Shu)	Pinelliae Rhizoma Praeparatum 9, Trichosanthis Semen 6, Bupleuri Radix 6, Coptidis Rhizoma 3, Scutellariae Radix 3, Ginseng Radix et Rhizoma 2, Glycyrrhizae Radix et Rhizoma 1.5, Zingiberis Rhizoma Recens 3, Jujubae Fructus 2. (Daily dosage 35.5 g)	Clear heat to dispel phlegm, soothe the chest to disperse nodules.	Binding of phlegm and heat, chest impediment and cough.
		Shen's Health Keeping			
	柴陷湯	沈氏尊生書			
118	Huang-Lian-Tang (Huang-Lian-Tang)	Shang-Han-Lun (Shang-Han-Lun)	Coptidis Rhizoma 4.5, Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 4.5, Zingiberis Rhizoma 4.5, Cinnamomi Ramulus 4.5, Ginseng Radix et Rhizoma 3,	Harmonize cold and heat, harmonize the stomach to downbear counterflow.	Chest heat, stomach cold, abdominal pain and feel nauseated.
		Treatise on Febrile Diseases			

No.	Formula Name	Reference	Composition	Effects	Indications
	黃連湯	傷寒論	Pinelliae Rhizoma Praeparatum 6, Jujubae Fructus 3. (Daily dosage 30 g)		
119	Sih-Ni-San (Si-Ni-San) 《San》	Shang-Han-Lun (Shang-Han-Lun)	Glycyrrhizae Radix et Rhizoma 6, Aurantii Fructus Immaturus 6, Bupleuri Radix 6, Paeoniae Radix Alba 6. (Daily dosage 24 g)	Soothe the liver and regulate the spleen.	Reversal cold of the extremities, cough and palpitations, inhibited urination, abdomina pain and heaviness dysentery.
		Treatise on Febrile Diseases			
	四逆散《散》	傷寒論			
120	Syuan-Fu-Dai-Jhe-Shih-Tang (Xuan-Fu-Dai-Zhe-Shi-Tang)	Shang-Han-Za-Bing-Lun (Shang-Han-Za-Bing-Lun)	Inulae Flos 4.5, Ginseng Radix et Rhizoma 3, Zingiberis Rhizoma Recens 7.5, Pinelliae Rhizoma Praeparatum 7.5, Haematitum 1.5, Jujubae Fructus 4, Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 4.5. (Daily dosage 32.5 g)	Reinforce the healthy qi and tonify stomach, downbear counterflow and resolve phlegm.	After sweating, vomiting and diarrhea, stuffiness below the heart and belch persistently.
		Treatise on Cold Damage and Miscellaneous Diseases			
	旋覆代赭石湯	傷寒雜病論			
121	Ban-Sia-Hou-Pu-Tang (Ban-Xia-Hou-Pu-Tang)	Jin-Kuei-Yao-Lyue (Jin-Kui-Yao-Lue)	Pinelliae Rhizoma Praeparatum 8, Magnoliae Cortex 4.5, Poria 6, Zingiberis Rhizoma Recens 7.5, Perillae Folium 3. (Daily dosage 29 g)	Move qi to open stagnation, downbear counterflow and resolve phlegm.	Plum-pit qi (a disease characterized by a sensation of a foreign body present in the throat which can be neither swallowed nor ejecte), fullness and oppression in the chest and stomach, cough or vomiting.
		Synopsis of Golden Cabinet			
	半夏厚朴湯	金匱要略			
122	Jyu-Pi-Jhu-Ru-Tang (Ju-Pi-Zhu-Ru-Tang)	Ji-Sheng-Fang (Ji-Sheng-Fang)	Poria Rubra 3, Citri Reticulatae Pericarpium 3, Eriobotryae Folium 3, Ophiopogonis Radix 3, Bambusae Caulis in Taenias 3, Pinelliae Rhizoma Praeparatum 3, Ginseng Radix et Rhizoma 1.5,	Regulate qi and clear heat, harmonize the middle and downbear counterflow.	Stomach heat and thirst, retching and poor appetite.
		Recipes for Saving Lives			

No.	Formula Name	Reference	Composition	Effects	Indications
	橘皮竹茹湯	濟生方	Glycyrrhizae Radix et Rhizoma 1.5, Zingiberis Rhizoma Recens 3, Jujubae Fructus 2. (Daily dosage 26 g)		
123	Jyu-He-Wan (Ju-He-Wan) 《Wan》	Ji-Sheng-Fang (Ji-Sheng-Fang) / Recipes for Saving Lives	Citri Reticulatae Semen 4, Sargassum 4, Eckloniae Thallus 4, Laminariae Thallus 4, Azedarach Fructus 4, Persicae Semen Praeparatum 4, Magnoliae Cortex 1, Akebiae Caulis 1, Aurantii Fructus Immaturus 1, Corydalis Rhizoma 1, Cinnamomi Cortex Centralis 1, Aucklandiae Radix 1. (Daily dosage 30 g)	Move qi to break stagnation, soften hardness and dissipate binds.	Genital disease, swollen testicle which varying in size or hard as stone, or inducing gripping pain in umbilicus and abdomen, and swollen scrotum.
	橘核丸《丸》	濟生方			
124	Fu-Yuan-Huo-Sie-Tang-Cyu-Chuan-Shan-Jia (Fu-Yuan-Huo-Xie-Tang-Qu-Chuan-Shan-Jia)	Yi-Syue-Fa-Ming (Yi-Xue-Fa-Ming) / Invention of Medicine	Bupleuri Radix 5, Angelicae Sinensis Radix 3, Trichosanthis Radix 3, ~~Manis Squama 2,~~ Glycyrrhizae Radix et Rhizoma 2, Carthami Flos 2, Persicae Semen 2, Rhei Radix et Rhizoma 10. (Daily dosage 27 g)	Activate blood and resolve stasis.	Knocks and falls, static blood stay below the hypochondrium and with severe pain.
	復元活血湯去穿山甲	醫學發明			
125	Da-Huang-Mu-Dan-Pi-Tang (Da-Huang-Mu-Dan-Pi-Tang)	Jin-Kuei-Yao-Lyue (Jin-Kui-Yao-Lue) / Synopsis of Golden Cabinet	Rhei Radix et Rhizoma 10, Moutan Radicis Cortex 2.5, Persicae Semen Praeparatum 2.5, Benincasae Semen 6, Natrii Sulfas 7. (Daily dosage 28 g)	Discharge heat and break stasis, dissipate binds to disperse swelling.	Intestinal abscess, swelling and stuffiness in lower abdomen which severe pain when pressing, aversion to cold with fever.
	大黃牡丹皮湯	金匱要略			
126	Shao-Yao-Tang (Shao-Yao-Tang)	Bing-Ji-Ci-Yi-Bao-Ming-Ji (Bing-Ji-Qi-Yi-Bao-Ming-Ji) / Pathogenesis Relieved Life Saving	Paeoniae Radix Alba 7, Angelicae Sinensis Radix 3.5, Scutellariae Radix 3.5, Coptidis Rhizoma 3.5, Rhei Radix et Rhizoma 2, Aucklandiae Radix 1.5, Arecae Semen 1.5, Glycyrrhizae Radix et Rhizoma	Clear dampness-heat, regulate qi and blood.	Dysentery, stool containing pus and blood, abdominal pain and tenesmus.

No.	Formula Name	Reference	Composition	Effects	Indications
	芍藥湯	病機氣宜保命集	Praeparatum cum Melle 1.5, Cinnamomi Cortex 1. (Daily dosage 25 g)		
127	Guei-Jhih-Fu-Ling-Wan (Gui-Zhi-Fu-Ling-Wan) 《Wan》	Jin-Kuei-Yao-Lyue (Jin-Kui-Yao-Lue)	Cinnamomi Ramulus 6, Poria 6, Moutan Radicis Cortex 6, Persicae Semen Praeparatum 6, Paeoniae Radix Rubra 6. (Daily dosage 30 g)	Activate blood and resolve stasis, eliminate masses mildly.	Woman commonly has aggregated accumulation, threatened abortion in pregnancy, persistent spotting, static blood and dysmenorrhea, amenorrhea.
		Synopsis of Golden Cabinet			
	桂枝茯苓丸《丸》	金匱要略			
128	Dang-Guei-Nian-Tong-Tang (Dang-Gui-Nian-Tong-Tang)	Li-Dong-Yuan-Fang (Li-Dong-Yuan-Fang)	Angelicae Sinensis Radix 1.5, Ginseng Radix et Rhizoma 1.5, Artemisiae Scopariae Herba 3.5, Notopterygii Rhizoma et Radix 3.5, Saposhnikoviae Radix 2, Cimicifugae Rhizoma 1.5, Puerariae Radix 1.5, Atractylodis Rhizoma 1.5, Atractylodis Macrocephalae Rhizoma 2, Glycyrrhizae Radix et Rhizoma 3.5, Scutellariae Radix Tostum 3.5, Sophorae Flavescentis Radix 1.5, Anemarrhenae Rhizoma 2, Polyporus 2, Alismatis Rhizoma 2. (Daily dosage 33 g)	Clear heat and dry dampness, activate blood to relieve pain.	Lower energizer dampness-heat, whole body and joint pain, shoulder and back heaviness and all dampness-heat.
		Dong-Yuan Li's Prescriptions			
	當歸拈痛湯	李東垣方			
129	Sih-Ni-Tang (Si-Ni-Tang)	Shang-Han-Lun (Shang-Han-Lun)	Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 10, Zingiberis Rhizoma 7.5, Aconiti Lateralis Radix Preparata 10. (Daily dosage 27.5 g)	Warm the meridian and restore yang.	Yin exuberance with yang debilitation, reversal cold of the extremities, clear-food diarrhea, vomiting and abdominal pain.
		Treatise on Febrile Diseases			
	四逆湯	傷寒論			

No.	Formula Name	Reference	Composition	Effects	Indications
130	Dang-Guei-Sih-Ni-Tang (Dang-Gui-Si-Ni-Tang)	Shang-Han-Lun (Shang-Han-Lun)	Angelicae Sinensis Radix 4.5, Cinnamomi Ramulus 4.5, Paeoniae Radix Alba 4.5, Asari Radix et Rhizoma 4.5, Jujubae Fructus 6, Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 3, Akebiae Caulis 3. (Daily dosage 30 g)	Warm the meridian to dissipate cold, nourish blood to unblock vessels.	Cold entering the reverting yin, reversal cold of the extremities, faint pulse scarcely perceptible.
		Treatise on Febrile Diseases			
	當歸四逆湯	傷寒論			
131	Jhen-Wu-Tang (Zhen-Wu-Tang)	Shang-Han-Lun (Shang-Han-Lun)	Poria 7.5, Paeoniae Radix Alba 7.5, Zingiberis Rhizoma Recens 7.5, Atractylodis Macrocephalae Rhizoma 5, Aconiti Lateralis Radix Preparata 3. (Daily dosage 30.5 g)	Warm the kidney and dissipate cold, fortify the spleen and drain water.	Spleen-kidney yang deficiency and internal stagnation of water qi.
		Treatise on Febrile Diseases			
	真武湯	傷寒論			
132	Siao-Jian-Jhong-Tang (Xiao-Jian-Zhong-Tang)	Shang-Han-Jin-Kuei-Fang (Shang-Han-Jin-Kui-Fang)	Cinnamomi Ramulus 4.5, Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 3, Jujubae Fructus 4.5, Paeoniae Radix Alba 9, Zingiberis Rhizoma Recens 4.5, Maltose 1. (Daily dosage 26.5 g)	Warm the middle to tonify deficiency, harmonize the interior and relax tension.	Spleen-stomach deficiency cold, abdominal urgency and abdominal pain.
		Febrile and Golden Cabinet Formula			
	小建中湯	傷寒金匱方			
133	Da-Jian-Jhong-Tang (Da-Jian-Zhong-Tang)	Jin-Kuei-Yao-Lyue (Jin-Kui-Yao-Lue)	Zanthoxyli Pericarpium 4, Zingiberis Rhizoma 16, Ginseng Radix et Rhizoma 8, Maltose 1. (Daily dosage 29 g)	Warm the middle to tonify deficiency, downbear counterflow and relieve pain.	Thoracic fluid retention in diaphragm, panting, stuffiness and fullness below the heart.
		Synopsis of Golden Cabinet			
	大建中湯	金匱要略			
134	Huang-Ci-Jian-Jhong-Tang (Huang-Qi-Jian-Zhong-Tang)	Jin-Kuei-Yao-Lyue (Jin-Kui-Yao-Lue)	Cinnamomi Ramulus 4.5, Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 3, Jujubae Fructus 4.5, Paeoniae Radix Alba 9, Zingiberis Rhizoma	Warm the middle to tonify deficiency, harmonize the interior and relax tension.	Consumptive disease, spleen-stomach deficiency cold and abdominal pain, spontaneous

No.	Formula Name	Reference	Composition	Effects	Indications
		Synopsis of Golden Cabinet	Recens 4.5, Maltose 1, Astragali Radix 2.5. (Daily dosage 29 g)		sweating, shortness of breath, fatigued limbs and body, yang deficiency and generalized pain.
	黃耆建中湯	金匱要略			
135	Liou-Yi-San (Liu-Yi-San) 《San》	Yi-Fang-Ji-Jie (Yi-Fang-Ji-Jie)	Talcum 24, Glycyrrhizae Radix et Rhizoma 4. (Daily dosage 28 g)	Clear summerheat and drain dampness.	Summerheat-dampness and fever, vexation and thirst, inhibited urination.
		Collected Explanation on Prescriptions			
	六一散《散》	醫方集解			
136	Wu-Ling-San (Wu-Ling-San) 《San》	Shang-Han-Lun (Shang-Han-Lun)	Polyporus 4.5, Alismatis Rhizoma 7.5, Poria 4.5, Cinnamomi Ramulus 3, Atractylodis Macrocephalae Rhizoma 4.5. (Daily dosage 24 g)	Resolve qi and drain water, fortify the spleen and dispel dampness.	Internal stagnation of fluid-dampness, exterior syndrome, inhibited urination, polydipsia and thirst, vomiting immediately when drinking water and diarrhea.
		Treatise on Febrile Diseases			
	五苓散《散》	傷寒論			
137	Jhu-Ling-Tang (Zhu-Ling-Tang)	Shang-Han-Lun (Shang-Han-Lun)	Polyporus 6, Poria 6, Asini Corii Colla 6, Talcum 6, Alismatis Rhizoma 6. (Daily dosage 30 g)	Nourish yin, clear heat and drain water.	Binding of water and heat, internal heat damage to yin, fever, thirst, inhibited urination, vexation and insomnia.
		Treatise on Febrile Diseases			
	豬苓湯	傷寒論			
138	Yue-Bi-Jia-Jhu-Tang (Yue-Bi-Jia-Zhu-Tang)	Jin-Kuei-Yao-Lyue (Jin-Kui-Yao-Lue)	Ephedrae Herba 6, Gypsum Fibrosum 8, Zingiberis Rhizoma Recens 3, Glycyrrhizae Radix et Rhizoma 2, Jujubae Fructus 3, Atractylodis Macrocephalae Rhizoma 4. (Daily dosage 26 g)	Disperse wind and discharge heat, promote sweating to move water.	Skin edema, limbs edema and inhibited urination.
		Synopsis of Golden Cabinet			
	越婢加朮湯	金匱要略			

No.	Formula Name	Reference	Composition	Effects	Indications
139	Ciang-Huo-Sheng-Shih-Tang (Qiang-Huo-Sheng-Shi-Tang)	Nei-Wai-Shang-Bian-Huo-Lun (Nei-Wai-Shang-Bian-Huo-Lun)	Notopterygii Rhizoma et Radix 7, Angelicae Pubescentis Radix 7, Ligustici Rhizoma et Radix 3.5, Saposhnikoviae Radix 3.5, Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 3.5, Chuanxiong Rhizoma 3.5, Viticis Simplicifoliae Fructus 2. (Daily dosage 30 g)	Promote sweating, dispel wind and drain dampness.	Exterior pathogenic dampness, headache and heavy-headedness, lumbar vertebrae pain or whole body pain, mild fever, dizziness and fatigue.
		Discourse on the Differentiation of Exogenous and Endogenous Diseases			
	羌活勝濕湯	內外傷辨惑論			
140	Yin-Chen-Hao-Tang (Yin-Chen-Hao-Tang)	Shang-Han-Lun (Shang-Han-Lun)	Artemisiae Scopariae Herba 18, Rhei Radix et Rhizoma 6, Gardeniae Fructus 6. (Daily dosage 30 g)	Clear heat and drain dampness.	Yang jaundice and fever, sweating from the head, body without sweating, thirst, abdominal slight fullness, short and reddish urine.
		Treatise on Febrile Diseases			
	茵陳蒿湯	傷寒論			
141	Yi-Yi-Ren-Tang (Yi-Yi-Ren-Tang)	Jhang-Shih-Yi-Tong (Zhang-Shi-Yi-Tong)	Coicis Semen 20, Paeoniae Radix Alba 3, Angelicae Sinensis Radix 3, Ephedrae Herba 1.5, Cinnamomi Ramulus 1.5, Atractylodis Rhizoma 2, Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 1.5, Zingiberis Rhizoma Recens 3. (Daily dosage 35.5 g)	Dispel dampness to free impediment.	Dampness impediment, swollen joint and heavy aching.
		Zhang's Treatise on General Medicine			
	薏苡仁湯	張氏醫通			
142	Ling-Guei-Jhu-Gan-Tang (Ling-Gui-Zhu-Gan-Tang)	Jin-Kuei-Yao-Lyue (Jin-Kui-Yao-Lue)	Poria 10, Cinnamomi Ramulus 7.5, Atractylodis Macrocephalae Rhizoma 7.5, Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 5. (Daily dosage 30 g)	Fortify the spleen and drain dampness, warm and resolve phlegm.	Phlegm-retained fluid disease, fullness and distention in the chest and hypochondrium, dizziness and palpitations, shortness of breath and cough.
		Synopsis of Golden Cabinet			
	苓桂朮甘湯	金匱要略			

No.	Formula Name	Reference	Composition	Effects	Indications
143	Siao-Ban-Sia-Jia-Fu-Ling-Tang (Xiao-Ban-Xia-Jia-Fu-Ling-Tang)	Jin-Kuei-Yao-Lyue (Jin-Kui-Yao-Lue)	Pinelliae Rhizoma Praeparatum 12, Zingiberis Rhizoma Recens 12, Poria 6. (Daily dosage 30 g)	Move water to eliminate stuffiness.	Sudden vomiting, stuffiness below the heart, fluid-dampness in the diaphragm, dizziness and palpitations.
		Synopsis of Golden Cabinet			
	小半夏加茯苓湯	金匱要略			
144	Shen-Jhu-Tang (Shen-Zhu-Tang)	Jin-Kuei-Yao-Lyue (Jin-Kui-Yao-Lue)	Glycyrrhizae Radix et Rhizoma 4, Atractylodis Macrocephalae Rhizoma 4, Zingiberis Rhizoma 8, Poria 8. (Daily dosage 24 g)	Warm the spleen and dispel dampness.	Cold-dampness damage the spleen, generalized heaviness, cold pain in lumbar and below lumbar.
		Synopsis of Golden Cabinet			
	腎著湯	金匱要略			
145	Run-Chang-Tang (Run-Chang-Tang)	Wan-Bing-Huei-Chun (Wan-Bing-Hui-Chun)	Angelicae Sinensis Radix 2.5, Rehmanniae Radix Praeparata 2.5, Rehmanniae Radix Recens 2.5, Cannabis Fructus 2.5, Persicae Semen Praeparatum 2.5, Armeniacae Semen Amarum Praeparatum 2.5, Aurantii Fructus Immaturus 2.5, Scutellariae Radix 2.5, Magnoliae Cortex 2.5, Rhei Radix et Rhizoma 2.5, Glycyrrhizae Radix et Rhizoma 1.5. (Daily dosage 26.5 g)	Moisten the intestines to relax the bowels.	Dryness-heat in intestines and stomach, constipation.
		Recovery from All Ailments			
	潤腸湯	萬病回春			
146	Siang-Sheng-Po-Di-Wan (Xiang-Sheng-Po-Di-Wan) 《Wan》	Wan-Bing-Huei-Chun (Wan-Bing-Hui-Chun)	Forsythiae Fructus 4, Platycodonis Radix 3, Chuanxiong Rhizoma 4, Amomi Fructus 1.5, Chebulae Fructus 1.5, Catechu 3, Menthae Herba 6, Rhei Radix et Rhizoma 1.5, Glycyrrhizae Radix et Rhizoma 3. (Daily dosage 27.5 g)	Clear the lung to moisten the throat.	Sore throat, hoarseness and loss of voice.
		Recovery from All Ailments			
	響聲破笛丸《丸》	萬病回春			
147	Ban-Sia-Sie-Sin-Tang (Ban-Xia-Xie-Xin-Tang)	Shang-Han-Lun (Shang-Han-Lun)	Pinelliae Rhizoma Praeparatum 7.5, Scutellariae Radix 4.5, Zingiberis Rhizoma 4.5, Ginseng Radix et	Harmonize the stomach to downbear counterflow.	Cold damage induced by early purgation, stuffiness and

No.	Formula Name	Reference	Composition	Effects	Indications
		Treatise on Febrile Diseases	Rhizoma 4.5, Coptidis Rhizoma 1.5, Jujubae Fructus 3, Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 4.5. (Daily dosage 30 g)		fullness below the heart, vomiting and borborigmus.
	半夏瀉心湯	傷寒論			
148	Sie-Bai-San (Xie-Bai-San)	Siao-Er-Yao-Jheng- Jhih-Jyue (Xiao-Er-Yao-Zheng-Zhi-Jue)	Lycii Radicis Cortex 10, Mori Radicis Cortex 10, Glycyrrhizae Radix et Rhizoma 1, Oryzae Semen 8. (Daily dosage 29 g)	Purge the lung and clear heat.	Lung heat and cough, asthma in severe cases, skin-steaming fever, worse in the late afternoon.
		Key to Therapeutics of Childen's Diseases			
	瀉白散	小兒藥證直訣			
149	Pu-Ji-Siao-Du-Yin (Pu-Ji-Xiao-Du-Yin) 《San》	Dong-Yuan-Shih-Siao-Fang (Dong-Yuan-Shi-Xiao-Fang)	Scutellariae Radix 5, Coptidis Rhizoma 5, Scrophulariae Radix 2, Bupleuri Radix 2, Platycodonis Radix 2, Glycyrrhizae Radix et Rhizoma 2, Forsythiae Fructus 1, Arctii Fructus 1, Isatidis Radix 1, Lasiosphaera (Calvatia) 1, Bombyx Batryticatus 0.7, Cimicifugae Rhizoma 0.7, Menthae Herba 1, Citri Reticulatae Pericarpium 2. (Daily dosage 26.4 g)	Disperse wind to clear the pathogen, clear heat and detoxicate.	Erysipelas facial syndrome, swelling and painful head, face and throat.
		Dongyuan's Effective Prescriptions			
	普濟消毒飲《散》	東垣試效方			
150	San-Huang-Sie-Sin-Tang (San-Huang-Xie-Xin-Tang) 《Wan》	Jin-Kuei-Yao-Lyue (Jin-Kui-Yao-Lue)	Rhei Radix et Rhizoma 12, Coptidis Rhizoma 6, Scutellariae Radix 6. (Daily dosage 24 g)	Purge fire and detoxicate.	Triple energizers excess heat, mouth and tongue sores, hematemesis and epistaxis, vexing heat in the chest and diaphragm, constipation and reddish painful urination.
		Synopsis of Golden Cabinet			
	三黃瀉心湯《丸》	金匱要略	Add honey q.s. to make pills in traditional formula. (or Add rice paste)		
151	Cing-Sin-Li-Ge-Tang (Qing-Xin-Li-Ge-Tang)	Jhong-Guo-Yi-Syue-Da-Cih-Dian (Zhong-Guo-Yi-Xue-Da-Ci-Dian)	Saposhnikoviae Radix 3, Nepetae Herba 3, Menthae Herba 3, Platycodonis Radix 3, Scutellariae Radix 3, Coptidis Rhizoma 3, Gardeniae Fructus 1.5, Forsythiae	Clear heat and detoxicate.	Heat in the heart and spleen, swelling and painful throat, cheeks and tongue.

No.	Formula Name	Reference	Composition	Effects	Indications
		Chinese Medical Science Dictionary	Fructus 1.5, Scrophulariae Radix 1.5, Rhei Radix et Rhizoma 1.5, Natrii Sulfas 1.5, Arctii Fructus 1.5, Glycyrrhizae Radix et Rhizoma 1.5, Lonicerae Flos 2, Lophatheri Caulis et Folium 4. (Daily dosage 34.5 g)		
	清心利膈湯	中國醫學大辭典			
152	Ban-Sia-Tian-Ma-Bai-Jhu-Tang (Ban-Xia-Tian-Ma-Bai-Zhu-Tang)	Pi-Wei-Lun (Pi-Wei-Lun)	Pinelliae Rhizoma Praeparatum 4.5, Phellodendri Cortex 0.5, Zingiberis Rhizoma 0.5, Gastrodiae Rhizoma 1.5, Atractylodis Rhizoma 1.5, Poria 1.5, Astragali Radix 1.5, Alismatis Rhizoma 1.5, Ginseng Radix et Rhizoma 1.5, Atractylodis Macrocephalae Rhizoma 3, Massa Medicata Fermentata 3, Hordei Fructus Germinatus 4.5, Citri Reticulatae Pericarpium 4.5. (Daily dosage 29.5 g)	Tonify the spleen and dry dampness, resolve phlegm and extinguish wind.	Phlegm syncope and headache, cough with sticky and slimy phlegm, dizziness, vexation and oppression, nausea and hiccup, heavy body and cold limbs.
		Treatise on the Spleen and stomach			
	半夏天麻白朮湯	脾胃論			
153	An-Jhong-San (An-Zhong-San) 《San》	Tai-Ping-Huei-Min-He-Ji-Jyu-Fang (Tai-Ping-Hui-Min-He-Ji-Ju-Fang)	Glycyrrhizae Radix et Rhizoma 6, Corydalis Rhizoma 3, Alpiniae Officinari Rhizoma 3, Zingiberis Rhizoma 3, Foeniculi Fructus 3, Cinnamomi Cortex 3, Ostreae Concha Preparata 3. (Daily dosage 24 g)	Warm the middle to dissipate cold and relieve pain.	Qi stagnation in spleen-stomach due to cold congealing, stomach duct and abdomen pain, acid vomiting, food accumulation and poor digestion, distention and fullness.
		Prescription of Peaceful Benevolent Dispensary			
	安中散《散》	太平惠民和劑局方			
154	Yu-Ping-Fong-San (Yu-Ping-Feng-San) 《San》	Shih-Yi-De-Siao-Fang (Shi-Yi-De-Xiao-Fang)	Astragali Radix 15, Saposhnikoviae Radix 5, Atractylodis Macrocephalae Rhizoma 5, Zingiberis Rhizoma Recens 3, Jujubae Fructus 2. (Daily dosage 30 g)	Tonify qi and secure the exterior to stop sweating.	Exterior deficiency and spontaneous sweating, weakness and wind-cold induced by exopathogen.
		Effective Prescriptions for Generations			

No.	Formula Name	Reference	Composition	Effects	Indications
	玉屏風散《散》	世醫得效方	Without Zingiberis Rhizoma Recens and Jujubae Fructus in traditional formula.		
155	Yi-Zih-Tang (Yi-Zi-Tang)	Yan-Fang (Yan-Fang)	Angelicae Sinensis Radix 6, Bupleuri Radix 6, Scutellariae Radix 3, Glycyrrhizae Radix et Rhizoma 3, Cimicifugae Rhizoma 2, Rhei Radix et Rhizoma 1.5. (Daily dosage 21.5 g)	Clear heat to relax the bowels.	Constipation and hemorrhoid pain.
		Experiential Prescriptions			
	乙字湯	驗方			
156	Siao-Jhih-Wan (Xiao-Zhi-Wan) 《Wan》	Yang-Yi-Da-Cyuan (Yang-Yi-Da-Quan)	Rehmanniae Radix Recens 4.8, Scutellariae Radix 1.8, Lonicerae Flos 1.2, Citri Fructus Immaturus 1.2, Gentianae Macrophyllae Radix 1.2, Saposhnikoviae Radix 2.4, Rhei Radix et Rhizoma 2.4, Angelicae Sinensis Radix 2.4, Atractylodis Rhizoma 2.4, Pheretima 2.4, Sophorae Flos Immaturus 2.4, Paeoniae Radix Rubra 2.4. (Daily dosage 27 g)	Clear heat to cool the blood and relax the bowels.	Anal fistula and constipation.
		Complete Works of Sore			
	消痣丸《丸》	瘍醫大全	Add honey q.s. to make pills in traditional formula.		
157	Zih-Yun-Gao (Zi-Yun-Gao)	Wai-Ke-Jheng-Zong (Wai-Ke-Zheng-Zong)	Arnebiae Radix 5, Angelicae Sinensis Radix 5, Beeswax 15, Sesame oil 13, oiliness based agent q.s.. (External application, apply to the affected area q.s. sparingly, several times a day.)	Moisten the skin to relieve itching and promote tissue regeneration.	Dry and itchy skin, cracked extremities, scald and frostbite.
		Orthodox Manual of External Disease			
	紫雲膏(Only for traditional formula.)	外科正宗			
158	Ba-Wei-Dai-Sia-Fang (Ba-Wei-Dai-Xia-Fang)	Yan-Fang (Yan-Fang)	Angelicae Sinensis Radix 5, Chuanxiong Rhizoma 3, Poria 3, Akebiae Caulis 3, Citri Reticulatae Pericarpium	Clear heat and detoxicate.	Dampness-heat vaginal discharge and heat strangury.
		Experiential Prescriptions			

No.	Formula Name	Reference	Composition	Effects	Indications
	八味帶下方	驗方	2, Smilacis Glabrae Rhizoma 6, Lonicerae Flos 3, Rhei Radix et Rhizoma 1. (Daily dosage 26 g)		
159	Wun-Jing-Tang (Wen-Jing-Tang)	Jin-Kuei-Yao-Lyue (Jin-Kui-Yao-Lue)	Evodiae Fructus 3, Angelicae Sinensis Radix 2, Chuanxiong Rhizoma 2, Paeoniae Radix Alba 2, Ginseng Radix et Rhizoma 2, Cinnamomi Ramulus 2, Asini Corii Colla 2, Moutan Radicis Cortex 2, Zingiberis Rhizoma Recens 2, Glycyrrhizae Radix et Rhizoma 2, Pinelliae Rhizoma Praeparatum 3, Ophiopogonis Radix 4. (Daily dosage 28 g)	Warm the meridian to nourish blood, activate blood to regulate menstruation.	Woman lower abdomen cold, constrained distention and contracture, menstrual irregularities and menorrhagia.
		Synopsis of Golden Cabinet			
	溫經湯	金匱要略			
160	Cyong-Guei-Jiao-Ai-Tang (Qiong-Gui-Jiao-Ai-Tang)	Jin-Kuei-Yao-Lyue (Jin-Kui-Yao-Lue)	Chuanxiong Rhizoma 2.5, Asini Corii Colla 2.5, Glycyrrhizae Radix et Rhizoma 2.5, Artemisiae Argyi Folium 4, Angelicae Sinensis Radix 4, Paeoniae Radix Alba 5, Rehmanniae Radix Recens 8. (Daily dosage 28.5 g)	Tonify blood to regulate menstruation, prevent abortion and stop flooding.	Persistent bleeding after abortion and profuse menstruation.
		Synopsis of Golden Cabinet			
	芎歸膠艾湯	金匱要略			
161	Dang-Guei-Shao-Yao- San (Dang-Gui-Shao-Yao-San) 《San》	Jin-Kuei-Yao-Lyue (Jin-Kui-Yao-Lue)	Angelicae Sinensis Radix 2, Paeoniae Radix Alba 10, Poria 2.5, Atractylodis Macrocephalae Rhizoma 2.5, Alismatis Rhizoma 5, Chuanxiong Rhizoma 5. (Daily dosage 27 g)	Tonify blood and nourish the liver, fortify the spleen and drain dampness.	Menstrual irregularities, lumbago occurring in pregnancy, dizziness, lumbar and feet cold.
		Synopsis of Golden Cabinet			
	當歸芍藥散《散》	金匱要略			
162	Sheng-Hua-Tang (Sheng-Hua-Tang)	Fu-Cing-Jhu-Nyu-Ke (Fu-Qing-Zhu-Nu-Ke)	Angelicae Sinensis Radix 16, Chuanxiong Rhizoma 6, Persicae Semen Praeparatum 3, Zingiberis Rhizoma Carbonisata 1, Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 1. (Daily dosage 27 g)	Engender blood, resolve stasis, warm the middle and dissipate cold.	Retention of the lochia after postpartum and lower abdomen pain.
		Fu Qingzhu's Gynecology and Obstetrics			
	生化湯	傅青主女科			
163	Yu-Cyuan-Wan	Gu-Jin-Yi-Tong			

No.	Formula Name	Reference	Composition	Effects	Indications
	(Yu-Quan-Wan) 《Wan》	(Gu-Jin-Yi-Tong) Complete Compendium of Medical Works, Ancient and Modern	Trichosanthis Radix 4.5, Puerariae Radix 4.5, Ophiopogonis Radix 3, Ginseng Radix et Rhizoma 3, Poria 3, Mume Fructus 3, Glycyrrhizae Radix et Rhizoma 3, Astragali Radix Recens 1.5, Astragali Radix Praeparata cum Melle 1.5. (Daily dosage 27 g)	Engender fluid to stop thirsting, tonify qi and yin.	Wasting-thirst and polydipsia, frequent urination, diarrhea and lassitude of essence-spirit.
	玉泉丸《丸》	古今醫統	Add honey q.s. to make pills in traditional formula.		
164	Huang-Lian-Shang-Cing-Wan (Huang-lian-Shang-Qing-Wan) 《Wan》	Jhong-Guo-Yi-Syue-Da-Cih-Dian (Zhong-Guo-Yi-Xue-Da-Ci-Dian) Chinese Medical Science Dictionary	Coptidis Rhizoma 3, Scutellariae Radix 3, Phellodendri Cortex 3, Gardeniae Fructus 3, Chrysanthemi Flos 1.5, Angelicae Sinensis Radix 1.5, Platycodonis Radix 0.8, Puerariae Radix 0.8, Menthae Herba 0.8, Scrophulariae Radix 0.8, Trichosanthis Radix 0.8, Chuanxiong Rhizoma 0.8, Curcumae Longae Rhizoma 2.2, Forsythiae Fructus 2.2, Rhei Radix et Rhizoma 4.4. (Daily dosage 28.6 g)	Disperse wind to clear heat and detoxicate.	Heat accumulated in upper energizer, eye and throat pain, mouth and tongue sores, vexing heat in the heart and diaphragm, liver fire bearing upward, wind-heat and rhinitis.
	黃連上清丸《丸》	中國醫學大辭典	Add honey q.s. to make pills in traditional formula.		
165	Jhih-Zih-Shih-Tang (Zhi-Zi-Shi-Tang)	Shang-Han-Lun (Shang-Han-Lun) Treatise on Febrile Diseases	Gardeniae Fructus 10, Sojae Semen Preparatum 15. (Daily dosage 25 g)	Clear heat to relieve agitation.	After sweating and vomiting, pathogenic heat accumulating in the chest, anguish body, vexation of deficiency type and insomnia.
	梔子豉湯	傷寒論			
166	Jie-Geng-Tang (Jie-Geng-Tang)	Shang-Han-Lun (Shang-Han-Lun) Treatise on Febrile Diseases	Platycodonis Radix 8, Glycyrrhizae Radix et Rhizoma 16. (Daily dosage 24 g)	Expel pus and detoxicate.	Lung abscess, pus vomiting with stinky smell, swelling and painful throat.
	桔梗湯	傷寒論			

No.	Formula Name	Reference	Composition	Effects	Indications
167	Cing-Fei-Yin (Qing-Fei-Yin) 清肺飲	Yi-Fang-Ji-Jie (Yi-Fang-Ji-Jie) Collected Explanation on Prescriptions 醫方集解	Armeniacae Semen Amarum Praeparatum 5, Fritillariae Cirrhosae Bulbus 5, Poria 5, Platycodonis Radix 2.5, Glycyrrhizae Radix et Rhizoma 2.5, Schisandrae Chinensis Fructus 2.5, Citri Exocarpium Rubrum 2.5, Zingiberis Rhizoma Recens 3. (Daily dosage 28 g)	Resolve phlegm and moisten dryness.	Cough induced by phlegm-dampness and qi counterflow.
168	Gua-Lou-Jhih-Shih-Tang (Gua-Lou-Zhi-Shi-Tang) 瓜蔞枳實湯	Wan-Bing-Huei-Chun (Wan-Bing-Hui-Chun) Recovery from All Ailments 萬病回春	Trichosanthis Fructus 3, Aurantii Fructus Immaturus 3, Platycodonis Radix 3, Poria 3, Fritillariae Cirrhosae Bulbus 3, Citri Reticulatae Pericarpium 3, Scutellariae Radix 3, Gardeniae Fructus 3, Angelicae Sinensis Radix 2, Amomi Fructus 1.5, Aucklandiae Radix 1.5, Glycyrrhizae Radix et Rhizoma 1, Zingiberis Rhizoma Recens 3. (Daily dosage 33 g)	Clear the lung and resolve phlegm, move qi and soothe the diaphragm.	Chronic cough, phlegm accumulated in the chest and diaphragm, phlegm clouding the pericardium, sluggish speech.
169	Bu-Huan-Jin-Jheng-Ci-San (Bu-Huan-Jin-Zheng-Qi-San) 不換金正氣散	Tai-Ping-Huei-Min-He-Ji-Jyu-Fang (Tai-Ping-Hui-Min-He-Ji-Ju-Fang) Prescription of Peaceful Benevolent Dispensary 太平惠民和劑局方	Magnoliae Cortex 4, Pogostemonis Herba 4, Citri Reticulatae Pericarpium 4, Pinelliae Rhizoma Praeparatum 4, Atractylodis Rhizoma 4, Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 4, Zingiberis Rhizoma Recens 3, Jujubae Fructus 2. (Daily dosage 29 g)	Move qi and resolve dampness, harmonize the stomach to stop vomiting.	Four seasons cold damage, miasma induced by seasonal qi, headache, alternating chills and fever, cholera, vomiting and diarrhea.
170	Jian-Pi-Wan (Jian-Pi-Wan) 《Wan》	Jheng-Jhih-Jhun-Sheng (Zheng-Zhi-Zhun-Sheng)	Atractylodis Macrocephalae Rhizoma 5, Aucklandiae Radix 1.5, Coptidis Rhizoma 1.5, Glycyrrhizae Radix et Rhizoma 1.5, Poria 4, Ginseng Radix et Rhizoma 3,	Replenish qi and fortify the spleen, harmonize the stomach to promote digestion.	Spleen-stomach weakness, poor appetite, distention and

No.	Formula Name	Reference	Composition	Effects	Indications
		Standards for Diagnosis and Treatment	Massa Medicata Fermentata 2, Citri Reticulatae Pericarpium 2, Amomi Fructus 2, Hordei Fructus Germinatus 2, Crataegi Fructus 2, Dioscoreae Rhizoma 2, Myristicae Semen 2. (Daily dosage 30.5 g)		fullness in stomach duct and abdomen.
	健脾丸《丸》	證治準繩			
171	Lian-Ciao-Bai-Du-San (Lian-Qiao-Bai-Du-San)	Yi-Fang-Ji-Jie (Yi-Fang-Ji-Jie)	Notopterygii Rhizoma et Radix 2, Angelicae Pubescentis Radix 2, Bupleuri Radix 2, Peucedani Radix 2, Chuanxiong Rhizoma 2, Citri Fructus Immaturus 2, Platycodonis Radix 2, Poria 2, Lonicerae Flos 2, Forsythiae Fructus 2, Glycyrrhizae Radix et Rhizoma 1, Zingiberis Rhizoma Recens 2, Menthae Herba 2. (Daily dosage 25 g)	Clear heat to release the exterior, disperse swelling and detoxicate.	Cold damage and headache, the initial stage of sore and ulcer.
		Collected Explanation on Prescriptions			
	連翹敗毒散	醫方集解			
172	Bu-Yin-Tang (Bu-Yin-Tang)	Wan-Bing-Huei-Chun (Wan-Bing-Hui-Chun)	Angelicae Sinensis Radix 2, Paeoniae Radix Alba 2, Rehmanniae Radix Recens 2, Rehmanniae Radix Praeparata 2, Citri Reticulatae Pericarpium 2, Foeniculi Fructus 2, Culleniae Fructus 2, Achyranthis Bidentatae Radix 2, Eucommiae Cortex 2, Poria 2, Ginseng Radix et Rhizoma 1, Phellodendri Cortex 1.5, Anemarrhenae Rhizoma 1.5, Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 1, Jujubae Fructus 2. (Daily dosage 27 g)	Nourish yin to tonify the kidney.	Kidney deficiency and lumbago.
		Recovery from All Ailments			
	補陰湯	萬病回春			
173	Mai-Wei-Di-Huang-Wan (Mai-Wei-Di-Huang-Wan) 《Wan》	Yi-Fang-Ji-Jie (Yi-Fang-Ji-Jie)	Rehmanniae Radix Praeparata 8, Corni Sarcocarpium 4, Dioscoreae Rhizoma 4, Poria 3, Moutan Radicis Cortex 3, Alismatis Rhizoma 3, Schisandrae Chinensis Fructus 2, Ophiopogonis Radix 3. (Daily dosage 30 g)	Constrain the lung and nourish yin.	Lung-kidney yin deficiency, cough and dyspnea of deficiency type, tidal fever and night sweating.
		Collected Explanation on Prescriptions			

No.	Formula Name	Reference	Composition	Effects	Indications
	麥味地黃丸《丸》	醫方集解	Add honey q.s. to make pills in traditional formula.		
174	Zih-Yin-Di-Huang-Wan (Zi-Yin-Di-Huang-Wan) Shou-Gan-Di-Huang-Wan (Shou-Gan-Di-Huang-Wan) 《Wan》	Lan-Shih-Mi-Cang (Lan-Shi-Mi-Cang) Medical Works Secretly Kept in Imperial Library	Ginseng Radix et Rhizoma 1, Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 1, Asparagi Radix 1.5, Lycii Radicis Cortex 1.5, Schisandrae Chinensis Fructus 1.5, Citri Fructus Immaturus 1, Coptidis Rhizoma 1.5, Angelicae Sinensis Radix 2.5, Scutellariae Radix 2.5, Rehmanniae Radix Recens 4, Bupleuri Radix 4, Rehmanniae Radix Praeparata 5. (Daily dosage 27 g)	Nourish yin and clear heat, tonify the liver and improve vision.	Deficiency of the liver and kidney, yin deficiency heat, dizziness and blurred vision.
	滋陰地黃丸 （熟乾地黃丸）《丸》	蘭室秘藏	Add honey q.s. to make pills in traditional formula.		
175	Dang-Guei-Bu-Sie-Tang (Dang-Gui-Bu-Xie-Tang)	Nei-Wai-Shang-Bian-Huo-Lun (Nei-Wai-Shang-Bian-Huo-Lun) Discourse on the Differentiation of Exogenous and Endogenous Diseases	Astragali Radix 25, Angelicae Sinensis Radix 5. (Daily dosage 30 g)	Tonify qi and engender blood.	Large and feeble pulse, qi weakness and blood deficiency, overexertion, fatigue and internal damage.
	當歸補血湯	內外傷辨惑論			
176	Da-Bu-Yin-Wan (Da-Bu-Yin-Wan) 《Wan》	Dan-Si-Sin-Fa (Dan-Xi-Xin-Fa) Danxi`s Experiential Therapy	Phellodendri Cortex 6, Anemarrhenae Rhizoma 6, Rehmanniae Radix Praeparata 9, Testudinis Carapax et Plastrum 9. (Daily dosage 30 g)	Nourish yin to downbear fire.	Yin deficiency with fire effulgence, lung atrophy and hemoptysis, hiccup and heat vexation, steaming bone and night sweating, feet and knees pain and heat.
	大補陰丸《丸》	丹溪心法	Add honey q.s. to make pills in traditional formula.		
177	Ci-Bao-Mei-Ran-Dan (Qi-Bao-Mei-Ran-Dan)	Yi-Fang-Ji-Jie (Yi-Fang-Ji-Jie)	Polygoni Multiflori Radix Praeparata 12, Poria 3, Achyranthis Bidentatae Radix 3, Angelicae Sinensis	Tonify the kidney and nourish the blood.	

No.	Formula Name	Reference	Composition	Effects	Indications
	《Wan》	Collected Explanation on Prescriptions	Radix 3, Lycii Fructus 3, Cuscutae Semen 3, Culleniae Fructus 1.5. (Daily dosage 28.5 g)		Kidney yin deficiency, fatigued sinew and bone, premature graying hair.
	七寶美髯丹《丸》	醫方集解	Add honey q.s. to make pills in traditional formula.		
178	Ban-Long-Wan (Ban-Long-Wan) 《Wan》	Gu-Jin-Yi-Tong (Gu-Jin-Yi-Tong)	Cervi Cornu Degelatinatum 5, Cervi Cornus Colla 5, Cuscutae Semen 5, Platycladi Semen 5, Rehmanniae Radix Praeparata 5, Poria 2.5, Culleniae Fructus 2.5. (Daily dosage 30 g)	Nourish qi and blood, tonify sinew and bone.	Kidney yang deficiency, limp lumbar and knees, frequent urination and cold limbs.
		Complete Compendium of Medical Works, Ancient and Modern			
	斑龍丸《丸》	古今醫統			
179	Zai-Zao-San (Zai-Zao-San)	Shang-Han-Liou-Shu (Shang-Han-Liu-Shu)	Astragali Radix 3, Ginseng Radix et Rhizoma 3, Cinnamomi Ramulus 3, Glycyrrhizae Radix et Rhizoma 3, Aconiti Lateralis Radix Preparata 1.5, Asari Radix et Rhizoma 1.5, Notopterygii Rhizoma et Radix 2.5, Saposhnikoviae Radix 2.5, Chuanxiong Rhizoma 2.5, Zingiberis Rhizoma Tostum 3, Paeoniae Radix Alba 3, Jujubae Fructus 3. (Daily dosage 31.5 g)	Warm yang and tonify qi.	Wind-cold induced by exopathogen, light heat and heavy cold, absence of sweating and cold limbs.
		Six Febrile Books			
	再造散	傷寒六書			
180	Yang-Gan-Wan (Yang-Gan-Wan) 《Wan》	Ji-Sheng-Fang (Ji-Sheng-Fang)	Angelicae Sinensis Radix 3.5, Plantaginis Semen 3.5, Paeoniae Radix Alba 3.5, Saposhnikoviae Radix 3.5, Prinsepiae Nux 3.5, Rehmanniae Radix Praeparata 3.5, Chuanxiong Rhizoma 3.5, Broussonetiae Fructus 3.5. (Daily dosage 28 g)	Nourish blood and improve vision.	Liver blood deficiency, blurred vision, eye discharge and fatigued vision.
		Recipes for Saving Lives			
	養肝丸《丸》	濟生方	Add honey q.s. to make pills in traditional formula.		

No.	Formula Name	Reference	Composition	Effects	Indications
181	Cing-Liang-San (Qing-Liang-San)	Wan-Bing-Huei-Chun (Wan-Bing-Hui-Chun)	Gardeniae Fructus 3, Forsythiae Fructus 3, Scutellariae Radix 3, Saposhnikoviae Radix 3, Citri Fructus Immaturus 3, Coptidis Rhizoma 3, Angelicae Sinensis Radix 3, Rehmanniae Radix Recens 3, Glycyrrhizae Radix et Rhizoma 3, Platycodonis Radix 1.5, Menthae Herba 1.5 , Junci Medulla 1, Camelliae Sinensis Folium 1, Sophorae Tonkinensis Radix 1. (Daily dosage 33 g)	Clear heat and purge fire, disperse swelling to relieve pain.	All the excess fire syndrome, swelling and painful throat.
		Recovery from All Ailments			
	清涼散	萬病回春			
182	Gan-Mai-Da-Zao-Tang (Gan-Mai-Da-Zao-Tang) Gan-Cao-Siao-Mai-Da-Zao-Tang (Gan-Cao-Xiao-Mai-Da-Zao-Tang)	Jin-Kuei-Yao-Lyue (Jin-Kui-Yao-Lue)	Glycyrrhizae Radix et Rhizoma 6, Tritici Fructus 12, Jujubae Fructus 6. (Daily dosage 24 g)	Nourish the heart to tranquilize, harmonize the middle to relax tension.	Woman hysteria, rapid sorrow and crying, night crying in babies and insomnia.
		Synopsis of Golden Cabinet			
	甘麥大棗湯 （甘草小麥大棗湯）	金匱要略			
183	Chai-Hu-Jia-Long-Gu-Mu-Li-Tang (Chai-Hu-Jia-Long-Gu-Mu-Li-Tang)	Shang-Han-Za-Bing-Lun (Shang-Han-Za-Bing-Lun)	Pinelliae Rhizoma Praeparatum 3, Jujubae Fructus 2, Bupleuri Radix 5, Zingiberis Rhizoma Recens 2, Ginseng Radix et Rhizoma 2, Draconis Os Preparata 2, Cinnamomi Ramulus 2, Poria 2, Rhei Radix et Rhizoma 2.5, Ostreae Concha Preparata 2, Scutellariae Radix 2. (Daily dosage 26.5 g)	Harmonize and release the lesser yang, settle fright and tranquilize.	Cold damage with inappropriate purgation, fullness in the chest, vexation and fright, delirious speech, heaviness of the whole body, inability to turn sides.
		Treatise on Cold Damage and Miscellaneous Diseases			
	柴胡加龍骨牡蠣湯	傷寒雜病論			
184	Bao-Chan-Wu-You-Fang (Bao-Chan-Wu-You-Fang)	Yan-Fang-Sin-Bian (Yan-Fang-Xin-Bian)	Magnoliae Cortex 1.4, Artemisiae Argyi Folium 1.4, Angelicae Sinensis Radix 3, Chuanxiong Rhizoma 3, Nepetae Herba 1.6, Fritillariae Cirrhosae Bulbus 2,	Tonify qi and blood, prevent abortion and stop flooding.	Threatened abortion.

No.	Formula Name	Reference	Composition	Effects	Indications
		New Compilation of Experiential Prescriptions	Cuscutae Semen 2, Notopterygii Rhizoma et Radix 1, Glycyrrhizae Radix et Rhizoma 1, Citri Fructus Immaturus 1.2, Paeoniae Radix Alba 4, Zingiberis Rhizoma Recens 3, Astragali Radix 1.6. (Daily dosage 26.2 g)		
	保產無憂方	驗方新編			
185	Dang-Guei-Yin-Zih (Dang-Gui-Yin-Zi)	Jheng-Jhih-Jhun- Sheng (Zheng-Zhi-Zhun-Sheng)	Angelicae Sinensis Radix 3, Paeoniae Radix Alba 3, Chuanxiong Rhizoma 3, Rehmanniae Radix Recens 3, Tribuli Fructus 3, Saposhnikoviae Radix 3, Nepetae Herba 3, Reynoutriae Multiflorae Radix 1.5, Astragali Radix 1.5, Glycyrrhizae Radix et Rhizoma 1.5, Zingiberis Rhizoma Recens 4.5. (Daily dosage 30 g)	Tonify qi and replenish blood, dispel wind and eliminate dampness.	Scabies and urticaria, dampness toxin and itch.
		Standards for Diagnosis and Treatment			
	當歸飲子	證治準繩			
186	Ning-Sou-Wan (Ning-Sou-Wan) 《Wan》	Jhong-Guo-Yi-Syue-Da-Cih-Dian (Zhong-Guo-Yi-Xue-Da-Ci-Dian)	Platycodonis Radix 3, Dendrobii Caulis 3, Pinelliae Rhizoma Praeparatum 3, Fritillariae Cirrhosae Bulbus 3, Perillae Fructus 3, Poria 3, Menthae Herba 2.3, Armeniacae Semen Amarum Praeparatum 2.3, Mori Radicis Cortex 2.3, Citri Exocarpium Rubrum 1.5, Oryzae Fructus Germinatus 1.5, Glycyrrhizae Radix et Rhizoma 0.8. (Daily dosage 28.7 g)	Suppress and calm cough, clear the lung and resolve phlegm.	Cough with copious phlegm and rapid breathing, white and sticky phlegm or yellow phlegm.
		Chinese Medical Science Dictionary			
	寧嗽丸《丸》	中國醫學大辭典			
187	Er-Chen-Tang (Er-chen-Tang) (Wan)《Wan》	Tai-Ping-Huei-Min-He-Ji-Jyu-Fang (Tai-Ping-Hui-Min-He-Ji-Ju-Fang)	Pinelliae Rhizoma Praeparatum 8, Citri Reticulatae Pericarpium 8, Poria 5, Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 2.5, Zingiberis Rhizoma Recens 2.5. (Daily dosage 26 g)	Dry dampness to resolve phlegm, regulate qi and harmonize the middle.	Phlegm-dampness and cough, copious and white phlegm, fullness and distention in the chest and diaphragm, nausea and vomiting, spleen-stomach disharmony.
		Prescription of Peaceful Benevolent Dispensary			
	二陳湯（丸）《丸》	太平惠民和劑局方			

No.	Formula Name	Reference	Composition	Effects	Indications
188	Guei-Jhih-Shao-Yao-Jhih-Mu-Tang (Gui-Zhi-Shao-Yao-Zhi-Mu-Tang)	Jin-Kuei-Yao-Lyue (Jin-Kui-Yao-Lue)	Cinnamomi Ramulus 4, Paeoniae Radix Alba 3, Glycyrrhizae Radix et Rhizoma 2, Ephedrae Herba 2, Zingiberis Rhizoma Recens 5, Atractylodis Macrocephalae Rhizoma 5, Anemarrhenae Rhizoma 4, Saposhnikoviae Radix 4, Aconiti Lateralis Radix Preparata 2. (Daily dosage 31 g)	Dispel wind and drain dampness, warm the meridian to relieve pain.	Wind-dampness arthralgia syndrome, painful limb joints, numbness of swollen feet, dizziness and shortness of breath, vexation and feel vomiting.
		Synopsis of Golden Cabinet			
	桂枝芍藥知母湯	金匱要略			
189	Cang-Er-San (Cang-Er-San) 《San》	Jheng-Jhih-Jhun-Sheng (Zheng-Zhi-Zhun-Sheng)	Magnoliae Flos 8, Xanthii Fructus 4, Angelicae Dahuricae Radix 16, Menthae Herba 1, Allii Fistulosi Bulbus Recens 3, Camelliae Sinensis Folium 2. (Daily dosage 34 g)	Disperse wind to clear heat.	Sinusitis (persistent excessive flow of turbid nasal discharge).
		Standards for Diagnosis and Treatment			
	蒼耳散《散》	證治準繩	Add Allii Fistulosi Bulbus Recens and Camelliae Sinensis Folium q.s. to make pills in traditional formula.		
190	Chai-Hu-Cing-Gan-Tang (Chai-Hu-Qing-Gan-Tang)	Yi-Zong-Jin-Jian (Yi-Zong-Jin-Jian)	Bupleuri Radix 3, Rehmanniae Radix Recens 3, Angelicae Sinensis Radix 4, Paeoniae Radix Rubra 3, Chuanxiong Rhizoma 2, Forsythiae Fructus 2, Arctii Fructus 3, Scutellariae Radix 2, Gardeniae Fructus 2, Trichosanthis Radix 2, Glycyrrhizae Nudus or Glycyrrhizae Radix et Rhizoma 2, Saposhnikoviae Radix 2. (Daily dosage 30 g)	Clear the liver and disperse wind, purge fire and detoxicate.	The initial stage of carbuncle occurring on sideburns, wind-heat in liver-gallbladder and triple energizer, anger-fire syndrome.
		Golden Mirror of Medicine			
	柴胡清肝湯	醫宗金鑑			
191	Tuo-Li-Siao-Du-Yin (Tuo-Li-Xiao-Du-Yin)	Wai-Ke-Jheng-Zong (Wai-Ke-Zheng-Zong)	Ginseng Radix et Rhizoma 3, Chuanxiong Rhizoma 3, Paeoniae Radix Alba 3, Astragali Radix 3, Angelicae		

No.	Formula Name	Reference	Composition	Effects	Indications
		Orthodox Manual of External Disease	Sinensis Radix 3, Atractylodis Macrocephalae Rhizoma 3, Lonicerae Flos 3, Poria 3, Angelicae Dahuricae Radix 1.5, Glycyrrhizae Radix et Rhizoma 1.5, Gleditsiae Spina 1.5, Platycodonis Radix 1.5. (Daily dosage 30 g)	Tonify qi and replenish blood, expel the interior and disinfecting.	Sore and ulcer, dual deficiency of qi and blood, promote tissue regeneration and expel pus.
	托裏消毒飲	外科正宗			
192	Sang-Piao-Siao-San (Sang-Piao-Xiao-San) 《San》	Ben-Cao-Yan-Yi (Ben-Cao-Yan-Yi)	Mantidis Oötheca 3, Polygalae Radix 3, Acori Graminei Rhizoma 3, Draconis Os Preparata 3, Ginseng Radix et Rhizoma 3, Poria 3, Angelicae Sinensis Radix 3, Testudinis Carapax et Plastrum 3. (Daily dosage 24 g)	Harmonize and tonify the heart and kidney, secure essence to stop seminal emission.	Frequent urination, enuresis, spermatorrhea, absentminded essence-spirit and forgetfulness.
		Amplification on Materia Medica			
	桑螵蛸散《散》	本草衍義			
193	Wun-Cing-Yin (Wen-Qing-Yin) Jie-Du-Sih-Wu-Tang (Jie-Du-Si-Wu-Tang)	Yi-Xue-Ru-Men (Yi-Xue-Ru-Men)	Coptidis Rhizoma 3.5, Phellodendri Cortex 3.5, Scutellariae Radix 3.5, Gardeniae Fructus 3.5, Angelicae Sinensis Radix 3.5, Chuanxiong Rhizoma 3.5, Paeoniae Radix Alba 3.5, Rehmanniae Radix Praeparata 3.5. (Daily dosage 28 g)	Clear heat and resolve dampness, nourish blood and harmonize the nutrient.	Profuse menstruation, sallow complexion, stabbing pain of umbilicus and abdomen, flooding and spotting.
		Introduction to Medicine			
	溫清飲(解毒四物湯)	醫學入門			
194	Jin-Suo-Gu-Jing-Wan (Jin-Suo-Gu-Jing-Wan) 《Wan》	Yi-Fang-Ji-Jie (Yi-Fang-Ji-Jie)	Astragali Complanati Semen 6, Euryales Semen 6, Nelumbinis Stamen 6, Draconis Os Preparata 3, Ostreae Concha Preparata 3, Nelumbinis Semen 6. (Daily dosage 30 g)	Secure the kidney and astringe essence.	Kidney deficiency, seminal emission, night sweating, sore lumbar and tinnitus, fatigued limbs.
		Collected Explanation on Prescriptions			
	金鎖固精丸《丸》	醫方集解			
195	Bao-He-Wan (Bao-He-Wan)	Dan-Si-Sin-Fa (Dan-Xi-Xin-Fa)	Crataegi Fructus 12, Massa Medicata Fermentata 4, Pinelliae Rhizoma Praeparatum 4, Poria 4, Citri	Resolve accumulation and harmonize the stomach.	Food accumulation and stagnation, stuffiness and

No.	Formula Name	Reference	Composition	Effects	Indications
	《Wan》	Danxi`s Experiential Therapy	Reticulatae Pericarpium 2, Forsythiae Fructus 2, Raphani Semen 2. (Daily dosage 30 g)		fullness in the chest and diaphragm, belching and acid regurgitation, abdominal pain and diarrhea.
	保和丸《丸》	丹溪心法			
196	Wei-Ling-Tang (Wei-Ling-Tang) 《San》	Jhong-Guo-Yi-Syue-Da-Cih-Dian (Zhong-Guo-Yi-Xue-Da-Ci-Dian)	Atractylodis Rhizoma 3, Magnoliae Cortex 3, Citri Reticulatae Pericarpium 3, Atractylodis Macrocephalae Rhizoma 3, Poria 3, Alismatis Rhizoma 2, Polyporus 2, Glycyrrhizae Radix et Rhizoma 1.2, Cinnamomi Cortex 1, Zingiberis Rhizoma Recens 3, Jujubae Fructus 2 (Daily dosage 26.2 g)	Dispel dampness to resolve stagnation, fortify the spleen and harmonize the middle.	Summerheat stroke and dampness damage, poor appetite, abdominal pain and diarrhea, vomiting and limb pain, inhibited urination.
		Chinese Medical Science Dictionary			
	胃苓湯《散》	中國醫學大辭典	Without Zingiberis Rhizoma Recens and Jujubae Fructus in traditional formula.		
197	Ping-Wei-San (Ping-Wei-San) (Wan)《Wan》	Tai-Ping-Huei-Min-He-Ji-Jyu-Fang (Tai-Ping-Hui-Min-He-Ji-Ju-Fang)	Citri Reticulatae Pericarpium 5, Magnoliae Cortex 5, Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 3, Atractylodis Rhizoma 8, Zingiberis Rhizoma Recens 3, Jujubae Fructus 2. (Daily dosage 26 g)	Dry dampness to fortify the spleen, regulate qi and harmonize the middle.	Spleen-stomach stagnation, distention and fullness in stomach duct and abdomen, nausea and vomiting, belching and acid regurgitation.
		Prescription of Peaceful Benevolent Dispensary			
	平胃散（丸）《丸》	太平惠民和劑局方			
198	Bai-Hu-Jia-Ren-Shen-Tang (Bai-Hu-Jia-Ren-Shen-Tang)	Shang-Han-Lun (Shang-Han-Lun)	Anemarrhenae Rhizoma 6, Gypsum Fibrosum 16, Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 2, Oryzae Semen 8, Ginseng Radix et Rhizoma 3. (Daily dosage 35 g)	Clear heat, replenish qi and engender fluid.	Dual damage of fluid and qi, polydipsia, summerheat stroke, fever and thirst, sweating and aversion to cold.
		Treatise on Febrile Diseases			
	白虎加人參湯	傷寒論			
199	Yi-Gan-San (Yi-Gan-San)	Jheng-Jhih-Jhun-Sheng (Zheng-Zhi-Zhun-Sheng)	Bupleuri Radix 2.5, Glycyrrhizae Radix et Rhizoma 2.5, Chuanxiong Rhizoma 4, Angelicae Sinensis Radix	Clear liver heat.	Dampness-heat in the liver meridian, fright palpitations

No.	Formula Name	Reference	Composition	Effects	Indications
		Standards for Diagnosis and Treatment	5, Atractylodis Macrocephalae Rhizoma 5, Poria 5, Uncariae Ramulus cum Uncis 5. (Daily dosage 29 g)		and convulsions, vomiting and phlegm drool, distention and fullness in abdomen, poor appetite, insomnia.
	抑肝散	證治準繩			
200	Wun-Dan-Tang (Wen-Dan-Tang)	Jhong-Guo-Yi-Syue-Da-Cih-Dian (Zhong-Guo-Yi-Xue-Da-Ci-Dian)	Pinelliae Rhizoma 5, Bambusae Caulis in Taenias 5, Aurantii Fructus Immaturus 5, Citri Reticulatae Pericarpium 7.5, Zingiberis Rhizoma Recens 5, Glycyrrhizae Radix et Rhizoma 2.5, Poria 4, Jujubae Fructus 1. (Daily dosage 35)	Warm the gallbladder and harmonize the stomach, dispel phlegm to stop vomiting.	Gallbladder deficiency and insomnia, phlegm-heat harassing upward, vexation of deficiency type and fright palpitations, bitter taste in the mouth and vomiting.
		Chinese Medical Science Dictionary			
	溫膽湯	中國醫學大辭典			

◎The above formulas are mainly concentrated granules preparations, if《Wan》,《San》or《Dan》is given following the formulas names, it means the traditional pill, powder or pellet dosage formulas is also available.

Decoction (preparation) (湯劑 Tang): A liquid medicine prepared by boiling the ingredients in water, and taken after the dregs are removed.

Pill preparation (丸劑 Wan): A solid globular mass, coated or uncoated, made of finely powdered medicinals with a suitable excipient or binder.

Powder preparation (散劑 San): A medicated preparation in the form of discrete fine particles, for internal administration or topical application.

Paste preparation (膏劑 Gao): A general term for soft extract, ointment and adhesive plaster.

Pellet (丹劑 Dan): A medicated preparation in the form of small particles, usually made from minerals by sublimation for topical application, but some also for internal administration.

XI. Comparison Table of Latin Names Revision of TCM Herbs

No.	Item	Origin of Latin names (The original plants in the third edition of Taiwan Chinese Pharmacopoeia are in parentheses)
1	Datoudianjhu 大頭典竹	*Bambusa beecheyana* Munro var.*pubescens* (P.F.Li) W.C.Lin (*Sinocalamus beecheyanus* (Munro) McClure var. *pubescens* P.F.Li)
2	Siaojyueming 小決明	*Senna tora* (L.) Roxb. (*Cassia tora* L.)
3	Huajhouyou 化州柚	*Citrus maxima* 'Tomentosa' (*Citrus grandis* 'Tomentosa')
4	Musiang 木香	*Aucklandia costus* Falc. (*Aucklandia lappa* Decne.)
5	Jhaowabaidoukou 爪哇白豆蔻	*Amomum compactum* Soland ex Maton (*Elettaria cardamomum* (L.) Maton)
6	Bansia 半夏	*Pinellia ternata* (Thunb.) Makino (*Pinellia ternata* (Thunb.) Breitenb.)
7	Wabubeimu 瓦布貝母	*Fritillaria unibracteata* P.K.Hsiao & K.C.Hsia var. *wabuensis* (S.Y.Tang & S.C.Yueh) Z.D.Liu, Shu Wang & S.C.Chen (*Fritillaria unibracteata* Hsiao et K.C.Hsia var. *wabuensis* (S.Y.Tang et S.C.Yue) Z.D.Liu,S.Wang et S.C.Chen)
8	Gangeteng 甘葛藤	*Pueraria montana* (Lour.) Merr. var. *thomsonii* (Benth.) M.R.Almeida (*Pueraria thomsonii* Benth.)
9	Baimao 白茅	*Imperata cylindrica* (L.) Raeusch. (*Imperata cylindrica* (L.) P.Beauv. var. *major* (Nees) C.E.Hubb.)
10	Bailashu 白蠟樹	*Fraxinus chinensis* Roxb. *(Fraxinus szaboana* Lingelsh.)
11	Heshouwu 何首烏	*Reynoutria multiflora* (Thunb.) Moldenke *(Polygonum multiflorum* Thunb.*)*
12	Jyueming 決明	*Senna obtusifolia* (L.) H.S.Irwin & Barneby (*Cassia obtusifolia* L.)
13	Moyaoshu 沒藥樹	*Commiphora myrrha* (T.Nees) Engl. (*Commiphora myrrha* Engl.)
14	Yalishandafansie 亞歷山大番瀉	*Senna alexandrina* Mill. (*Cassia acutifolia* Dehile；*Cassia angustifolia* Vahl)
15	Cihercai 刺兒菜	*Cirsium arvense* (L.) Scop. (*Cirsium setosum* (Willd.) M.Bieb.)
16	Dongbeitiesianlian 東北鐵線蓮	*Clematis terniflora* DC. var. *manshurica* (Rupr.) Ohwi (*Clematis manshurica* Rupr.)

No.	Item	Origin of Latin names (The original plants in the third edition of Taiwan Chinese Pharmacopoeia are in parentheses)
17	Hujhang 虎杖	*Reynoutria japonica* Houtt. (*Polygonum cuspidatum* Siebold et Zucc.)
18	Changbingbiantao 長柄扁桃	*Prunus pedunculata* (Pall.) Maxim. (*Prunus pedunculata* Maxim.)
19	Hengchungouteng 恆春鉤藤	*Uncaria lanosa* Wall. var. *appendiculata* (Benth.) Ridsdale (*Uncaria lanosa* Wall. var. *appendiculata* Ridsd.)
20	Biandou 扁豆	*Lablab purpureus* (L.) Sweet (*Dolichos lablab* L.)
21	Bianjinghuangci 扁莖黃耆	*Astragalus complanatus* R.Br. ex Bunge (*Astragalus complanatus* Bunge)
22	You 柚	*Citrus maxima* (Burm.) Merr. (*Citrus grandis* (L.) Osbeck)
23	Shih 柿	*Diospyros kaki* L.f. (*Diospyros kaki* Thunb.)
24	Pangdahai 胖大海	*Scaphium affine* (Mast.) Pierre (*Sterculia lychnophora* Hance)
25	Kulian 苦楝	*Melia azedarach* L. (*Melia toosendan* Siebold et Zucc.)
26	Kulibailashu 苦櫪白蠟樹	*Fraxinus chinensis* Roxb. subsp. *rhynchophylla* (Hance) A.E.Murray (*Fraxinus rhynchophylla* Hance)
27	Yegan 射干	*Iris domestica* (L.) Goldblatt & Mabb. (*Belamcanda chinensis* (L.) DC.)
28	Jhenjyunfuling 真菌茯苓	*Wolfiporia extensa* (Peck) Ginns (*Poria cocos* (Schwein.) F.A.Wolf)
29	Jhenjyunjhuling 真菌豬苓	*Polyporus umbellatus* (Pers.) Fr. (*Polyporu umbellatus* (Pers.) Fries)
30	Fenbeishuyu 粉背薯蕷	*Dioscorea collettii* Hook.f. var. *hypoglauca* (Palib.) S.J.Pei & C.T.Ting (*Dioscorea hypoglauca* Palib.)
31	Caodoukou 草豆蔻	*Alpinia hainanensis* K.Schum. (*Alpinia katsumadai* Hayata)
32	Tiancheng 甜橙	*Citrus sinensis* (L.) Osbeck (*Citrus sinensis* Osbeck)
33	Tongtuomu 通脫木	*Tetrapanax papyrifer* (Hook.) K.Koch (*Tetrapanax papyriferus* (Hook.) K.Koch)

No.	Item	Origin of Latin names (The original plants in the third edition of Taiwan Chinese Pharmacopoeia are in parentheses)
34	Yege 野葛	*Pueraria montana* (Lour.) Merr. var. *lobata* (Willd.) Maesen & S.M.Almeida ex Sanjappa & Predeep (*Pueraria lobata* (Willd.) Ohwi)
35	Maidong 麥冬	*Ophiopogon japonicus* (Thunb.) Ker Gawl. (*Ophiopogon japonicus* (L.f.) Ker Gawl.)
36	Songlan 菘藍	*Isatis tinctoria* L. (*Isatis indigotica* Fortune)
37	Anzihbeimu 暗紫貝母	*Fritillaria unibracteata* P.K.Hsiao & K.C.Hsia (*Fritillaria unibracteata* Hsiao et K.C.Hsia)
38	Bugujhih 補骨脂	*Cullen corylifolium* (L.) Medik. (*Psoralea corylifolia* L.)
39	Gouteng 鉤藤	*Uncaria rhynchophylla* (Miq.) Miq. (*Uncaria rhynchophylla* (Miq.) Jacks.)
40	Huai 槐	*Styphnolobium japonicum* (L.) Schott (*Sophora japonica* L.)
41	Mengguhuangci 蒙古黃耆	*Astragalus mongholicus* Bunge (*Astragalus membranaceus* (Fisch.) Bunge var. *mongholicus* (Bunge) P.K.Hsiao)
42	Hujisheng 槲寄生	*Viscum coloratum* (Kom.) Nakai (*Viscum coloratum* (Komarov) Nakai)
43	Lunyeshashen 輪葉沙參	*Adenophora triphylla* (Thunb.) A.DC. (*Adenophora tetraphylla* (Thunb.) Fisch.)
44	Bohe 薄荷	*Mentha canadensis* L. (*Mentha haplocalyx* Briq.)
45	Shuyu 薯蕷	*Dioscorea polystachya* Turcz. (*Dioscorea opposita* Thunb.)
46	Sioucioutenq 繡球藤	*Clematis montana* Buch.-Ham. ex DC. (*Clematis montana* Buch.-Ham.)
47	Suoyang 鎖陽	*Cynomorium coccineum* L. subsp. *songaricum* (Rupr.) J.Léonard (*Cynomorium songaricum* Rupr.)
48	Luohanguo 羅漢果	*Siraitia grosvenorii* (Swingle) C.Jeffrey ex A.M.Lu & Zhi Y.Zhang (*Siraitia grosvenorii* (Swingle) C.Jeffrey ex A.M.Lu et Z.Y.Zhang)
49	Lichang 鱧腸	*Eclipta prostrata* (L.) L. (*Eclipta prostrata* L.)

Monographs

Chinese Materia Medica

Official Name Lists

ABRI HERBA 1
ABUTILI SEMEN 2
ACANTHOPANACIS CORTEX 3
ACHYRANTHIS BIDENTATAE RADIX 4
ACONITI KUSNEZOFFII RADIX 5
ACONITI LATERALIS RADIX PRAEPARATA 7
ACONITI RADIX 9
ACORI TATARINOWII RHIZOMA 10
ADENOPHORAE RADIX 11
AGASTACHIS HERBA 13
AGRIMONIAE HERBA 13
AILANTHI CORTEX 14
AKEBIAE CAULIS 15
ALBIZIAE CORTEX 16
ALISMATIS RHIZOMA 18
ALLII MACROSTEMONIS BULBUS 19
ALLII TUBEROSI SEMEN 20
ALOE 20
ALPINIAE KATSUMADAI SEMEN 21
ALPINIAE OFFICINARUM RHIZOMA 23
ALPINIAE OXYPHYLLAE FRUCTUS 24
AMOMI FRUCTUS 26
AMOMI FRUCTUS ROTUNDUS 28
AMPELOPSIS RADIX 29
AMYNTHAS ET METAPHIRE 30
ANDROGRAPHIS HERBA 31
ANEMARRHENAE RHIZOMA 32
ANGELICAE DAHURICAE RADIX 34
ANGELICAE PUBESCENTIS RADIX 35
ANGELICAE SINENSIS RADIX 37
ANISI STELLATI FRUCTUS 39
AQUILARIAE LIGNUM RESINATUM 40
ARCTII FRUCTUS 41
ARECAE PERICARPIUM 42
ARECAE SEMEN 43
ARISAEMATIS RHIZOMA 44
ARMENIACAE SEMEN AMARUM 46
ARNEBIAE RADIX 47
ARTEMISIAE ANNUAE HERBA 48
ARTEMISIAE ARGYI FOLIUM 49
ARTEMISIAE HERBA 50
ARTEMISIAE LACTIFLORAE HERBA 51
ASARI RADIX 53
ASPARAGI RADIX 54
ASTERIS RADIX ET RHIZOMA 55
ASTRAGALI COMPLANATI SEMEN 56
ASTRAGALI RADIX 57
ATRACTYLODIS MACROCEPHALAE RHIZOMA 59
ATRACTYLODIS MACROCEPHALAE RHIZOMA 60
ATRACTYLODIS RHIZOMA 61
AUCKLANDIAE RADIX 62
AURANTII FRUCTUS IMMATURUS 64
AZEDARACH FRUCTUS 65
BAMBUSAE CAULIS IN TAENIAS 66
BAMBUSAE CONCRETIO SILICEA 67
BENINCASAE SEMEN 67
BLETILLAE RHIZOMA 68
BOMBYCIS FAECES 70
BOMBYX BATRYTICATUS 71
BORNEOLUM 72
BOVIS CALCULUS 72
BROUSSONETIAE FRUCTUS 73
BUDDLEJAE FLOS 74
BUPLEURI RADIX 75
CANNABIS FRUCTUS 77
CARPESII FRUCTUS 78
CARTHAMI FLOS 79
CARYOPHYLLI FLOS 80
CASSIAE SEMEN 81
CATECHU 83
CELOSIAE CRISTATAE FLOS 84
CELOSIAE SEMEN 85
CENTELLAE HERBA 85
CENTIPEDAE HERBA 87
CHAENOMELIS FRUCTUS 88
CHEBULAE FRUCTUS 89
CHRYSANTHEMI FLOS 91
CHUANXIONG RHIZOMA 92
CIBOTII RHIZOMA 94
CICADAE PERIOSTRACUM 95
CIMICIFUGAE RHIZOMA 96
CINNAMOMI CORTEX 97
CINNAMOMI CORTEX CENTRALIS 98
CINNAMOMI RAMULUS 99
CIRSII HERBA 100
CIRSII JAPONICI HERBA SEU RADIX 101

CISTANCHIS HERBA 103
CITRI FRUCTUS IMMATURUS 104
CITRI MAXIMAE EXOCARPIUM 105
CITRI RETICULATAE PERICARPIUM 107
CITRI RETICULATAE PERICARPIUM VETUM ... 108
CITRI RETICULATAE PERICARPIUM VIRIDE 109
CITRI EXOCARPIUM RUBRUM 111
CITRI SARCODACTYLIS FRUCTUS 112
CLEMATIDIS CAULIS 113
CLEMATIDIS RADIX ET RHIZOMA 114
CNIDII FRUCTUS 115
CODONOPSIS RADIX 117
COICIS SEMEN 119
COPTIDIS RHIZOMA 120
CORDYCEPS 121
CORNI SARCOCARPIUM 122
CORYDALIS RHIZOMA 123
CRASSOSTREAE CONCHA 125
CRATAEGI FRUCTUS 125
CROCI STIGMA 127
CROTONIS SEMEN 128
CULLENIAE FRUCTUS 129
CURCULIGINIS RHIZOMA 131
CURCUMAE LONGAE RHIZOMA 132
CURCUMAE RADIX 133
CURCUMAE RHIZOMA 134
CUSCUTAE SEMEN 136
CYATHULAE RADIX 137
CYNANCHI ATRATI RADIX ET RHIZOMA 138
CYNANCHI STAUNTONII RHIZOMA ET RADIX 140
CYNOMORII HERBA 141
CYPERI RHIZOMA 142
DENDROBII CAULIS 143
DESCURAINIAE SEMEN 223
DESMODII STYRACIFOLII HERBA 145
DIANTHI HERBA 146
DICHROAE RADIX 147
DICTAMNI CORTEX 148
DIOSCOREAE HYPOGLAUCAE RHIZOMA 149
DIOSCOREAE RHIZOMA 150
DIPSACI RADIX 151
DOLOMIAEAE RADIX 153
DRACONIS SANGUIS 154
DRYNARIAE RHIZOMA 155
DRYOPTERIS CRASSIRHIZOMAE RHIZOMA 156
ECLIPTAE HERBA 157
ECKLONIAE THALLUS 220
EPHEDRAE HERBA 159
EPIMEDII FOLIUM 160
EQUISETI HYEMALIS HERBA 162
ERIOBOTRYAE FOLIUM 163
ERIOCAULI FLOS 165
EUCOMMIAE CORTEX 166
EUODIAE FRUCTUS 167
EUPATORII HERBA 168
EURYALES SEMEN 169
FAGOPYRI SEMEN 170
FARFARAE FLOS 171
FOENICULI FRUCTUS 172
FORSYTHIAE FRUCTUS 173
FRAXINI CORTEX 175
FRITILLARIAE CIRRHOSAE BULBUS 176
FRITILLARIAE THUNBERGII BULBUS 177
GALLI GIGERII CORNEUM ENDOTHELIUM 178
GARDENIAE FRUCTUS 179
GASTRODIAE RHIZOMA 180
GECKO 182
GENTIANAE MACROPHYLLAE RADIX 183
GENTIANAE RADIX ET RHIZOMA 185
GINKGO SEMEN 187
GINSENG RADIX ET RHIZOMA 187
GLEDITSIAE FRUCTUS 190
GLEDITSIAE FRUCTUS ABNORMALIS 191
GLEDITSIAE SPINA 192
GLEHNIAE RADIX 193
GLYCYRRHIZAE RADIX ET RHIZOMA 193
GRANATI PERICARPIUM 195
GYPSUM FIBROSUM 196
HAEMATITUM 197
HALIOTIDIS CONCHA 197
HEDYSARI RADIX 199
HELMINTHOSTACHYDIS RADIX ET RHIZOMA 200
HIRUDO 200
HOMALOMENAE RHIZOMA 201
HORDEI FRUCTUS GERMINATUS 202
HOUTTUYNIAE HERBA 203
HOVENIAE SEMEN 204
ILICIS PUBESCENTIS RADIX ET CAULIS 205
IMPERATAE RHIZOMA 206
INDIGO NATURALIS 207

INULAE FLOS 209
IRIS RHIZOMA 210
ISATIDIS FOLIUM 211
ISATIDIS RADIX 212
JUJUBAE FRUCTUS 213
JUNCI MEDULLA 214
KAEMPFERIAE RHIZOMA 215
KAKI CALYX 216
KANSUI RADIX 217
KAOLINUM 393
KOCHIAE FRUCTUS 219
LABLAB SEMEN ALBUM 219
LAMINARIAE THALLUS 220
LEONURI FRUCTUS 221
LEONURI HERBA 222
LEPIDII SEMEN 223
LIGUSTICI RHIZOMA ET RADIX 225
LIGUSTRI LUCIDI FRUCTUS 226
LILII BULBUS 228
LINDERAE RADIX 229
LIQUIDAMBARIS FRUCTUS 230
LITCHI SEMEN 231
LITSEAE FRUCTUS 232
LONICERAE FLOS 234
LONICERAE JAPONICAE CAULIS 235
LONICERAE JAPONICAE FLOS 237
LOPHATHERI HERBA 238
LYCII FRUCTUS 239
LYCII RADICIS CORTEX 240
LYCOPI HERBA 241
LYCOPODII HERBA 242
LYGODII SPORA 243
LYSIMACHIAE HERBA 243
MAGNOLIAE CORTEX 245
MAGNOLIAE FLOS 246
MANTIDIS OÖTHECA 248
MAYDIS STYLUS 249
MENTHAE HERBA 249
MERETRICIS SEU CYCLINAE CONCHA 251
MOMORDICAE SEMEN 251
MORI CORTEX 252
MORI FOLIUM 253
MORI RAMULUS 254
MORINDAE OFFICINALIS RADIX 256
MOSLAE HERBA 257
MOUTAN RADICIS CORTEX 258
MUME FRUCTUS 259
MYRISTICAE SEMEN 260
MYRRHA 262
NATRII SULFAS 262
NELUMBINIS FOLIUM 263
NELUMBINIS PLUMULA 264
NELUMBINIS RHIZOMATIS NODUS 266
NELUMBINIS SEMEN 266
NELUMBINIS STAMEN 267
NEOPICRORHIZAE RHIZOMA 269
NEPETAE HERBA 270
NEPETAE SPICA 271
NOTOGINSENG RADIX ET RHIZOMA 272
NOTOPTERYGII RHIZOMA ET RADIX 274
OLDENLANDIAE DIFFUSAE HERBA 276
OLIBANUM 277
OPHIOPOGONIS RADIX 278
ORIGANI VULGARIS HERBA 279
OROXYLI SEMEN 280
ORTHOSIPHONIS HERBA 281
ORYZAE FRUCTUS GERMINATUS 282
PAEONIAE RADIX ALBA 283
PAEONIAE RADIX RUBRA 284
PANACIS QUINQUEFOLII RADIX 286
PATRINIAE HERBA 288
PELODISCCI CARAPAX 289
PERILLAE CAULIS 289
PERILLAE FOLIUM 291
PERILLAE FRUCTUS 292
PERSICAE SEMEN 293
PEUCEDANI RADIX 295
PHARBITIDIS SEMEN 296
PHELLODENDRI CORTEX 297
PHRAGMITIS RHIZOMA 299
PHYTOLACCAE RADIX 300
PINELLIAE RHIZOMA 301
PIPERIS FRUCTUS 302
PLANTAGINIS HERBA 303
PLANTAGINIS SEMEN 305
PLATYCLADI CACUMEN 306
PLATYCLADI SEMEN 307
PLATYCODONIS RADIX 308
POGOSTEMONIS HERBA 311
POLYGALAE RADIX 312

POLYGONATI ODORATI RHIZOMA 313
POLYGONATI RHIZOMA 314
POLYGONI AVICULARIS HERBA 315
POLYPORUS 316
PORIA 317
PORIA CUM PINI RADIX 319
PORIAE CUTIS 320
PORTULACAE HERBA 321
PRINSEPIAE NUX 322
PRUNELLAE SPICA 322
PRUNI SEMEN 324
PSEUDOSTELLARIAE RADIX 325
PTERIS MULTIFIDAE HERBA 326
PUERARIAE FLOS 327
PUERARIAE RADIX 328
PUERARIAE THOMSONII RADIX 330
PULSATILLAE RADIX 331
PYROLAE HERBA 332
PYRROSIAE FOLIUM 333
QUISQUALIS FRUCTUS 334
RAPHANI SEMEN 336
REHMANNIAE RADIX 337
REYNOUTRIAE MULTIFLORAE CAULIS 338
REYNOUTRIAE MULTIFLORAE RADIX 340
REYNOUTRIAE RHIZOMA ET RADIX 341
RHAPONTICI RADIX 343
RHEI RADIX ET RHIZOMA 344
RHODIOLAE CRENULATAE RADIX ET RHIZOMA 346
RHOIS GALLA 347
ROSAE LAEVIGATAE FRUCTUS 349
RUBI FRUCTUS IMMATURUS 350
RUBIAE RADIX ET RHIZOMA 350
RUBRA PORIA 351
SALVIAE MILTIORRHIZAE RADIX ET RHIZOMA 353
SANGUISORBAE RADIX 354
SAPOSHNIKOVIAE RADIX ET RHIZOMA 356
SAPPAN LIGNUM 357
SCAPHII SEMEN 358
SCHISANDRAE FRUCTUS 359
SCHISANDRAE SPHENANTHERAE FRUCTUS .. 360
SCORPIO 362
SCROPHULARIAE RADIX 362
SCUTELLARIAE BARBATAE HERBA 364
SCUTELLARIAE RADIX 365
SELAGINELLAE HERBA 367
SEMIAQUILEGIAE RADIX 368
SENNAE FOLIUM 369
SEPIAE ENDOCONCHA 370
SESAMI SEMEN NIGRUM 371
SIGESBECKIAE HERBA 372
SINAPIS ALBAE SEMEN 373
SIPHONOSTEGIAE HERBA 374
SIRAITIAE FRUCTUS 375
SMILACIS GLABRAE RHIZOMA 377
SOJAE SEMEN PREPARATUM 378
SOPHORAE FLAVESCENTIS RADIX 379
SOPHORAE FLOS ET FLOS IMMATURUS 380
SOPHORAE FLOS IMMATURUS 381
SOPHORAE FRUCTUS 382
SOPHORAE TONKINENSIS RADIX ET RHIZOMA 383
SPARGANII RHIZOMA 385
SPATHOLOBI CAULIS 386
SPIRODELAE HERBA 387
STEMONAE RADIX 388
STEPHANIAE TETRANDRAE RADIX 389
STROBILANTHII CUSIAE RHIZOMA ET RADIX 391
STRYCHNI SEMEN 391
TALCUM 393
TARAXACI HERBA 394
TAXILLI HERBA 395
TETRAPANACIS MEDULLA 397
THLASPI HERBA 397
TRACHELOSPERMI CAULIS CUM FOLIUM 399
TRIBULI FRUCTUS 400
TRICHOSANTHIS RADIX 400
TRICHOSANTHIS SEMEN 401
TRIGONELLAE SEMEN 402
TRITICI FRUCTUS LEVIS 404
TSAOKO FRUCTUS 404
TYPHAE POLLEN 405
UNCARIAE RAMULUS CUM UNCIS 406
VACCARIAE SEMEN 407
VERBENAE HERBA 408
VIGNAE SEMEN 410
VIOLAE HERBA 411
VISCI HERBA 412
VITICIS FRUCTUS 413

SHRUB CHASTETREE FRUIT 413
XANTHII FRUCTUS 415
ZANTHOXYLI PERICARPIUM 416
ZINGIBERIS RHIZOMA 417
ZINGIBERIS RHIZOMA RECENS 418
ZIZIPHI SPINOSAE SEMEN 419

CONCENTRATED TRADITIONAL CHINESE MEDICINE PREPARATIONS

CORYDALIS TUBER CONCENTRATED PREPARATION (GRANULES, POWDER) 425
LIQUORICE ROOT AND RHIZOME CONCENTRATED PREPARATION (GRANULES, POWDER) 426
PUERARIAE RADIX CONCENTRATED PREPARATION (GRANULES, POWDER) 427
RHUBARB CONCENTRATED PREPARATION (GRANULES, POWDER) 428
SCUTELLARIA ROOT CONCENTRATED PREPARATION (GRANULES, POWDER) 429
BANSIA XIESIN TANG CONCENTRATED PREPARATION (GRANULES, POWDER) 431
GE GEN TANG CONCENTRATED PREPARATION (GRANULES, POWDER) 433
JAIWEI XIAOYAO SAN CONCENTRATED PREPARATION (GRANULES, POWDER) 435
SIAOCINGLONG TANG CONCENTRATED PREPARATION (GRANULES, POWDER) 438

ABRI HERBA
雞骨草
Ji Gu Tsao / Ji Gu Cao
Abrus Herb

Abrus herb is the dried herb with fruit pod removed of *Abrus pulchellus* Wall. ex Voigt. subsp. *cantoniensis* (Hance) Verdc. (Fam. Leguminosae).
It contains not less than 3.0% of dilute ethanol-soluble extractives and not less than 2.0% of water extractives and not less than 0.01% of abrine.

Description: Conical, thick at the upper part and slender at the lower part, branched, varing in length. 0.5~1.5 cm in diameter. Extermally grayish-brown, coarse, with fine longitudinal wrinkles. Branches extremely slender, some dropped or residued remained, texture hard. Branches fascicled, 50~100 cm in length, 0.2 cm in diameter, grayish-brown to purplish-brown, young branches slender, sparely coverd with pubescence. Pinnately compound leaf alternated, leaflets 8~11, oblong, mostly fallen off, 0.8~1.2 in length; apex truncate with small protuberant, the lower surface covered with. Odour slightly aromatic; taste slightly bitter.

Microscopic identification:

1. **Transverse section:**
   Root of *Abrus pulchellus*: Cork reddish-brown, composed of several rows of cells, with cells rectangular or subsquare. Cortex narrow, with prisms of calcium oxalate and stone cells present, arranged in an interrupted ring. Phloem relatively narrow; cambium ring; xylem vessels scattered, arranged radially; rays distinct, 2 to several cells wide. In the tansverse section of stem, cork brown, composed of several rows of cells, rectangular or subsquare. Cortex narrow, with prisms of calcium oxalate and stone cells present. Numerous phloem fibers arranged in a ring. Phloem narrow; rays distinct; xylem broad, vessels scattered, arranged radially. Pith broad, parenchymatous cells subrounded, mostly broken and hollow. In the tansverse section of leaf, upper epidermis composed of 1 row of cells, rectangular or subsquare, prisms of calcium oxalate sometimes present underneath epidermis cells, with prisms of calcium oxalate sometimes present. Spony tissue with cells subrunded, arranged loosely. Collateral vascular bundles, 2~4 layers of fibers present in the upside and downsinde of the xylem and phloem. Lower epidermis composed of 1 row of irregulaer cells, with non-glandular hairs occasionally present.
2. **Powder:** Grayish-green. Cork cells yellowish-brown, rectangular, oblong or irregular in shape. Epidermis cells of leaf with walls slightly curved, stomata paracytic. Fiber bundles surrounded by cells containing prisms of calcium oxalate, forming crystal fibers, polychromatic under the polarized microscope, walls of crystal cells irregularly thickened. Non-glandular hair unicellar, apex acute or acuminate, 60~970 μm in length, 12~22 μm in diameter, walls 3~6 μm thick, striations distinct, warty protrusions and yellowish-brown contents visible. Fibers singly scatterd or several in boundle, 8~36 μm in diameter, with walls relatively thick. Vessels mostly Bordered-pitted, 10~53 μm in diameter. Stone cells rounded, subsquare or long-rounded, 6~40 μm in diameter, with some walls slightly thickened. Prisms of calcium oxalate numerous, 6~43 μm in diameter, bright white or polychromatic under the polarized moicroscope. Starch granules numerous, simple granules rounded or subrunded; compound granules mostly composed of 2~4 components, black and cruciate-shaped under the polarized microscope.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 2.0 g of powdered sample to 20 mL of methanol, ultrasonicate for 30 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 1 mL of methanol.
2. Reference drug solution: Take 2.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of abrine and dissolve in methanol to produce a solution containing 0.5 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-butanol, glacial acetic acid, and water (3:1:1) as the developing solvent. Apply 2 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with ninhydrin and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 11.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 6.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Abrine:
   (1) Mobile phase: Methanol as the mobile phase A, and 0.1% phosphoric acid as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of abrine and dissolve in 50% methanol to produce a solution containing 2 μg per mL.
   (3) Sample solution: Weigh accurately 0.5 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 20 mL of 50% methanol, ultrasonicate for 30 minutes, centrifuge for 10 minutes. Transfer the supernatant to a 50-mL volumetric flask. Repeat the extraction of the residue one more time, combine the supernatant, and make up to volume with 50% methanol, mix well, filter and use the filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (278 nm) and a column packing L1. The column temperature is maintained at 25℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of abrine should not be less than 4,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~20	11→31	89→69

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Abrine (%)=0.005 (r_U/r_S) (C_S) / (W)

r_U: peak area of abrine of sample solution
r_S: peak area of abrine of reference standard solution
C_S: concentration of abrine reference standard solution (μg /mL)
W: weight of test sample (g) calculated with dried sample.

Storage: Store in a ventilated and dry place.
Usage: Heat-clearing medicinal (Heat-clearing and detoxicating medicinal).
Property and flavor: Cool, sweet and mild bitter.
Meridian tropism: Liver and stomach meridians.
Effects: Clear heat and drain dampness, soothe the liver to relive pain, activate blood and dissipate stasis.
Administration and dosage: 15~30 g.

ABUTILI SEMEN
苘麻子
Cing Ma Zih / Qing Ma Zi
Chingma Abutilon Seed

Chingma abutilon seed is the dried ripe seed of *Abutilon theophrasti* Medik. (Fam. Malvaceae).
It contains not less than 5.0% of dilute ethanol-soluble extractives and not less than 5.0% of water extractives.

Description: Triangular or flattened reniform, relatively acute at one edge, 3~5 mm in length, about 3 mm in width. Externally grayish-brown, with grayish-brown tomenta, a pale brown linear hilum at the dented part in the edge. Testa hard, with cylindrical radicle inside, cotyledons 2, folded into W-shaped, inserted into the endosperm. Odour slight; taste weak.

Microscopic identification:
Transverse section:
Seed of *Abutilon theophrasti*: Epidermis composed of 1 layer of flattened-rectangular cells, occasionally differentiate into unicellular non-glandular hairs, wall thickened and slightly lignified. Hypodermis consists of 1 layer cells, slightly elongated radially. Palisade cells cylindrical, 75~88 μm in length, heavily thick-walled, with lower part lignified. linear lumina visible at the upper part, the terminal end expended, containing small globular crystals or reddish-brown contents. Pigment cells 4~5 layers, containing yellowish-brown or reddish-brown contents. Endosperm and cotyledon cells containing fatty oil droplets and aleurone grains, with a few of fine clusters of calcium oxalate occasionally present in cotyledon cells.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of ethanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of petroleum ether (30~60℃) and ethyl ether (7:4) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air and expose to iodine vapor until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:

1. Loss on drying: Not more than 12.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 7.0% (General rule 6007).

3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place.
Usage: Heat-clearing medicinal (Heat-clearing and dampness-drying medicinal).
Property and flavor: Neutral; bitter.
Meridian tropism: Large intestine, small intestine and bladder meridians.
Effects: Induce diuresis and relieve strangury, promote lactation, moisten the intestines to relax the bowels.
Administration and dosage: 3~10 g.

ACANTHOPANACIS CORTEX
五加皮
Wu Jia Pi/ Wu Jia Pi
Slenderstyle Acanthopanax Root-bark

Slenderstyle acanthopanax root-bark is the dried bark of root of *Acanthopanax gracilistylus* W.W.Sm. (Fam. Araliaceae).
It contains not less than 12.0% of dilute ethanol-soluble extractives and not less than 9.0% of water extractives.

Description:
Irregular quills, 5~15 cm in length,0.4~1.4 cm indiameter, 0.2 cm thick. Outer surface grayish-brown, Slightly twisted longitudinal wrinkles and horizontally long lenticels, Inner surface pale yellow or grayish-yellow, Fine vertical stripes. light, brittle, easy to break, and the section is not neat, grayish white. Odour slight, the taste is slightly spicy and bitter.

Microscopic identification:
1. **Transverse section:**
   Rhizodermis of *Acanthopanax gracilistylus*: Outermost layer of cork composed of 7~14 rows of parenchymatous cells, arranged tangentially, subsquare, subrectangular or subpolygonal. Cortex narrow, cells elongated tangentially, with some secretory canals scattered. Parenchyma cells contain abundant clusters of calcium oxalate. The major portion of the root is phloem, clefts existed in the outer part of phloem, rays 1~5 cells wide, containing abundant secretory canals, subrounded, with 4~11 secretory cells, Parenchymatous cells contain starch granules, as well as columnar crystals of calcium oxalate. Bast fibers are sometimes found in the old root bark, with a single or 2~4 bundles scattered.
2. **Powder:** Pale brown. Cork cells polygona or rectangle, walls thin, pale yellow or pale tan, cork cells of the old root bar sometimes have uneven wall thickening and a few pits. Secretory debris contains colorless or light yellow secretions. Starch granules relatively numerous, simple granules polygon or subrounded, 2~8 μm in diameter, compound granules composed of 2~7 components. Clusters of calcium oxalate scattered, mostly existed in parenchymatous cells, 8~76 μm in diameter, angles blunt, short and pointed, multicolor under polarized light. Bast fibers are a single or 2~4 bundles scattered, long strip, walls thick, ignified.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 3.0 g of powdered sample to 10 mL of 70% ethanol, ultrasonicate for 10 minutes, filter and use the filtrate.
2. Reference drug solution: Take 3.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of syringoside and dissolve in ethanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of dichloromethane, methanol, and water (10:2:0.1) as the developing solvent. Apply 5 μL of each of the sample solution and reference drug solution and 2 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 254 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 11.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 14.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 4.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).

7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 15.0 ppm (General rule 2251, 6301).

Assay:
1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place, and protect from mold and insects.
Usage: Dampness-dispelling medicinal (Wind-dampness-dispelling medicinal).
Property and flavor: Warm; pungent and bitter.
Meridian tropism: Liver and kidney meridians.
Effects: Dispel wind-dampness, tonify liver and kidney, strengthen sinew and bone reduce edema.
Administration and dosage: 5~12 g.

ACHYRANTHIS BIDENTATAE RADIX
牛膝
Niou Si / Niu Xi
Twotooth Achyranthes Root

Twotooth achyranthes root is the dried root of *Achyranthes bidentata* Blume (Fam. Amaranthaceae), commonly known as "Huai Niou Shi".
It contains not less than 55.0% of dilute ethanol-soluble extractives, not less than 57.0% of water extractives and not less than 0.03% of *β*-ecdysterone.

Description: Slender cylindrical, yellowish-brown or grayish-yellow, slightly smooth, straight or slightly curved, 15~90 cm in length, 0.2~1 cm in diameter. Fine longitudinal wrinkles and protuberant transverse lenticels present in surface, with obvious branch root and fine root scars. Texture hard and fragile, easily broken, fracture even, slightly translucent, pale brown. Fine and yellow-white heartwood, with many yellowish-white spotted vascular bundles outside interruptedly arranged in 2~4 whorls. Odour slight; taste slightly sweet, bitter and astringent.

Microscopic identification:
1. **Transverse section:**
Root of *Achyranthes bidentata*: Cork composed of 3~7 rows of flattened cells. Cortex composed of dozens of layers of flat-rectangular parenchymatous cells. Stele occupied the major portion of the roo, with collateral vascular bundles interruptedly arranged in 2~4 whorls. Vascular bundles relatively small in the outermost whorl, while relatively large inward, cambium nearly in a ring. Xylem consists of vessels and xylem fibers. Primary xylem located in the centre of the root, usually fissured, mainly consisting of pitted and reticulate vessels. Parenchymatous cells contain sandy crystals of calcium oxalate.
2. **Powder:** Yellowish-brown. Vessels mainly pitted or reticulated, 80~110 μm in diameter. Sandy crystals of calcium oxalate triangle or subsquare in shape, scattered in the parenchyma cells, about 7 μm in diameter. Walls of xylem parenchymatous cells singly pitted or reticulate thickened.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 2 mL of methanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of *β*-ecdysterone and dissolve in methanol to produce a solution containing 0.2 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate and methanol (4:1) as the developing solvent. Apply 2 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Total ash: Not more than 6.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
3. Sulfur dioxide: Not more than 400 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 5.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
1. *β*-Ecdysterone
   (1) Mobile phase: Acetonitrile as the mobile phase A, and water as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of *β*-ecdysterone, and dissolve in methanol to produce a solution containing 20 μg per mL.
   (3) Sample solution: Weigh accurately 1.0 g of the powdered sample and place it in a 50-mL

centrifuge tube, add accurately 12.5 mL of 75% methanol, ultrasonicate for 30 minutes, centrifuge for 5 minutes, filter with filter paper, use the filtrate. Repeat the extraction of the residue one more time. Combine the filtrate, transfer the filtrate to a 25-mL volumetric flask, make up to volume with 75% methanol, mix well, filter and use the successive filtrate.

(4) Chromatographic system: The liquid chromato - graphy is equipped with an UV detector (246 nm) and a column packing L1. The column temperature is maintained at 30℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of *β*-ecdysterone should not be less than 5,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~25	15	85
25~40	15→45	85→55
40~50	45→100	55→0

(5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

***β*-Ecdysterone: (%)= 0.0025(r_U/r_S) (C_S) / (W)**

r_U: peak area of *β*-ecdysteron of sample solution

r_S: peak area of *β*-ecdysteron of reference standard solution

C_S: concentration of *β*-ecdysteron of reference standard solution (μg/mL)

W: weight of test sample (g) calculated with dried sample.

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place, and protect from moisture and oil seeping.
Usage: Blood-regulating medicinal (Blood-activating and stasis-dispelling medicinal).
Property and flavor: Neutral; bitter and sour.
Meridian tropism: Liver and kidney meridians.
Effects: Activate blood and resolve stasis, unblock the meridian, tonify liver and kidney, strengthen sinew and bone.
Administration and dosage: 5~15 g.

【Decoction pieces】

ACHYRANTHIS BIDENTATAE RADIX

It contains not less than 55.0% of dilute ethanol-soluble extractives, not less than 57.0% of water extractives and not less than 0.03% of *β*-ecdysterone.
Raw medicinal materials are processed to remove remove impurities, clean selection, soften thoroughly, remove remains of rhizomes, cut into sections, and dry, mostly oblique slices or in cylindrical sections, externally pale brown, with fine longitudinal wrinkles and transverse lenticel-like protrudings. Texture hard and fragile, easily broken, softened when moistened. Cut surface even, pale brown to brown, slight horny and oily, central vascular bundles with larger xylem in yellowish-white colour, scattered many yellowish-white dotted vascular bundles in 2-4 whorls in outer part. Odour slight, taste slight sweet and slight t bitter and astringent, sour.
Thin layer chromatographic identification test: The method is the same as that for crude herb.
Impurities and other requirements: Methods and specifications are the same as those for crude herb.
Assay: The method is the same as that for crude herb.
Storage: The method is the same as that for crude herb.
Usage: Blood-regulating medicinal (Blood-activating and stasis-dispelling medicinal).
Property and flavor: Neutral; bitter and sour.
Meridian tropism: Liver and kidney meridians.
Effects: Activate blood and eliminate stasis, promoting menstruation, strengthen sinew and bone.
Administration and dosage: 5~15 g.

ACONITI KUSNEZOFFII RADIX
草烏
Cao Wu / Cao Wu
Kusnezoff Monkshood Root

Kusnezoff monkshood root is the dried root tuber of *Aconitum kusnezoffii* Rchb. (Fam. Ranunculaceae).
It contains not less than 2.0% of dilute ethanol-soluble extractives, not less than 4.0% of water extractives and among 0.1~0.5% of the total amount of aconitine, hypaconitine, and mesaconitine.

Description: Irregularly long-conical, slightly curved, 2~7 cm in length, 1~3 cm in diameter. Apex usually with remains of stem base or its scar. Externally grayish-brown or dark brown, crumpled and uneven, with dotted rootlet scars and several tubercular lateral roots. Texture hard, fracture grayish-white or dark gray, with fissures, cambium ring polygonal, pith relatively large or hollow. Odour slight; taste pungent and numb.

Microscopic identification:

1. **Transverse section:**
   Root tuber of *Aconitum kusnezoffii*: Metaderm composed of 7~8 rows of yellowish-brown suberized cells. Cortex contains subrectangular or suboblong stone cells, singly scattered or 2~5 in a group, with large lumen. Endodermis distinct. Phloem broad, usually with irregular clefts, a few stone cells scattered near endodermis, sieve tube

groups scattered. Cambium in a ring, cells irregularly polygonal or subrounded. Xylem vessels 1~4 rows or several in groups, located inside of cambium corners, some containing brownish-yellow contents, vessels mainly pitted and reticulate, a few spiral and scalariform vessels occasionally found. Pith relatively large, parenchymatous cells filled with starch granules.

2. **Powder:** Grayish to brown. Simple starch granules subrounded, 2~23 μm in diameter; compound granules composed of 2~16 components. Stone cells subrectangular or suboblong, 60~160 μm in length, 25~50 μm in width, walls varying in thickness, thick wall with distinct striations, some containing brown contents. Metaderm cells brown, subsquare or subpolygonal in surface view, wall unevenly thickened, some with protuberance inward the lumina. Vessels mainly pitted and reticulate, 25~130 μm in diameter, the terminal with round protuberance, vessel elements connected.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 2.0 g of powdered sample to 2 mL of ammonia solution, add 20 mL of ethyl ether, ultrasonicate for 30 minutes and filter, evaporate the filtrate to dryness, and dissolve the residue in 1 mL of dichloromethane.
2. Reference drug solution: Take 2.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of aconitine and dissolve in a solution of chloroform and isopropanol (1:1) to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane, ethyl acetate and methanol (6.4:3.6:1) as the developing solvent. Apply 10 μL of each of the above solutions to the plate, developing in a chamber pre-equilibrated with ammonia vapor for 20 minutes. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with modified Dragendorff's reagent. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Total ash: Not more than 7.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Aconitine, hypaconitine, and mesaconitine:
   (1) Mobile phase: A solution of tetrahydrofuran and acetonitrile (15:25) as the mobile phase A, and 0.1 M ammonium acetate (add 0.5 mL of glacial acetic acid per 1,000 mL) as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of aconitine, hypaconitine, and mesaconitine and dissolve in a solution of chloroform and isopropanol (1:1) to produce a solution containing 0.3 mg, 0.18 mg and 1.0 mg per mL of each.
   (3) Sample solution: Weigh accurately 2.0 g of powdered sample and place it in a conical flask with stopper, then add 3 mL of ammonia solution, add accurately 50 mL of a solution of ethyl acetate and isopropanol (1:1), weigh, ultrasonicate for 30 minutes, cool, weigh again, replenish the loss of the weight with a solution of isopropanol and ethyl acetate (1:1), mix well and filter. Measure accurately 25 mL of the successive filtrate and evaporate to dryness under reduced pressure below 40°C. Dissolve exactly the residue in 3 mL of the mixture of chloroform and isopropanol (1:1), stopper tightly, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (235 nm) and a column packing L1. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of mesaconitine should not be less than 2,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~48	15→26	85→74
48~48.1	26→35	74→65
48.1~58	35	65
58~65	35→15	65→85

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Aconitine, hypaconitine, or mesaconitine (%)=0.6(r_U/r_S) (C_S) / (W)
   r_U: peak area of aconitine, hypaconitine, or mesaconitine of sample solution
   r_S: peak area of aconitine, hypaconitine, or mesaconitine of reference standard solution

Cs: concentration of aconitine, hypaconitine, or mesaconitine of reference standard solution (mg/mL)

W: weight of test sample (g) calculated with dried sample.

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place, and protect from insects.
Usage: Interior-warming medicinal.
Property and flavor: Hot; pungent and bitter; highly toxic.
Meridian tropism: Heart, liver, kidney, and spleen meridians.
Effects: Dispel wind-dampness, relieve pain, disperse swelling.
Administration and dosage: 1.5~3 g, generally processed before application.
Precaution and warning: Unprocessed one highly toxic, should be used cautiously for oral admininistration. Forbit to use during pregnancy. Incompatible with Fritillariae Thunbergii Bulbus, Pinelliae Rhizoma, Bletillae Rhizoma, Ampelopsis Radix, Trichosanthis Radix, Trichosanthis Semen, and Trichosanthis Fructus.

ACONITI LATERALIS RADIX PRAEPARATA
附子
Fu Zih / Fu Zi
Prepared Monkshood Daughter Root

Prepared monkshood daughter root is the dried lateral root of *Aconitum carmichaelii* Debeaux (Fam. Ranunculaceae). According to the different process methods, monkshood daughter root separate into "Yan Fu Zi", "Hei Shun Pian" and "Bai Fu Pian", etc.
It contains not less than 0.01% of the total amount of benzoylmesaconine, benzoylaconine, and benzoylhypaconine and not more than 0.02% of diester-alkaloids, calculated with the total amount of mesaconitine, hypaconitine, and aconitine.

Description:
1. Fu Zi: Conical, varying in sizes, about 1.5~5 cm in length, about 1.5~4 cm in diameter. Externally grayish-brown, with fine wrinkles, apex with dented bud scars and the scars of parent root at lateral side, surrounded with numerous tubercle rootlets, commonly known as "Jiau Ding". Texture hard, fracture grayish-white, starchy, with an irregular cambium ring in transverse section, polygonal. Odour slight; taste pungent.
2. Yan Fu Zi (salted aconite daughter root tuber): Larger, about 4~7 cm in length, about 3~5 cm in diameter. Externally grayish-black, covered with fine powder of salt. Texture heavy. Grayish-brown in transverse section, with irregular striations. Hollow center filled with salt. Odourless; taste salty, numb and pungent.
3. Hei Shun Pian (black slice): Irregular longitudinal slices, the upper portion board and the lower portion narrow, about 2~5 mm thick. The outer bark blackish-brown, fracture yellowish-brown, oily and lustrous, translucent, with longitudinal vascular bundles. Texture hard and fragile. Odour slight; taste weak.
4. Bai Fu Pian (white slice): Transverse slices, without outer bark, about 3~5 mm thick, yellowish-white, translucent, with vascular bundles.

Microscopic identification:
1. **Transverse section:**
   Root of *Aconitum carmichaelii*: Metaderm composed of 1 row of sclerenchymatous cells, varying in shape, primary cortex composed of 8~13 rows of relatively thickened cells, suboblong, subtriangular or subpolygonal, with intercellular spaces. Endodermal cells relatively small, with walls yellow and slightly lignified. Phloem relatively broad, parenchymatous cells filled with starch granules, scattered with small sieve tube groups. Cambium composed of 2~4 rows of flattened cells. Xylem composed of polygonal cells, with intercellular spaces, arranged irregularly in V-shaped at the inner side of cambium, containing starch granules. Pith in the center, cells filled with starch granules.
2. **Powder:** Yellowish-white. Starch granules extremely abundant, simple granules spheroidal, long-rounded or reniform, 3~22 μm in diameter; compound granules composed of 2~7 components. Metaderm cells subpolygonal in surface view, with anticlinal walls irregularly thickened, some with tubercularly thickened walls and intruding into lumina. Stone cells relatively rare, subsquare or subrectangular. Vessels mainly scalariform, about 10~48 μm in diameter.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 5.0 g of powdered sample to 20 mL of ethanol, heat under reflux for 60 minutes, filter and evaporate the filtrate to 1.0 mL.
2. Reference drug solution: Take 5.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-butanol, glacial acetic acid, and water (7:1:2) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with *p*-anisaldehyde/H_2SO_4 TS and heat at 105℃ until the spots become visible. The spots in the chromatogram obtained from the sample solution

corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:

1. Diester-alkaloids (mesaconitine, hypaconitine, and aconitine):
   (1) Mobile phase: A solution of tetrahydrofuran and acetonitrile (15:25) as the mobile phase A, and 0.1 M ammonium acetate (0.5 mL glacial acetic acid per 1,000 mL) as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of mesaconitine, hypaconitine, and aconitine and dissolve in a solution of isopropanol and dichloromethane (1:1) to produce a solution containing 5 μg per mL of each.
   (3) Sample solution: Weigh accurately 2.0 g of powdered sample, and place it in a conical flask with stopper, add 3 mL of ammonia solution, accurately add 50 mL of a solution of isopropanol and ethyl acetate (1:1), weigh, ultrasonicate for 30 minutes, cool, weigh again, replenish the loss of the weight with a solution of isopropanol and ethyl acetate (1:1), mix well, filter, transfer 25 mL of successive filtrate, evaporate the filtrate to dryness on 40℃, dissolve the residue in a solution of isopropanol and dichloromethane (1:1) to 3 mL, filter and use the filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (235 nm) and a column packing L1. Program the chromatographic gradient system as follows.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0～48	15→26	85→74
48～49	26→35	74→65
49～58	35	65
58～65	35→15	65→85

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Diester-alkaloids (mesaconitine, hypaconitine, and aconitine) (%)=0.0006 (r_U/r_S) (C_S)/(W)

r_U: peak area of diester-alkaloids (mesaconitine, hypaconitine, and aconitine) of sample solution

r_S: peak area of diester-alkaloids (mesaconitine, hypaconitine, and aconitine) of reference standard solution

C_S: concentration of diester-alkaloids (mesaconitine, hypaconitine, and aconitine) of reference standard solution (μg/mL)

W: weight of test sample (g) calculated with dried sample.

2. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
3. Arsenic (As): Not more than 5.0 ppm (General rule 2211, 6301).
4. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
5. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
6. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

Benzoylmesaconine,benzoylaconine,and benzoylhypaconine:

1. Mobile phase: A solution of tetrahydrofuran and acetonitrile (15:25) as the mobile phase A, and 0.1 M ammonium acetate (0.5 mL glacial acetic acid per 1,000 mL) as the mobile phase B.
2. Reference standard solution: Weigh accurately a quantity of benzoylmesaconine, benzoylaconine, benzoylhypaconine and dissolve in a solution of isopropanol and dichloromethane (1:1) to produce a solution containing 10 μg per mL of each.
3. Sample solution: Weigh accurately 2.0 g of powdered sample, transfer to a conical flask with stopper, add 3 mL of ammonia solution, accurately add 50 mL of a solution of isopropanol and ethyl acetate (1:1), weigh, ultrasonicate for 30 minutes, cool, weigh again, replenish the loss of the weight with a solution of isopropanol and ethyl acetate (1:1), mix well, filter, transfer 25 mL of successive filtrate, evaporate the filtrate to dryness on 40℃, dissolve the residue in a solution of isopropanol and dichloromethane (1:1) to 3 mL, filter and use the filtrate.
4. Chromatographic system: The liquid chromatography is equipped with an UV detector (235 nm) and a column packing L1. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of benzoylmesaconine should not be less than 3,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0～48	15→26	85→74
48～49	26→35	74→65
49～58	35	65
58～65	35→15	65→85

5. Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution

into the liquid chromatography apparatus, and calculate the content.

Benzoylmesaconine, benzoylaconine, or benzoylhypaconine (%)=0.0006 (r_U/r_S) (C_S) / (W)

r_U: peak area of benzoylmesaconine, benzoylaconine, or benzoylhypaconine of sample solution

r_S: peak area of benzoylmesaconine, benzoylaconine, or benzoylhypaconine of reference standard solution

C_S: concentration of benzoylmesaconine, benzoylaconine, or benzoylhypaconine of reference standard solution (μg/mL)

W: weight of test sample (g) calculated with dried sample.

Storage: Yan Fu Zi should be stored in a dry place and preserved in a well-closed container; Hei Shun Pian and Bai Fu Pian should be stored in a cool and dry place, and protected from mold and insects.

Usage: Interior-warming medicinal.

Property and flavor: Highly hot; pungent and sweet; toxic.

Meridian tropism: Heart, kidney and spleen meridians.

Effects: Restore yang and rescuing patient from collapse, dissipate cold and relieve pain.

Administration and dosage: 3~15 g, It should be decocted first and for a long time.

Precaution and warning: Unprocessed one toxic, using processed one for oral administration. Use cautiously during pregnancy.

ACONITI RADIX
川烏
Chuan Wu / Chuan Wu
Common Monkshood Mother Root

Common monkshood mother root is the dried main root of *Aconitum carmichaelii* Debeaux (Fam. Ranunculaceae). It contains not less than 10.0% of dilute ethanol-soluble extractives, not less than 10.0% of water extractives and 0.05~0.17% of the total amounts of aconitine, hypaconitine, and mesaconitine.

Description: long conical, slightly curved, 2~7.5 cm in length, 1.5~3 cm in diameter. Externally grayish-brown, with coarse longitudinal wrinkles, conical protuberant rootlets (undeveloped prepared monkshood daughter root tuber) and scar of prepared monkshood daughter root tuber surrounded, apex occasionally with remains of stem base. Texture compact, fracture grayish-white, starchy. Odour slight; taste pungent and numb.

Microscopic identification:

1. **Transverse section:**
   Main root of *Aconitum carmichaelii*: Metaderm composed of brown suberized cells; stone cells occasionally scattered in cortical parenchyma as individual or in groups, subrectangular, square, or oblong, each with a large lumen; endodermis indistinct. Sieve tube groups scattered in phloem; fiber bundles occasionally present in the inner part of phloem. Cambium ring subpolygonal, 1 or more abnormal vascular bundles occasionally present inside or outside. Vessels in xylem composed of several rows, arranged radially or in V-shape. Pith distinct. Parenchymatous cells filled with starch granules.
2. **Powder:** Grayish-yellow. Starch granules extremely abundant, simple granules spheroidal, oblong or reniform, 3~22 μm in diameter; compound granules composed of 2~15 components. Metaderm cells subrectangular or long-polygonal in surface view, with anticlinal walls slightly thickened, some walls occasionally curved and sinuous in lateral wall, some tubercularly thickened and intruding into lumina. Stone cells relatively less, subrectangular, subsquare, polygonal or with one side oblique, 49~117 μm in diameter, walls 4~13 μm thick, pits sparse. Bordered-pitted vessels 29~70 μm in diameter, some vessel cells thick and short; tortuous or connected in crisscross pattern, pits dense. Fibers few, slat-shaped, some with short branches; pits cruciate, V-shaped or bordered-pitted.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 2.0 g of powdered sample moisten with 2 mL of ammonia solution, add 20 mL of ethyl ether, ultrasonicate for 30 minutes and filter, evaporate the filtrate to dryness, dissolve the residue in 1 mL of dichloromethane.
2. Reference drug solution: Take 2.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of aconitine, hypaconitine, and mesaconitine and dissolve in a solution of dichloromethane and isopropanol (1:1) to produce a solution containing 1.0 mg per mL of each.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane, ethyl acetate, and methanol (6:4:1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate, developing in a chamber pre-equilibrated with the vapor of ammonia for 20 minutes. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Expose to iodine vapor for 3~5 minutes. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 12.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 8.0% (General rule 6007).

3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Aconitine, hypaconitine, and mesaconitine:
   (1) Mobile phase: A solution of acetonitrile and tetrahydrofuran (25:15) as the mobile phase A, and 0.1 M ammonium acetate (add 0.5 mL glacial acetic acid in each 1,000 mL solution) as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of aconitine, hypaconitine, and mesaconitine and dissolve in a solution of isopropyl and dichloromethane (1:1) to produce a solution containing 50 μg per mL of each.
   (3) Sample solution: Weigh accurately 2.0 g of powdered sample and place it in a conical flask with stopper, add 3 mL of ammonia, accurately add 50 mL of a mixture isopropanol and ethyl acetate (1:1) and weigh. Ultrasonicate for 30 minutes, cool, and weigh again, replenish the loss of the solvent with the above mixture, mix well and filter. Measure accurately 25 mL of the successive filtrate, recover the solvent to dryness in vacuum below 40℃, dissolve the residue in 3 mL of the above mixture, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (235 nm) and a column packing L1. Program the chromatographic gradient system as follows. The ratio may be adjusted if necessary. The number of theoretical plates of the peak of mesaconitine should not be less than 2,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~48	15→26	85→74
48~49	26→35	74→65
49~58	35	65
58~65	35→15	65→85

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   Aconitine, hypaconitine, or mesaconitine: (%)=0.000636 (r_U/r_S) (C_S) / (W)

   r_U: peak area of aconitine, hypaconitine, or mesaconitine of sample solution

   r_S: peak area of aconitine, hypaconitine, or mesaconitine of reference standard solution

   C_S: concentration of aconitine, hypaconitine, or mesaconitine of reference standard solution (μg/mL)

   W: weight of test sample (g) calculated with dried sample.
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place, and protect from insects.
Usage: Interior-warming medicinal.
Property and flavor: Hot; pungent and bitter; highly toxic.
Meridian tropism: Heart, liver, kidney, and spleen meridians.
Effects: Dispel wind and eliminate dampness, warm the meridian to relieve pain.
Administration and dosage: 1.5~3 g, generally processed before application, it should be decocted first and for a long time.
Precaution and warning: Highly toxic, should be store with care. Avoid to use during pregnancy. Use cautiously with Pinelliae Rhizoma, Trichosanthis Fructus, Trichosanthis Semen, Trichosanthis Radix, Fritillariae Cirrhosae Bulbus, Fritillariae Thunbergii Bulbus, Bletillae Rhizoma and Ampelopsis Radix.

ACORI TATARINOWII RHIZOMA
石菖蒲
Shih Chang Pu / Shi Chang Pu
Acorus Rhizome

Acorus rhizome is the dried rhizome of *Acorus tatarinowii* Schott (Fam. Araceae).
It contains not less than 12.0% of dilute ethanol-soluble extractives, not less than 11.0% of water extractives, not less than 1.0% (v/w) of volatile oil.

Description: Compressed-cylindrical, curved and branched, 3~20 cm in length, 0.5~1 cm in diameter. Externally brown or reddish-brown, annulations arranged closely, internodes with triangular leaf scar and fine longitudinal wrinkles, arranged alternately, with hairy and scaly remains, with rounded protuberant root scars below. Texture hard, easily broken, fracture fibrous, yellowish-white or grayish-white, an endodermis ring distinct. Odour aromatic; taste slightly pungent.

Microscopic identification:

1. **Transverse section:**
   Rhizome of *Acorus tatarinowii*: Epidermis composed of brown cells with thickened outer wall, subsquare, occasionally containing reddish-brown contents. Cortex broad, composed of many layers of parenchymatous cells, cells filled with starch granules; cortex scattered with numerous fiber bundles and leaf-trace vascular bundles; fiber bundles vary in size, 6~21 μm in diameter, surrounded by parenchymatous cells, containing crystals of calcium oxalate, forming crystal fibers in longitudinal view. Leaf-trace vascular bundles collateral; phloem cells small; xylem vessels in groups, 9~32 μm in diameter, mainly spiral and annular. Vascular bundles sheath composed of lignified fibers. Endodermis distinct. Stele occupy 1/3 portion of rhizome, scattered with numerous vascular bundles, densely arranged close to the endodermis, vascular bundles amphivasal, phloem cells small, vessels 9~32 μm in diameter, mainly spiral and reticulate. Fibers of vascular bundles sheath relatively less, surrounded by parenchymatous cells containing prisms of calcium oxalate, forming crystal fibers.
2. **Powder:** Pale yellowish-brown. Fibers in bundles, extremely lignified, 6~21 μm in diameter, up to 350~780 μm in length, the outer layer surrounded by parenchymatous cells, containing prisms, forming crystal fibers. Vessels spiral and reticulate, 9~32 μm in diameter. Starch granules vary in size, simple granules 3~9 μm in diameter, hilum dotted and V-shaped, with indistinct striations; compound granules also exist.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol in an erlenmeyer flask, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane and ethyl acetate (4:1) as the developing solvent. Apply each 2 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:

1. Loss on drying: Not more than 15.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 10.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 3.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 5.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).
3. Volatile oil: Carry out the method for determination of volatile oil (General rule 6013).

Storage: Store in a dry place, and protect from mold.
Usage: Orifice-opening medicinal.
Property and flavor: Warm; pungent and bitter.
Meridian tropism: Heart, liver and stomach meridians.
Effects: Open the orifices, tranquilize the mind, arouses spirit and sharpens mind, sweep phlegm, transforms dampness to opens stomach.
Administration and dosage: 3~10 g.

ADENOPHORAE RADIX
南沙參
Nan Sha Shen / Nan Sha Shen
Ladybell Root

Ladybell root is the dried root of *Adenophora stricta* Miq., or *Adenophora triphylla* (Thunb.) A.DC. (*Adenophora tetraphylla* (Thunb.) Fisch.) (Fam. Campanulaceae).
It contains not less than 10.0% of dilute ethanol-soluble extractives and not less than 10.0% of water extractives.

Description:

1. Root of *Adenophora stricta*: Root long conical or cylindrical, slightly curved, less with 2~3 branched, 8~27 cm in length, 1~4.3 cm in diameter. Externally yellowish-white (peeled) or grayish-brown, with wax-like lustrous and irregularly twisted and longitudinal wrinkles, upper part with dense fine transverse striations. Cork fine squamous, squamous at the upper, smooth at the base. Rhizome single or no more than 6, 2~7 cm in length, surrounded by numerous semilunar scars of stems, gathered. Texture light and loose, fracture whitish, uneven, with numerous irregular clefts. Odour slight; taste sweetish and bitter.
2. Root of *Adenophora triphylla*: Root 5.5~14 cm in length, 0.5~2.1 cm in diameter. Externally without

longitudinal wrinkles, upper part with transverse annul striations. Cork wide strip.

Microscopic identification:

1. **Transverse section:**
   Root of *Adenophora stricta*: Phelloderm 68~358 μm thick. Cork composed of thickened cork cells arranging into 1~3 rings, each ring 1 layer of cells thick, cells rectangular, outer walls 4~23 μm thick, the lateral wall usually thickened and forming inverted U-shaped, some outer walls ridge-like thickened and intruding into lumina; phelloderm composed of 2~4 rings cork cells, each ring composed of 2~7 layers, wall thin. Cortex narrow, with horizontal laticiferous tubes. Stele forming tertiary structure, slightly eccentric; tertiary vascular tissue arranged alternately with secondary vascular tissue near center; cambium and tertiary cambium short-arciform, arranged in an interrupted ring, tertiary vascular tissue bundle-shaped or xylem bundles mostly branched outwards; rays distinct, usually pressed and broken. Laticiferous tubes mostly accompanied by sieve tube groups; cells containing inulin are extremely rare.
2. **Powder:**
   (1) Root of *Adenophora stricta*: Grayish-yellow. Reticulate, scalariform, reticular bordered-pitted and scalariform-reticulate vessels 18~90 μm in diameter; reticulate vessels with dents mostly slit-shaped, some dents dense and large. Thickened cork cells subrectangular, long strip-shaped, suboblong or subpolygonal in surface view, 18~170 μm in length, 18~150 μm in diameter, wall 2~7 μm thick, some with anticlinal walls moniliform thickened, some with warty protrusions and intruding into lumina; rectangular in sectional view, outer wall 5~7 μm thick, lateral wall slightly thickened. Cork cells subrectangular, long strip-shaped or irregular in shape in surface view, anticlinal walls straight or curved; subrectangular in sectional view, strip-shaped striations rare. Articulated laticiferous tubes usually reticulately linked, 12~56 μm in diameter. Inulin crystals fan-shaped, subrounded or irregular in shape.
   (2) Root of *Adenophora triphylla*: Grayish-yellow. Reticulate, pitted and scalariform vessels 12~88 μm in diameter. Thickened cork cells subrectangular in surface view, 93~240 μm in length, 21~59 μm in diameter, wall 1~27 μm thick, with dense clefts and pits; rectangular in sectional view, outer walls thickened, lateral walls slightly U-shaped thickened.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of ethanol, ultrasonicate for 30 minutes, filter, evaporate to dryness and dissolve the residue in 1 mL of ethanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of *β*-sitosterol and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of petroleum ether (30~60 ℃), ethyl acetate, and formic acid (5:3:0.06) as the developing solvent. Apply 5 μL of each of the sample solution and reference drug solution and 2 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 15.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 5.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from mold and insects.
Usage: Tonifying and replenishing medicinal (Yin-tonifying medicinal).
Property and flavor: Mild cold; sweet.
Meridian tropism: Lung and stomach meridians.

Effects: Nourish yin to clears lung, resolve phlegm, boost qi.
Administration and dosage: 9~15 g.

AGASTACHIS HERBA
藿香
Huo Siang / Huo Xiang
Agastache Herb

Agastache herb is the dried aerial part of *Agastache rugosa* (Fisch. & C.A.Mey.) Kuntze (Fam. Labiatae).
It contains not less than 5.0% of dilute ethanol-soluble extractives, not less than 5.0% of water extractives.

Description: Agastache herb is the branch with leaves and inflorescence occasionally present. Stem quadrangular, up to 5 mm in diameter, externally dark brown, with ridges on the four angles, four surfaces relatively even or depress into broad furrows, with longitudinal wrinkles, nodes distinct, internode 3~10 cm in length.

Microscopic identification:
1. **Transverse section:**
   (1) Stem of *Agastache rugosa*: Epidermis composed of 1 layer of rectangular cells, 6~10 μm; inside showing cortex, composed of 3~5 layers of irregular polygonal parenchymatous cells, 15~20 μm in diameter. Phloem surrounded inside cortex, sieve tubes composed of 2~3 layers of cells, 7~8 μm in diameter. Xylem composed of 10~15 layers of vessel cells, arranging neatly, 12~16 μm in diameter. Pith in the center, parenchyma tissue of pith gradually large inward, 30~120 μm in diameter, about 10 layers from xylem to the center.
   (2) Leaf of *Agastache rugosa*: Epidermal cells with anticlinal walls curved. Stomata diacytic, arranged in lower epidermis. Conical hairs with warty protrusions on the surface and 3~4 cells on the base, striations of cuticle distinct, arranged radially, present on the upper and lower surface of epidermis, especially abundant on the lower epidermis, Non-glandular hairs on the upper epidermis composed of 1~2 layers of cells, 16~18 μm in length. Non-glandular hairs on lower epidermis composed of 1~4 layers of cells, 70~460 μm in length. Glandular hairs with the head 1- to 2-celled, unicellular easily visible, the stalk unicellular. Glandular scales with the head 8-celled, oblate spherical, 56~80 μm in diameter, the stalk unicellular.
2. **Powder:** Brownish-yellow. Non-glandular hairs 1- to 5-celled, slightly curved and leaned to one side, 17~303 μm in length, 12~28 μm in diameter, wall slightly thickened, with warty protuberance on the surface. Glandular scales with the head 4- or 8-celled, 63~91 μm in diameter, containing pale yellow contents; the stalk unicellular, extremely short. Small glandular hairs with the head 1- to 2-celled, 13~27 μm in diameter; the stalk unicellular. Raphides of calcium oxalate extremely fine, scattered in mesophyll and epidermal cells of stem, about to 8 μm in length. Stone cells singly scattered, pericyclic fibers, xylem fibers and vessels also visible.

Impurities and other requirements:
1. Total ash: Not more than 12.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 5.0% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place.
Usage: Dampness-dispelling medicinal (Dampness-resolving with aroma medicinal).
Property and flavor: Mild warm; pungent.
Meridian tropism: Lung, spleen, and stomach meridians.
Effects: Nourish yin to clears lung, resolve phlegm, boost qi.
Administration and dosage: 4.5~11.5 g.

AGRIMONIAE HERBA
仙鶴草
Sian He Cao / Xiao He Cao
Hairyvein Agrimonia Herb

Hairyvein agrimonia herb is the dried herb of *Agrimonia pilosa* Ledeb. (Fam. Rosaceae).
It contains not less than 8.0% of dilute ethanol-soluble extractives and not less than 7.0% of water extractives.

Description: 50~100 cm in length, with white hairs. The lower part of stem cylindrical, 4~6 mm in diameter, reddish-brown; the upper part of stem in square or flat-cylindrical, the four sides slightly depressed, greenish-brown, furrowed longitudinally and ridged present, nodose distinct; texture light and hard, easily broken; fracture yellowish-white or hollow. Leaves odd-pinnate, alternate, dark green, crumpled and rolled; texture fragile

and easily broken; two sizes of small leaflets, the small leaflets interposed between the large ones at the leaf axis, the ones at the apex relatively large, oblong to lanceolate as whole, base cuneate, margin serrate, the ones at the base with more hairs, stipules 2, amplexicaul, oblique-ovate. Raceme slender; the lower part of calyx tubular, with hairs and grooves, with hooked bristles at the upper part of calyx tube; petals yellow. Odour slight; taste slightly bitter.

Microscopic identification:

1. **Transverse section:**
   Stem of *Agrimonia pilosa*: Non-glandular hairs adhered to the epidermis, mostly unicellular, vary in length, usually 300~400 μm, thick-walled. Epidermal cells composed of 1 layer of subrectangular or suboblong cells, the outer wall slightly thickened; inner part composed of layers of large parenchymatous cells. Inner side of cortex composed of pericycle fiber layers, lignified, arranged as a ring. Fibers 5~18 μm in diameter. Collateral vascular bundles arranged as a ring. Rays distinct. Vessels mainly spiral and scalariform, 6~25 μm in diameter. Pith broad, composed of subrounded parenchymatous cells.
2. **Powder:** Dark green. Non-glandular hairs mostly unicellular, thick-walled, vary in length, 80~450 μm in length, commonly with 300~400 μm in length. Glandular hairs few, glandular head small and ovoid, composed of 1~4 cells; stalk 1~4 cells. Starch granules relatively numerous, simple granules oblong, 2~5 μm in diameter, compound granules composed of 2~4 components. Clusters of calcium oxalate 10~45 μm in diameter. Fibers 5~18 μm in diameter. Vessels mainly spiral or scalariform, 6~25 μm in diameter.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 30 mL of petroleum ether (30~60℃), ultrasonicate for 30 minutes, filter, evaporate the filtrate to dryness, dissolve the residue in 2 mL of dichloromethane.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and the upper layer of petroleum ether (30~60℃), ethyl acetate, and acetic acid (20:2:1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with a 10% solution of sulfuric acid in ethanol (H_2SO_4/EtOH TS) and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:

1. Loss on drying: Not more than 13.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 10.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 3.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place, and protect from moisture and mold.
Usage: Blood-regulating medicinal (Hemostatic medicinal).
Property and flavor: Neutral; bitter and astringent.
Meridian tropism: Lung, liver and spleen meridians.
Effects: Astringes and hemostatic, relieves diarrhea, kills worms.
Administration and dosage: 6~15 g.

AILANTHI CORTEX
臭椿皮
Chou Chun Pi / Chou Chun Pi
Ailanthus Bark

Ailanthus bark is the dried bark of root or stem of *Ailanthus altissima* (Mill.) Swingle (Fam. Simarubaceae), commonly known as “Chun Pi”.

Description:

1. Root bark of *Ailanthus altissima*: Slat pieces or irregular quills, 2~10 mm thick. Outer surface grayish-yellow or yellowish-brown, with irregular longitudinal and transverse striations, rough, with numerous large and distinct fusiform protuberant lenticels, occasionally several transverse lenticels connected. Yellowish-white when peeled, inner surface pale yellow, with densely fine fusiform dots spots or pores. Texture hard and fragile; fracture granular at the outer part, fibrous at the inner part, inner part easily exfoliated from outer part. Odour slight; taste bitter.
2. Stem bark of *Ailanthus altissima*: Slat pieces, 0.5~2 cm thick. Outer surface grayish-black, very rough,

with irregular longitudinal and transverse striations, lenticels large, occasionally several transverse lenticels connected. Fracture granular. Odour slight; taste bitter.

Microscopic identification:

1. **Powder:**
   (1) Root bark of *Ailanthus altissima*: Pale grayish-yellow. Stone cells mostly in bundles or linked with fibers, subrounded, subsquare, subrectangular or irregular in shape, occasionally with margins acute and protrude, 24~96 μm in diameter and up to 150 μm in length, wall extremely thickened, occasionally walls vary in thickness or walls relatively thickened on three sides and thin on one side, lumen usually containing clusters of calcium oxalate, 11~48 μm in diameter. Fibers 20~40 μm in diameter, wall extremely thickened and lignified. Clusters of calcium oxalate 15~56 μm in diameter. Prisms of calcium oxalate, starch granules and cork cells also present.
   (2) Stem bark of *Ailanthus altissima*: greyish-yellow, fragments of cork cells numerous, clusters of calcium oxalate occasionally present, starch granules absent.

Identification:

Take 10.0 g of powdered sample, add 50 mL of methanol, heat under reflux for 30 minutes, filter. Evaporate the filtrate to dryness, dissolve the residue in 1 mL of glacial acetic acid, add 1 mL of a solution of acetic anhydride and sulfuric acid (19:1), the yellowish-green color turns to dark green immediately.

Impurities and other requirements:

1. Loss on drying: Not more than 12.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 11.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 3.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Storage: Store in a ventilated and dry place, and protect from insects.
Usage: Astringent medicinal.
Property and flavor: Cold; bitter and astringent.
Meridian tropism: Large intestine, stomach, and liver meridians.
Effects: Clear heat and dry dampness, astringent intestines, hemostatic, stanch vaginal discharge.
Administration and dosage: 6~9 g.

AKEBIAE CAULIS
木通
Mu Tong / Mu Tong
Akebia Stem

Akebia stem is the dried stem of *Akebia quinata* (Thunb.) Decne., *Akebia trifoliata* (Thunb.) Koidz. or *Akebia trifoliata* (Thunb.) Koidz. var. *australis* (Diels) Rehder (Fam. Lardizabalaceae).
It should not contain aristolochic acid I & aristolochic acid II.

Description:

1. Stem of *Akebia quinata*: Cylindrical and twisted, 30~60 cm in length, 1.2~1.8 cm in diameter. Externally grayish-brown, rough, with irregular cracks, nodes indistinct, with scars of later branches. Texture compact, fracture uneven, bark yellowish-brown, wood yellowish-white, rays arranged radially, pith small. Odour slight; taste slightly bitter and astringent.
2. Stem of *Akebia trifoliata*: Cylindrical and tortuous, 0.6~1.8 cm in diameter. Externally gray, grayish-brown or dark brown, uneven color, extremely rough, with several irregular longitudinal and transverse cracks, sometimes adhered grayish-green bryophyte, protuberant lenticels rounded or transverse oblong, brown, indistinct, 1~2 mm in diameter, with scars of branches. Market sliced pieces slightly oblique, bark and wood exfoliated. Brownish-yellow when peeled. Dark brown longitudinal furrows present in rays. Texture tenacious, difficult to break, wood yellowish-white. Vessel pores fine, arranged irregular, rays pale brown. Pith in the center, subrounded and large. Odour slight; taste slightly bitter and astringent.

Microscopic identification:

1. **Transverse section:**
   (1) Stem of *Akebia quinata*: Cork composed of several layers of cork cells. Cortex composed of several layers of tangentially elongated cells. Pericycle fibers are crystal fibers, crescent-shaped, almost scattered in an undulating ring; fiber walls thick and lignified. Collateral vascular bundles 12~28 in a ring; rays narrow, containing crystal-containing sclerenchyma cells, the wall lignified, mostly scattered among phloem rays. Pith cells gradually large from outer to inner, wall thickened and mostly lignified.
   (2) Stem of *Akebia trifoliata*: Similar to *Akebia quinata.* The main difference is *Akebia trifoliata* without brown contents in cork cells. Cortex with crystal-containing fibers and stone

cell groups arranged alternately in continuous ring. Crystal-containing stone cells only present in the opposite of rays. Vascular bundles 26~32 in a ring. Rays distinct. Pith in the center, many parenchymatous cells with unlignified walls visible. The tissue of *Akebia trifoliata* (Thunb.) Koidz. var. *australis* (Diels) Rehder. is extremely similar to *Akebia trifoliate* (Thunb.) Koidz.

2. **Powder:** Dark yellow. Orange-yellow cork cells, fiber pieces, vessels and tracheid bordered pits are visible. Stone cells irregular in shape, 34~50 μm in length, wall pits distinct. Crystals of calcium oxalate 40 μm in diameter.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 50 mL of 70% methanol, ultrasonicate for 30 minutes, filter, evaporate the filtrate to dryness, dissolve the residue in 10 mL of water, extract shaking for three times, each time with 10 mL of ethyl acetate, combine the ethyl acetate extracts, evaporate to dryness, dissolve the residue in 1 mL of methanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of calceolarioside B and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of chloroform, methanol, and water (30:10:1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with a solution of 2% vanillin/H_2SO_4 TS and heat at 105°C until the spots become visible. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 14.0% dry at 105°C for 5 hours (General rule 6015).
2. Total ash: Not more than 8.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).
9. Should not contain aristolochic acid I & aristolochic acid II:
   (1) Sample solution: Add 3.0 g of powdered sample to 10 mL of ethanol, ultrasonicate for 30 minutes, filter.
   (2) Reference standard solution: Weigh accurately a quantity of osthole and dissolve in ethanol to produce a solution containing 0.2 mg per mL.
   (3) Procedure: Carry out the method for thin layer chromatography (General rule 1621.3), use silica gel F_{254} as the coating substance and a solution of chloroform, ethyl acetate and ethanol (17:1:3) as the developing solvent. Apply 10 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air, and examine under the ultraviolet light at 254 nm. Spray with vanillin/H_2SO_4 TS, dry in air, and examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution should not corresponding in R_f values and color to the spots in the chromatogram obtained from the reference standard solution.

Storage: Store in a cool and dry place.
Usage: Dampness-dispelling medicinal (Dampness-draining diuretic medicinal).
Property and flavor: Cold; bitter.
Meridian tropism: Heart, small intestine and bladder meridians.
Effects: Induce diuresis and relieve strangury, clear heart to downbear fire, promoting lactation.
Administration and dosage: 3~6 g.

ALBIZIAE CORTEX
合歡皮
He Huan Pi / He Huan Pi
Silktree Albizia Bark

Silktree albizzia bark is the dried bark of trunk of *Albizia julibrissin* Durazz. (Fam. Leguminosae).
It contains not less than 4.0% of dilute ethanol-soluble extractives, not less than 5.0% of water extractives and not less than 0.03% of (-)-syringaresinol - 4 - *O* - β - D - apio-furanosyl- (1→2) - β - D - glucopyranoside.

Description: Quilled or channeled, 2~3.5 cm in diameter, 1~2 mm thick. Outer surface grayish-brown, slight rough, with dense transversal or elliptical lenticels, brown or reddish-brown, scattered or gathered. Inner surface pale yellowish-white, with fine longitudinal striations. Texture hard and fragile, fracture laminated, fiber layer stripped into pieces. Odour slightly aromatic; taste weak, slightly astringent and slightly irritating, with a disagreeable sensation in the throat afterwards.

Microscopic identification:

1. **Transverse section:**
   Bark of *Albizia julibrissin*: Cork composed of several layers of cork cells, containing brown contents. Cortex composed of tangentially elongated cells, some cells containing prisms of calcium oxalate, mostly located near cork. Pericycle mainly stone cell groups and few fiber bundles, arranged in a ring. Phloem contains numerous fiber bundles, arranged elongated in layers, occasionally containing some stone cell groups, fiber bundles surrounded by cells, containing prisms of calcium oxalate, forming crystal fibers; stone cell groups also surrounded by crystal-containing cells; rays 2 layers of cells wide.
2. **Powder:** Pale yellow. Fibers slender, 7~22 μm in diameter, walls extremely thickened and lignified, some primary walls separated from epigenetic and secondary walls. Fiber bundles surrounded by sclerenchyma cells which containing prisms of calcium oxalate, forming crystal fibers. Stone cells subsquare, subrectangular or subpolygonal, 11~56 μm in diameter, walls extremely thickened, striations and pit canals distinct, some branched, relatively thin walls and extremely large lumen less. Stone cells surrounded by sclerenchyma cells which usually contain prisms. Crystal-containing sclerenchyma cells relatively small, subsquare or suboblong, 16~24 μm in diameter, walls thickened unevenly, slightly lignified or some part lignified, lumen contains prisms. Prisms of calcium oxalate polygonal, a few cube-shaped or flat-square, up to 16 μm in diameter. Parenchymatous cells of phloem occasionally round-bordered pits visible in radial view or cell walls moniliform thickened in tangential view. Cork cells, sieve tube elements and starch granules also present.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 1 mL of methanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of (-)-syringaresnol-4-*O*-β-D-apiofuranosyl-(1 → 2)- β -D-glucopyranoside and dissolve in methanol to produce a solution containing 0.2 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and the lower layer of a solution of dichloromethane, methanol, and water (7:3:1) added 0.1 mL formic acid per 10 mL as the developing solvent. Apply 5 μL of each of the sample solution and reference drug solution and 2 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 12.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 7.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. (-)-Syringaresinol-4-*O*-β-D-apiofuranosyl-(1 → 2)-β-D-glucopyranoside:
   (1) Mobile phase: A solution of acetonitrile and 0.1% phosphoric acid (18:82). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of (-)-Syringaresinol -4-*O*-β-D-apiofuranosyl-(1→2)-β-D-glucopyranoside, and dissolve in methanol to produce a solution containing 10 μg per mL.
   (3) Sample solution: Weigh accurately 0.5 g of the powdered sample and place it in a 50-mL conical flask, then add accurately 20 mL of 70% methanol, ultrasonicate for 30 minutes, filter with filter paper. Repeat the extraction of the residue one more time. Combine the extract, evaporate the filtrate and transfer to a 20-mL volumetric flask and make up to volume with 70% methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (204 nm) and a column packing L1. The column temperature is maintained at 35℃. The flow rate is about 0.8 mL/min. The number of theoretical plates of the peak of -Syringaresinol-4-*O*-β-D-apiofuranosyl-(1 → 2)-β-D-glucopyranoside should not be less than 3,000.
   (5) Procedure: Inject accurately 20 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   (-)-Syringaresinol-4-*O*-β-D-apiofuranosyl-(1→2)-β-D-glucopyranoside:

(%)= 0.002(r_U/r_S) (C_S) / (W)

r_U: peak area of (-)-syringaresinol-4-*O*-β-D-apiofuranosyl-(1→2)-β-D-glucopyranoside of sample solution

r_S: peak area of (-)-syringaresinol-4-*O*-β-D -apiofuranosyl-(1→2)-β-D-glucopyranoside of reference standard solution

C_S: concentration of (-)-syringaresinol-4-*O*-β-D-apiofuranosyl-(1 → 2)-β-D-glucopyranoside of reference standard solution (μg/mL)

W: weight of test sample (g) calculated with dried sample.

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place.
Usage: Tranquillizing medicinal (Heart-nourishing tranquillizing medicinal).
Property and flavor: Neutral; sweet.
Meridian tropism: Heart and liver meridians.
Effects: Tranquilize and release depression, activate blood to alleviate edema.
Administration and dosage: 6~15 g.

ALISMATIS RHIZOMA
澤瀉
Ze Sie / Ze Xie
Alisma Rhizome

Alisma rhizome is the dried rhizome of *Alisma plantago-aquatica* L. subsp. *orientale* (Sam.) Sam. (Fam. Alismataceae).
It contains not less than 8.0% of dilute ethanol-soluble extractives, not less than 10.0% of water extractives and not less than 0.03% of alisol B monoacetate.

Description: Subspheroidal, oblong or obovate, 4~7 cm in length, 3~5 cm in diameter. Externally yellowish-white or pale brown with remained coarse bark, with irregular transverse-annular shallow furrows and scattered with numerous small protuberant fibrous root scars, relatively dense in the bottom. Texture compact, fracture yellowish-white, granular, with numerous small pores. Odour slight; taste extremely bitter.

Microscopic identification:

1. **Transverse section:**
   Rhizome of *Alisma plantago-aquatica*: The outer tissue mostly removed, cortex aerenchyma remained, composed of parenchymatous cells, with extremely large intercellular spaces, inside showing 1 layer of endodermal cells, wall thickened and lignified with pits. Stele aerenchyma scattered with amphivasal vascular bundles and pale yellow secretory cavities. Parenchymatous cells filled with starch granules.
2. **Powder:** Pale yellow or slightly brown. Starch granules abundant, simple granules long-ovoid, subspheroidal or ellipsoid, 3~14 μm in diameter, hilum V-shaped, slit-shaped, cross-shaped or Y-shaped, located at the center or at the larger end of the granule; compound granules composed of 2~3 components. Parenchymatous cells polygonal, lateral walls moniliform thickened, with distinct pits; some contain elliptical pits crowded into pitted areas. Endodermal cells large, anticlinal walls undulate, walls thickened and lignified, with distinct pit canals. Vessels mainly spiral, scalariform, reticulate, single-pitted and bordered-pitted, 10~24 μm in diameter. Fibers rare, 16~24 μm in diameter, walls relatively thickened and lignified. Secretory cavities and its fragments are also visible.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 2.0 g of powdered sample to 20 mL of ethyl acetate, ultrasonicate for 30 minutes. Apply the filtrate to an alumina column (200～300 mesh, 5 g, 1 cm in inner diameter, packed by dry method) elute with 10 mL of ethyl acetate, collect the eluates, evaporate to dryness, and dissolve the residue in 1 mL of ethyl acetate.
2. Reference drug solution: Take 2.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and *n*-hexane and ethyl acetate (1:1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with *p*-anisaldehyde/H_2SO_4 TS and heat at 105°C until the spots become visible. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:

1. Total ash: Not more than 6.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 5.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Alisol B monoacetate:
   (1) Mobile phase: A solution of acetonitrile and water (60:40). The ratio may be adjusted, if

necessary.

(2) Reference standard solution: Weigh accurately a quantity of alisol B monoacetate, and dissolve in methanol to produce a solution containing 8 μg per mL

(3) Sample solution: Add 0.5 g of powdered sample to 20 mL of methanol, ultrasonicate for 20 minutes, filter, and make up the filtrate to 20 mL, mix well, filter and use the successive filtrate.

(4) Chromatographic system: The liquid chromatography is equipped with an UV detector (208 nm) and a column (4~6 mm × 15~25 cm) packing L1. The column temperature is maintained at 35℃. The flow rate is about 0.8 mL/min. Inject reference standard solution into the liquid chromatography apparatus for 5 times, and record the peak areas. The relative standard deviation of the peak area of alisol B monoacetate should not be more than 1.5%.

(5) Procedure: Inject accurately 5 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Alisol B monoacetate (%)=0.002(r_U/r_S) (C_S) / (W)

r_U: peak area of alisol B monoacetate of sample solution

r_S: peak area of alisol B monoacetate of reference standard solution

C_S: concentration of alisol B monoacetate of reference standard solution (μg /mL)

W: weight of test sample (g) calculated with dried sample.

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from insects.

Usage: Dampness-dispelling medicinal (Dampness-draining diuretic medicinal).

Property and flavor: Cold, sweet and bland.

Meridian tropism: Kidney and bladder meridians.

Effects: Induce diuresis to drain dampness, clear kidney fire.

Administration and dosage: 6~12 g.

ALLII MACROSTEMONIS BULBUS
薤白
Sie Bai / Xie Bai
Longstamen Onion Bulb

Longstamen onion bulb is the dried bulb of *Allium macrostemon* Bunge or *Allium chinense* G.Don (Fam. Liliaceae).

It contains not less than 64.0% of dilute ethanol-soluble extractives and not less than 64.0% of water extractives.

Description:

1. Bulb of *Allium macrostemon*: Irregularly oval, 0.5~2.0 cm in length, 0.7~1.8 cm in diameter. Externally yellowish-white or pale yellowish-brown, crumpled, translucent, covered with whitish membranous scales, apex with remained stem bases or stem scars, base with bulged plateau. Texture hard, horny, uneasily broken, fracture yellowish-white. Odour alliaceous; taste slightly pungent.
2. Bulb of *Allium chinense*: Long-oval, 1~3 cm in length, 0.3~1.5 cm in diameter. Externally pale yellowish-brown or brown, with shallowly longitudinal wrinkles. Texture soft, cut fracture showing 2~3 layers of scale leaves, sticky on chewing.

Microscopic identification:

Powder:

Bulb of *Allium macrostemon*: Yellowish-brown. Epidermal cells of scale leaf subrectangular, 60~260 μm in length, 20~60 μm in width, a few polygonal, without intercellular spaces. Stomata occasionally scattered, rounded, 10~16 μm in diameter, with 5~6 subsidiary cells. Epidermal cells of old scale leaf contain prisms of calcium oxalate, 5~10 μm in length, each cell contains 2~4 prism crystals. Vessels mostly spiral, 6~16 μm in diameter.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, cool, filter, and make up the filtrate to 10 mL.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane and ethyl acetate (10:1) as the developing solvent. Apply 10 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:
1. Loss on drying: Not more than 17.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 3.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place, and protect from insects.
Usage: Qi-regulating medicinal.
Property and flavor: Warm; pungent and bitter.
Meridian tropism: Heart, lung, stomach, and large intestine meridians.
Effects: Active yang and removing obstruction, move qi and remove food stagnation, strengthen stomach and improve intestinal disorder.
Administration and dosage: 5~10 g.

ALLII TUBEROSI SEMEN
韭菜子
Jiou Cai Zih / Jiu Cai Zi
Tuber Onion Seed

Tuber onion seed is the dried ripe seed of *Allium tuberosum* Rottler ex Spreng. (Fam. Liliaceae).
It contains not less than 7.0% of dilute ethanol-soluble extractives and not less than 10.0% of water extractives.

Description: Flattened ovate, 2~4 cm in length, 0.15~0.3 cm in width. Externally black, with distinct reticulate striations at the protuberant side, the dented side with indistinct wrinkles, apex obtuse, base slightly acute, hilum dotted and protuberant. Testa thin at the longitudinal section, endosperm grayish-white, embryo white and curved, cotyledon 1. Fracture grayish-yellow, oily. Texture hard. Odour characteristic; taste leek flavor on chewing.

Microscopic identification:
1. **Transverse section:**
   Seed of *Allium tuberosum*: Epidermis of testa relatively smooth, wall thick, outer walls covered with thin cuticle, cells containing dark brown contents, inside showing several rows of brownish-yellow parenchymatous cells. Endosperm cells large, wall extremely thickened with large pits, lumen containing aleurone grains and fatty oil.
2. **Powder:** Grayish-black. Epidermal cells of testa black or brownish-black, long strip-shaped, subrounded, polygonal or irregular in shape, 37~200 μm in diameter, with reticular striations on the surface. Endosperm cells abundant, mostly broken, with large subrounded or oblong pits.

Impurities and other requirements:
1. Loss on drying: Not more than 11.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 7.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place.
Usage: Tonifying and replenishing medicinal (Yang-tonifying medicinal).
Property and flavor: Warm; pungent and sweet.
Meridian tropism: Liver and kidney meridians.
Effects: Warm tonify the liver and kidney, invigorate yang to secure essence.
Administration and dosage: 3~9 g.

ALOE
蘆薈
Lu Huei/Lu hui
Aloes

Aloes is the dried concentrated matter obtained from the juice of the leaf of *Aloe vera* (L.) Burm.f. or *Aloe ferox* Mill. (Fam. Liliaceae), commonly known as ”Lao Luhui”.
It contains not less than 85.0% of dilute ethanol-soluble extractives and not less than 35.0% of water extractives and not less than 16.0% of aloin.

Description: irregular masses, often polygonal in shape after broken, varying in size. Extermally yellowish-brown with slightly green, sometimes lustrous. Fracture waxy, melted when heating, hygroscopic. Odour characteristic; taste extremely bitter.

Microscopic identification:
Powder: Yellowish-Brown. Observing under the microscope with lactic phenol (mixing 1 lactic acid, 1 phenol and 2 glycerin) mounting. The surface of masses with fine acicular, granular, short granular crystal adhered. Rest for 24 hour, when the powder slightly dissolve, the crystal visible clearly.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 0.5 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 0.5 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of aloin and dissolve in methanol to produce a solution containing 5.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, methanol, and water (100:17:13) as the developing solvent. Apply 1 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 8.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 5.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 4.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
Aloin:
1. Mobile phase: Acetonitrile as the mobile phase A, and water as the mobile phase B.
2. Reference standard solution: Weigh accurately a quantity of aloin and dissolve in methanol to produce a solution containing 0.35 mg per mL.
3. Sample solution: Weigh accurately 0.1 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 20 mL of methanol, ultrasonicate for 30 minutes, centrifuge for 10 minutes. Transfer the supernatant to a 50-mL volumetric flask and make up to volume with methanol, mix well, filter and use the filtrate.
4. Chromatographic system: The liquid chromatography is equipped with an UV detector (355 nm) and a column packing L1. The column temperature is maintained at 25℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of aloin should not be less than 10,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~30	15→30	85→70
30~35	30→95	70→5

5. Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Aloin (%)=5 (r_U/r_S) (C_S) / (W)

r_U: peak area of aloin of sample solution
r_S: peak area of aloin of reference standard solution
C_S: concentration of aloin of reference standard solution (mg /mL)
W: weight of test sample (g) calculated with dried sample.

Storage: Store in a cool and dry place.
Usage: Purgative medicinal (Offensive purgative medicinal).
Property and flavor: Cold, bitter.
Meridian tropism: Liver, stomach, and large intestine meridians.
Effects: Purgation, clear liver, kill worms.
Administration and dosage: 1~5 g, usually used in pills or powder, and used an appropriate amount for external use.
Precaution and warning: Use cautiously during pregnancy.

ALPINIAE KATSUMADAI SEMEN
草豆蔻
Cao Dou Kou / Cao Dou Kou
Katsumada Galangal Seed

Katsumada galangal seed is the dried and almost ripe seed of *Alpinia hainanensis* K.Schum. (*Alpinia katsumadai* Hayata) (Fam. Zingiberaceae).
It contains not less than 5.0% of dilute ethanol-soluble extractives, not less than 2.0% of water extractives, not less than 0.4% of alnustone and not less than 1.4% of the total amount of alpinetin, pinocembrin and cardamonin.

Description: Masses of seeds subspheroidal and flattened or elliptical-spheroidal, with relatively distinct 3 obtuse ridged and 3 shallow furrows, 1.5~2.5 cm in length, 1.5~3 cm in diameter. Externally grayish-brown or yellowish-brown, with yellowish-white or pale brown septa in central part dividing the masses into 3 groups, each containing 25~110 seeds, agglutinated closely. Seed ax-shaped oval or cylindrical polyhedral, thicker at one end, the other end relatively flat, dorsal slightly protuberant, 3~5 mm in length, 2.5~3 mm in diameter, covered with grayish-white membranous aril. The thicker end with a round hilum, chalaza occurring at the dented center of relatively flat end, raphe of the lateral side occurring as a longitudinal furrow connected with two ends, the other furrow of the dorsal side occurring at the chalaza disconnected with hilum. Texture hard, fracture milky-white. Odour aromatic; taste pungent.

Microscopic identification:

1. **Transverse section:**
   Seed of *Alpinia hainanensis*: Aril occasionally found, cells elongated tangentially, subrectangular, suboblong or irregularly long strip-shaped. Epidermis of testa composed of 1 layer of cells, mostly elongated radially, cells subrectangular, subsquare or oblong, arranged in order, 11~28 μm in length, 9~18 μm in diameter, wall slightly thickened. Hypodermis composed of 2 layers of tangentially elongated cells, without pigments. Pigment layer composed of 3~5 layers of cells, containing reddish-brown or pale yellow pigments. Oil cells arranged interruptedly in pigment layer, 1~2 layers, elongated tangentially, containing oil droplets. Endotesta composed of 1 layer of sclerenchymatous cells, reddish-brown, elongated tangentially, cylindrical, protuberant inward in raphe and crease, 24~39 μm in length, 11~29 μm in diameter, outer wall thin, inner wall about 18 μm thick, unlignified, lumen located at the upper part, subrounded or subovate, containing subrounded silica bodies, 10~18 μm in diameter. Perisperm cells oblong, subrectangular, subsquare or subrounded, 11~164 μm in length, 10~57 μm in diameter, the inner and outer side cells relatively small, the cells large in the center; cells filled with masses of tiny starch granules; some cells containing fine prisms of calcium oxalate. Endosperm cells subsquare, filled with aleurone grains. Embryo cells subrounded, containing aleurone grains and oil droplets.
2. **Powder:** Grayish-brown. Epidermal cells of testa long strip-shaped in surface view, the terminal gradually acute, 9~31 μm in diameter, wall 2~5 μm thick, unlignified. Hypodermal cells 1~3 layers overlapped, usually vertically arranged with epidermal cells of testa in an upper and lower layered pattern; long-polygonal or subrectangular, up to 150 μm in length, 14~31 μm in diameter, wall thin, lumen without dark pigments. Pigment cells reddish-brown, shrunken, with indistinct boundaries, containing reddish-brown pigments. Oil cells colorless or pale yellow, scattered among pigment cells; subrounded, oblong or rounded-polygonal, 18~54 μm in diameter, containing yellowish-green oil contents. Sclerenchymatous cells of endotesta yellowish-brown or reddish-brown, polygonal in surface view, 14~25 μm in diameter, wall thick and unlignified, lumen containing silica bodies, 8~15 μm in diameter; cells 1 layer in sectional view, arranged in palisade-shaped. Perisperm cells, prisms or clusters of calcium oxalate, endosperm cells, parenchymatous cells of embryo, pigment masses and aril cells present occasionally.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 5 mL of methanol, ultrasonicate for 5 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of alpinetin and dissolve in methanol to produce a solution containing 1.0 mg per mL
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of toluene, ethyl acetate, and methanol (18:1:1) as the developing solvent. Apply 2 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 254 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 15.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 6.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 3.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).
   ※Note: "When this TCM herb is sold commercially, the limit of heavy metals, sulfur dioxide and aflatoxins should follow the food standard."

Assay:

1. Alnustone, alpinetin, pinocembrin, and cardamonin:

(1) Mobile phase: Acetonitrile as the mobile phase A, and water as the mobile phase B.
(2) Reference standard solution: Weigh accurately a quantity of alnustone, alpinetin, pinocembrin and cardamonin and dissolve in methanol to produce a solution containing 0.5 μg per mL of each.
(3) Sample solution: Weigh accurately 0.2 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 10 mL of methanol, ultrasonicate for 30 minutes. Centrifuge for 10 minutes, filter the supernatant. Repeat the extraction of the residue one more time. Combine the filtrate, transfer to 20-mL volumetric flask and make up to volume with methanol, mix well, filter and use the successive filtrate.
(4) Chromatographic system: The liquid chromatography is equipped with an UV detector (300 nm) and a column packing L1. The column temperature is maintained at 35℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of alnustone, alpinetin, pinocembrin and cardamonin should not be less than 10,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~20	40→50	60→50
20~50	50→100	50→0

(5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Alnustone, alpinetin, pinocembrin, or cardamonin (%)=0.002(r_U/r_S) (C_S) / (W)

r_U: peak area of alnustone, alpinetin, pinocembrin or cardamonin of sample solution
r_S: peak area of alnustone, alpinetin, pinocembrin, or cardamonin of reference standard solution
C_S: concentration of alnustone, alpinetin, pinocembrin, or cardamonin of reference standard solution (μg/mL)
W: weight of test sample (g) calculated with dried sample.

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from moisture and color changing.

Usage: Dampness-dispelling medicinal (Dampness-resolving with aroma medicinal).
Property and flavor: Warm; pungent.
Meridian tropism: Spleen and stomach meridians.
Effects: Dry dampness, warm middle, move qi.
Administration and dosage: 3~7 g.

ALPINIAE OFFICINARUM RHIZOMA
高良薑
Gao Liang Jiang / Gao Liang Jiang
Galangal Rhizome

Galangal rhizome is the dried rhizome of *Alpinia officinarum* Hance (Fam. Zingiberaceae).
It contains not less than 7.0% of dilute ethanol-soluble extractives, not less than 6.0% of water extractives and not less than 0.7% of galangin.

Description: Cylindrical, often branched, 4~9 cm in length, 1~1.5 cm in diameter. Externally dark reddish-brown, with grayish-brown undulate annular nodes, internode about 5 mm in length, with longitudinal wrinkles, lower part with round scars of root. Texture hard and tenacious, uneasily broken, fracture grayish-brown or reddish-brown, fibrous, endodermis distinct, scattered with dots of vascular bundles. Odour aromatic; taste pungent.

Microscopic identification:

1. **Transverse section:**
Rhizome of *Alpinia officinarum*: Epidermis with thickened outer walls. Cortex scattered with abundant leaf-trace vascular bundles, collateral, relatively large than vascular bundles in stele. Endodermis distinct. Collateral vascular bundles in stele extremely numerous, the vascular bundles relatively small and dense near endodermis, arranged in a ring; vascular bundle sheath fibers arranged in a ring, wall thick, unlignified or slightly lignified. Secretory cells numerous, containing orange-red or brownish-red resinous contents; parenchymatous cells contain starch granules.
2. **Powder:** Purplish-brown. Simple starch granules rod-shaped, reniform, oblong, rhombic or long-ovate, 24~90 μm in length, 8~27 μm in diameter, hilum dotted, short cleft-shaped or Y-shaped, oblique at one end or located in the center, striations faintly visible; compound granules composed of 2~8 components. Secretory cells mostly broken, intact ones subrounded or oblong, 40~48 μm in diameter, wall slightly thickened with pits, lumen containing orange-red or brownish-red resinous contents. Parenchymatous cells with walls slightly thickened, subrounded pits distinct; fine prisms of calcium oxalate occasionally found. Endodermal cells (roots) usually singly scattered, slender, the terminal truncate or slightly acute, 120~200 μm in length, 22~27 μm in diameter, walls extremely thickened on three sides and thin on one side, four

sides evenly thickened occasionally found, unlignified, with distinct pit canals. Fibers slender, 22~37 μm in diameter, wall slightly thickened and unlignified, some lumina contain reddish-brown contents. Scalariform, reticulate or spiral vessels present, 18~56 μm in diameter; epidermal cells of scale leaf long-polygonal, wall slightly thickened, some parts moniliform.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of toluene and ethyl acetate (3:1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 5% vanillin/H_2SO_4 TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:

1. Loss on drying: Not more than 15.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 4.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 5.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Galangin:
   (1) Mobile phase: A solution of methanol and 0.2% phosphoric acid (55:45). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of galangin and dissolve in methanol to produce a solution containing 40 μg per mL.
   (3) Sample solution: Weigh accurately 0.2 g of powdered sample and place it in a conical flask with stopper, add accurately 50 mL of methanol then weigh, stopper tightly, heat and reflux for 1 hour, cool, weigh again, replenish the loss of the weight with methanol, mix well, filter and use the filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (266 nm) and a column packing L1. The column temperature is maintained at 25℃. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of galangin should not be less than 6,000.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Galangin (%)=0.005(r_U/r_S) (C_S) / (W)
   r_U: peak area of galangin of sample solution
   r_S: peak area of galangin of reference standard solution
   C_S: concentration of galangin of reference standard solution (μg/mL)
   W: weight of test sample (g) calculated with dried sample.
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place, and protect from insects.
Usage: Interior-warming medicinal.
Property and flavor: Hot; pungent.
Meridian tropism: Spleen and stomach meridians.
Effects: Warm middle and dissipate cold, promote digestion and relieve pain.
Administration and dosage: 3~6 g.

ALPINIAE OXYPHYLLAE FRUCTUS
益智
Yi Jhih / Yi Zhi
Sharpleaf Galangal Fruit

Sharpleaf galangal fruit is the dried ripe fruit of *Alpinia oxyphylla* Miq. (Fam. Zingiberaceae).
It contains not less than 8.0% of dilute ethanol-soluble extractives, not less than 10.0% of water extractives, not less than 1.0% (v/w) of volatile oil and not less than 0.1% of nootkatone.

Description: Ellipsoidal, both ends slightly acute, 1~2 cm in length, 0.8~1.2 cm in diameter. Externally brown or dark brown, with 13~20 longitudinal, uneven and bulged lines, apex with a protuberant scar of perianth, base with short fruit stalk or its scar. Pericarp thin and slightly tenacious, adhering closely to seeds. Seeds gathered in masses and divided to three valves by brown septum with 6~11 seeds in each valve. Seed irregularly depressed-rounded, about 0.3 cm in diameter, brown, covered with

yellow membranous aril, dorsal side slightly dented, and center of ventral side with dented hilum. Odour characteristically aromatic; taste pungent and slightly bitter.

Microscopic identification:

1. **Transverse section:**
   (1) Pericarp of *Alpinia oxyphylla*: Exocarp composed of 1 row of subsquare cells, covered with cuticle. Mesocarp composed of parenchymatous cells, scattered with oil cells and vascular bundles; oil cells 16~20 μm in diameter, phloem coverd with fiber bundle, some cells containing prisms of calcium oxalate. Endocarp composed of 1 row of tangentially elongated parenchymatous cells.
   (2) Seed of *Alpinia oxyphylla*: Aril occasionally found, composed of several layers of parenchymatous cells. Epidermis of testa composed of 1 row of cells, subsquare or subrounded, with walls relatively thickened. Hypodermis composed of 1 row of parenchymatous cells, containing yellowish-brown contents. Oil cells 1 row, varying in shape and size, containing yellow oil droplets. Pigment layer composed of several layers of yellowish-brown cells, containing reddish-brown or yellowish- brown contents, oil cells arranged interruptedly. Endotesta composed of 1 row of sclerenchymatous cells, yellowish-brown or reddish-brown, wall extremely thickened, lumen small, containing silica bodies, about 10~15 μm in diameter. Perisperm relatively large and thick, containing starch granules, occasionally containing fine prisms or clusters of calcium oxalate. Endosperm cells relatively small, containing aleurone grains and fatty oil droplets.
2. **Powder:** Yellowish-brown. Epidermal cells of testa long strip-shaped, walls slightly thickened. Cells of pigment layer wrinkled, yellowish-brown, border indistinct, most cells broken into irregular fragments of pigment. Oil cells vary in shape and size, subsquare or suboblong, 20~50 μm in diameter, usually linked with cells of pigment layer, or occasionally scattered among cells of pigment layer. Sclerenchymatous cells of endotesta yellowish-brown or reddish-brown, subpolygonal, walls extremely thickened, containing silica bodies, about 10~15 μm in diameter. Perisperm cells contain starch granules, occasionally containing fine prisms or clusters of calcium oxalate. Endosperm cells contain aleurone grains and fatty oil droplets.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of nootkatone and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of petroleum ether (30~60℃) and ethyl acetate (3:2) as the developing solvent. Apply 10 μL of each of the sample solution and reference drug solution and 5 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 15.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 9.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 3.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Nootkatone:
   (1) Mobile phase: Methanol as the mobile phase A, and water as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of nootkatone, and dissolve in methanol to produce a solution containing 0.1 mg per mL.
   (3) Sample solution: Weigh accurately 1.0 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 12.5 mL of methanol, ultrasonicate for 30 minutes, filter to a 25-mL volumetric flask with filter paper. Repeat the extraction of the residue one more time. Combine the filtrate and make up to volume with methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (240 nm) and a column packing L1. The column temperature is maintained at

30.5℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of nootkatone should not be less than 10,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~10	65	35
10~30	65→70	35→30
30~40	70→100	30→0

(5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Nootkatone (%)=2.5(r_U/r_S) (C_S) / (W)

r_U: peak area of nootkatone of sample solution

r_S: peak area of nootkatone of reference standard solution

C_S: concentration of nootkatone of reference standard solution (mg/mL)

W: weight of test sample (g) calculated with dried sample.

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).
4. Volatile oil: Carry out the method for determination of volatile oil (General rule 6013).

Storage: Refrigerate or store in a cool and dry place, and protect from mold and insects.
Usage: Tonifying and replenishing medicinal (Yang-tonifying medicinal).
Property and flavor: Warm; pungent.
Meridian tropism: Spleen and kidney meridians.
Effects: Warm middle and dissipate cold, promote digestion and relieve pain.
Administration and dosage: 3~10 g.

AMOMI FRUCTUS
砂仁
Sha Ren / Sha Ren
Villous Amomum Fruit

Villous amomum fruit is the dried ripe fruit of *Amomum villosum* Lour., *Amomum villosum* Lour. var. *xanthioides* (Wall. ex Baker) T.L.Wu & S.J.Chen or *Amomum longiligulare* T.L.Wu (Fam. Zingiberaceae).
It contains not less than 8.0% of dilute ethanol-soluble extractives, not less than 12.0% of water extractives and not less than 0.7% (v/w) of volatile oil.

Description:

1. Fruit of *Amomum villosum*: Ellipsoidal or ovate, with indistinct obtuse 3-ridged, 1.2~2.5 cm in length, 0.8~1.8 cm in diameter. Outer surface reddish-brown or brown, densely with soft, fragile and curved spiny protrudance, with reticular striations, the dorsal site with longitudinal striations faintly visible, apex with protuberant scars of perianth, base with a fruit stalk or its scars. Pericarp thin, longitudinal loculicidal dehiscence. Inner surface pale brown, with longitudinal vascular bundles and thin diaphragms distinct, axile placenta, 3-locular. Seeds gathered in masses, ellipsoidal or oval. Seed irregular polygonal, 2~5 mm in length, 1.5~4 mm in diameter, 6~20 in each loculus, externally mostly reddish-brown, with irregular wrinkles, covered with pale brownish-yellow membranous aril, disc-shaped hilum dent at the smaller end, chalaza at the broad end, raphe longitudinally furrowed. Texture hard, fracture of perisperm creamy white, starchy, fracture of endosperm and embryo pale yellow or brownish-yellow, oily. Odour strongly aromatic; taste pungent, cool and slightly bitter.
2. Fruit of *Amomum villosum* var. *xanthioides*: Ovate or oval, with indistinct obtuse 3-ridged, 1.2~2.2 cm in length, 1~1.6 cm in diameter. Outer surface yellowish-brown or brown, with densely slightly flattened spiny protrudance. Inner surface pale yellow or yellowish-brown. Seeds gathered in masses, subspheroidal. Seed 8~22 in each loculus, externally pale brown or brown, with regular wrinkles, covered with pale yellowish-white membranous aril. Odour strongly aromatic; taste pungent, cool and slightly bitter, slight lower than fruit of *Amomum villosum*.
3. Fruit of *Amomum longiligulare*: Oval, ellipsoidal, fusiform-ellipsoidal or pyriform, with indistinct obtuse 3-ridged, 1~1.7 cm in length, 0.7~1.7 cm in diameter. Externally grayish-brown, with flaky and branched soft spines. Seeds gathered in masses, oval, ellipsoidal or spheroidal. Seed 4~15 in each loculus, 2~4 mm in diameter. Odour slight; taste weak.

Microscopic identification:

1. **Transverse section:**

Fruit of *Amomum villosum*: Aril occasionally remained. Epidermal cells of testa 1 layered, elongated radially, with slightly thick walls; hypodermis 1 layered, containing brown or reddish-brown contents. Oil cells layer composed of 1 layer of oil cells, 76~106 μm in length and 16~25 μm in width, containing yellow oil droplets. Pigment layer composed of several rows of brown cells, cells polygonal and irregularly arranged. Endotesta composed of 1 layer of palisade-shaped sclerenchymatous cells, yellowish-brown, with extremely thickened inner and lateral walls, cells small and containing silica masses. Perisperm containing starch granules in cells, a few of fine prisms of calcium oxalate occasionally present.

Endosperm containing fine aleurone grains and fatty oil droplets in cells.

2. **Powder:**
   (1) Fruit of *Amomum villosum*: Reddish-gray. Epidermal cells of testa pale or light yellow, long strip-shaped in surface view, terminal gradually acute or obtuse-rounded, up to 346 μm in length, 9~54 μm in diameter, wall slightly thickened and unlignified. Hypodermal cells rectangular, 11~34 μm in diameter, usually vertically arranged with epidermal cells in an upper and lower layered pattern, filled with brown or brownish-red contents, easily broken and forming pigment masses. Clusters of calcium oxalate occasionally present. Oil cells colorless or pale yellow, 1 layered in sectional view, subrectangular or irregularly long strip-shaped, 40~90 μm in length, 11~36 μm in diameter; subsquare or subrounded in surface view, some lumina containing oil droplets. Sclerenchymatous cells of endotesta flaky, yellowish-brown or brown, subpolygonal in surface view, 13~23 μm in diameter, wall about 2 μm thick, unlignified, lumen containing silica masses, 9~18 μm in diameter; cells palisade-shaped in sectional view, 15~40 μm in length, 11~23 μm in diameter, with thin outer wall and extremely thick inner wall, lumina inclined to the upper side and containing silica masses. Clusters and prisms of calcium oxalate, endosperm and perisperm cells, aril cells and pigment cells also present; perisperm cells filled with masses of starch granules.
   (2) Fruit of *Amomum villosum* var. *xanthioides*: Reddish-gray or dark gray. Epidermal cells of testa, up to 320 μm in length, 17~38 μm in diameter. Hypodermal cells subrectangular or irregular in shape in surface view, 9~44 μm in diameter. Oil cells rectangular in sectional view, 33~102 μm in length, 20~36 μm in diameter. Sclerenchymatous cells of endotesta polygonal in surface view, 9~18 μm in diameter, wall about 3 μm thick, lumina containing silica masses, 5~16 μm in diameter; 14~35 μm in length and 12~22 μm in diameter in sectional view.
   (3) Fruit of *Amomum longiligulare*: Grayish-brown. Epidermal cells of testa light or pale yellow, long strip-shaped in surface view, terminal gradually acute or slightly obtuse-rounded, up to about 405 μm in length, 34~54 μm in diameter. Hypodermal cells long strip-shaped, long-rounded or rectangular in surface view, 13~38 μm in diameter, wall relatively curved, containing reddish-brown or yellow pigments. Oil cells long strip-shaped, long-rounded or subrectangular in sectional view, 40~110 μm in length, 18~26 μm in diameter. Sclerenchymatous cells of endotesta polygonal or subovate in surface view, 9~23 μm in diameter, wall about 1.5 μm thick, lumina containing silica masses, 8~25 μm in diameter; 19~30 μm in length and 10~20 μm in diameter in sectional view.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add a quantity of powdered sample, extract with water, and dissolve the volatile oil in ethanol to produce a solution containing 20 μL per mL.
2. Reference drug solution: Take a quantity of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of bornyl acetate and dissolve in ethanol to produce a solution containing 10 μL per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of cyclohexane and ethyl acetate (22:1) as the developing solvent. Apply 1 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 5% vanillin/H_2SO_4 TS and heat at 105 ℃ until the spots become visible. Examine under visible light. The purplish-red spots in the chromatogram obtained from the sample solution correspondings in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 14.0% dry at 105 ℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 13.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 4.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

※Note: "When this TCM herb is sold commercially, the limit of heavy metals, sulfur dioxide and aflatoxins should follow the food standard."

Assay:

1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

3. Volatile oil: Carry out the method for determination of volatile oil (General rule 6013).

Storage: Refrigerate or store in a cool and dry place.
Usage: Dampness-dispelling medicinal (Dampness-resolving with aroma medicinal).
Property and flavor: Warm; pungent.
Meridian tropism: Spleen, stomach, and kidney meridians.
Effects: Invigorate stomach with aroma, regulates qi and calms fetus and warm middle, move qi to relieve pain and stop vomiting.
Administration and dosage: 3~7.5 g.

AMOMI FRUCTUS ROTUNDUS
豆蔻
Dou Kou / Dou Kou
Whitefruit Amomim Fruit

Cardamom fruit is the dried ripe fruit of *Amomum compactum* Soland ex Maton (*Elettaria cardamomum* (L.) Maton) (Fam. Zingiberaceae).
It contains not less than 4.0% (v/w) of whitefruit amomim fruit oil. The fruit should be kept in capsule, removed the peel when use.

Description: Capsule subspheroidal, pale yellow , 15 mm in diameter. Externally smooth, with 3 longitudinally obtuse edges and 3 longitudinal furrows arranging alternative, apex with 1~2 mm long protuberant. Ovary 3-celled, each containing about 10~13 seeds, gathered in masses. Seed irregularly triangular or quadrilateral, about 4 mm in length, about 3 mm thick, externally pale reddish-brown to blackish-brown, with fine reticular striations, showing deeply longitudinal furrows at one surface. Testa membranous, brown. Perisperm starchy, white. Endosperm yellow, surrounding pale yellow embryo. Odour aromatic; taste pungent, with a cooling sensation, slightly camphor-like.

Microscopic identification:
1. **Transverse section:**
   Fruit of *Amomum compactum*: Aril composed of decadent parenchymatous tissue. The outermost layer of testa composed of thick-walled epidermal cells; secondary layer composed of 1 row of fine pigment cells, containing red to orange contents; third layer composed of 1 row of large cells, with walls lignified, containing volatile oil. The innermost layer of testa composed of 1 row of elongated stone cells, wtih walls U-shaped thickened, lumina extremely small, containing crystals of silicon dioxide. Perisperm composed of polygonal parenchymatous cells, containing starch granules, small prisms of calcium oxalate occasionally present. Endosperm contains oil droplets and aleurone granules.
2. **Powder:** Brown to pale yellow. The major portion of powder is occupied by fragments of perisperm and testa. Perisperm cells contain starch granules, small prisms of calcium oxalate occasionally present; simple starch granules 1~4 μm in diameter. Endosperm cells contain aleurone granules and oil droplets. Testa cells long-polygonal, containing fragments of orange-red pigment cells and blackish-brown lignified and thick-walled stone cell groups.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 2.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 1 hour, filter and use the filtrate.
2. Reference drug solution: Take 2.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of toluene and ethyl acetate (95:5) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 1% vanillin/H_2SO_4 TS. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:
1. Acid-insoluble ash: Not more than 4.0% (General rule 6007).
2. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
3. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
4. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
5. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
6. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
Volatile oil: Carry out the method for determination of volatile oil (General rule 6013).

Storage: Store in a ventilated and dry place, preserve in a well-closed container, and protect from insects.
Usage: Dampness-dispelling medicinal (Dampness-resolving with aroma medicinal).
Property and flavor: Warm; pungent.
Meridian tropism: Lung spleen and stomach meridians.
Effects: Transform dampness and moves qi, warm the middle, stop vomiting.
Administration and dosage: 3~6 g, added when the decoction is nearly done.

AMPELOPSIS RADIX
白薇
Bai Lian / Bai Lian
Japanese Ampelopsis Root

Japanese ampelopsis root is the dried root tuber of *Ampelopsis japonica* (Thunb.) Makino (Fam. Vitaceae). It contains not less than 13.0% of dilute ethanol-soluble extractives, not less than 12.0% of water extractives, not less than 0.014% of gallic acid and not less than 0.02%.of catechin.

Description: Oblong or fusiform, 5~12 cm in length, 1.5~3.5 cm in diameter, often cutting into 2 or 4 longitudinal segments or oblique slices. Externally reddish-brown or blackish-brown, with longitudinal wrinkles, transverse fine striations and whitish elongated transverse lenticels, cork easily exfoliated to scaly, the exposed layer whitish or reddish-brown, crumpled, a protuberant ridge occurring at the edges. Texture hard and fragile, starchy. Odour slight; taste sweetish.

Microscopic identification:

1. **Transverse section:**
   Root tuber of *Ampelopsis japonica*: Cork composed of several layers of cells, occasionally fallen off. Phloem bundles narrow; rays broad; cambium in a ring; xylem vessels arranged sparsely, surrounded by xylem fibers. Parenchymatous tissue contains mucilage cells containing raphides of calcium oxalate; parenchymatous cells contain starch granules or clusters of calcium oxalate.
2. **Powder:** Pale reddish-brown. Simple starch granules clavate, oblong, ovate, reniform, flat-triangular or rhombic, small spheroidal granules, occasionally both ends acute, 3~26 μm in diameter, 25~43 μm in length, with indistinct hilum and striations; compound granules few, 2 particles arranged in parallel. Mucilage cells subrounded or oblong, containing pale yellow mucilage contents, scattered with raphides of calcium oxalate, 86~169 μm in length, occasionally in bundles. 4 Clusters of calcium oxalate 25~78 μm in diameter, angles broad, some prisms like or some clusters and prisms accrete. Bordered-pitted vessels 356~383 μm in diameter, bordered pits arranged scalariform or reticulate, pit apertures linear. Stone cells subrounded or oblong, 18~30 μm in diameter, walls 2~12 μm thick, pit canals sparse, lumen contains yellowish-brown contents. Cork cells, xylem parenchymatous cells and xylem fibers also present.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 5.0 g of powdered sample to 40 mL of methanol, ultrasonicate for 30 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 10 mL of water, extract by shaking with 10 mL of ethyl acetate, and discard the water layer. Evaporate the ethyl acetate extract to dryness and dissolve the residue in 1 mL of methanol.
2. Reference drug solution: Take 5.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of gallic acid and dissolve in methanol to produce a solution containing 0.2 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of toluene, ethyl acetate, and formic acid (6:3:1) as the developing solvent. Apply 8 μL of each of the sample solution and reference drug solution and 2 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 254 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Total ash: Not more than 11.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 3.0% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Gallic acid and catechin:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and a solution of 0.1% phosphoric acid as the mobile phase B
   (2) Reference standard solution: Weigh accurately a quantity of gallic acid and catechin and dissolve in 60% methanol to produce a solution containing 5 μg per mL of each.
   (3) Sample solution: Weigh accurately 0.5 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 10 mL of 60% methanol, ultrasonicate for 30 minutes. Centrifuge for 10 minutes, filter the supernatant. Repeat the extraction of the residue one more time. Combine the extracts, transfer to a 25-mL volumetric flask and make up to volume with 60% methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (202 nm) and a column packing L1.

The column temperature is maintained at 35℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The ratio may be adjusted if necessary. The number of theoretical plates of the peak of gallic acid and catechin should not be less than 4,000 and 20,000 of each.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~10	2	98
10~55	2→15	98→85

(5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Gallic acid or **catechin: (%)= 0.0025(r_U/r_S) (C_S) / (W)**

r_U: peak area of gallic acid and catechin of sample solution

r_S: peak area of gallic acid and catechin of reference standard solution

C_S: concentration of gallic acid and catechin of reference standard solution (μg/mL)

W: weight of test sample (g) calculated with dried sample.

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place, and protect from insects.

Usage: Heat-clearing medicinal (Heat-clearing and detoxcating medicinal).

Property and flavor: Mild cold; bitter and pungent.

Meridian tropism: Heart and stomach meridians.

Effects: Clear heat and detoxicate, wound healing, disperse abscesses and nodules, promote tissue regeneration and relieve pain.

Administration and dosage: 3~10 g.

Precaution and warning: Incompatible with *Aconitum* sp.

AMYNTHAS ET METAPHIRE
地龍
Di Long / Di Long
Earthworm

Earthworm is the dried body of *Amynthas aspergillum* (E.Perrier), *Metaphire vulgaris* (Chen), *Metaphire guillelmi* (Michaelsen) or *Amynthas pectinifera* (Michaelsen) (Fam. Megascolecidae). The former one is commonly known as “Guang Di Long”, the latter three are commonly known as “Hu Di Long”. It contains not less than 9.0% of dilute ethanol-soluble extractives and not less than 8.0% of water extractives.

Description:

1. Guang Di Long: Slat-shaped thin slices, curved, margin slightly rolled, 15~20 cm in length, 1~2 cm in width, with segments throughout the body. The outer surface brown to purplish-gray on the dorsal part, pale yellowish-brown on the abdomen part; the clitellum at the segment 14~16, relatively bright, commonly known as “Bai Jing” (white neck). Tapered at the anterior part, blunt and rounded at the caudal end. The setae coarse and stiff, slightly light in color. Male opening on a small protuberance of setae ring at the ventral side of segment 18, outer margin with several rings of shallow skin fold, inner setae ring protuberant, 1 or 2 ranks of small papillae on both sides of the anterior part, number varies from 10~20 on each side. Two pairs of seminal receptacle opening located on an elliptical protuberance between segments 7/8~8/9, occupying about 5/11 girth of the segment. Texture light and slightly coriaceous, uneasily broken. Odour stinking; taste slightly salty.
2. Hu Di Long: 8~15 cm in length, 0.5~1.5 cm in width, the whole body composed of segments, dorsal part brown to yellowish-brown, ventral part pale yellowish-brown; 3 pairs of seminal receptacle openings located between 6/7~8/9 segment. The clitellum at the segment 14~16, relatively bright. A pair of male opening on segment 18. The male copulatory pouch of *Metaphire vulgaris* can turn out completely, as the shape of cauliflower or penis; of *Metaphire guillelmi* longitudinally slit-like; the male openings of *Amynthas pectinifera* with 1 or more papillae at the inner side.

Microscopic identification:

Powder:

Guang Di Long: Pale grayish-yellow or pale gray. Obliquely striated muscle fibers mainly colorless, very few pale brown, muscle fibers easily scattered or twisted with each other, mostly curved, 4~66 μm in diameter, margin usually uneven, some margin partly inflated, light and dark striations indistinct, arranged alternately. Epidermal cells yellowish-green or yellowish-brown, cell boundary indistinct, containing blackish-brown pigment granules, scattered or gathered into strip. Setae rarely present, usually broken and scattered, pale brown or yellowish-brown, 34~63 μm in diameter at the center, apex mostly blunt, some with longitudinal striations on the surface.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of water, heat to boil, cool and centrifuge and use the supernatant.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of lysine, leucine, and valine and dissolve

in water to produce a solution containing 1.0 mg, 1.0 mg and 0.5 mg per mL of each.

4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-butanol, glacial acetic acid, and water (4:1:1) as the developing solvent. Apply 3 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with ninhydrin TS and heat at 105℃ until the spots become visible. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 12.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 20.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 10.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Total heavy metals: Not more than 30.0 ppm (General rule 6301).
6. Aflatoxins
   (1) Aflatoxins (sum of B_1, B_2, G_1 and G_2): Not more than 10.0 ppb (General rule 6307).
   (2) Aflatoxin B_1: Not more than 5.0 ppb (General rule 6307).

Assay:

1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from mold and insects.
Usage: Liver-pacifying and wind-extinguishing medicinal.
Property and flavor: Cold; salty.
Meridian tropism: Liver, spleen, and bladder meridians.
Effects: Pacify liver and extinguish wind, clears heat to settle fright, calm panting, free collateral vessels, promote urination.
Administration and dosage: 3~10 g.

ANDROGRAPHIS HERBA
穿心蓮
Chuan Sin Lian/Chuan Sin Lian
Common Andrographis Herb

Common andrographis herb is the dried herb of *Andrographis paniculata* (Burm.f.) Nees (Fam. Acanthaceae).
It contains not less than 4.0% of dilute ethanol-soluble extractives and not less than 9.0% of water extractives and not less than 0.97% of the total amount of andrographolide and dehydroandrographolide.

Description: Square prismatic, multi-branched, 2~50 cm in length, 2~5 mm in diameter; column slightly enlarged. Brittle, easy break, section of the pith white. Leaves opposite, petiole short or nearly sessile; leaf blade compressed, fragile, intact, lanceolate to ovate-lanceolate, 3~12 cm in length, 2~5 cm wide, Tip tapered, base wedge-shaped, whole edge wavy; upper epidermis green, lower epidermis grayish green, both sides smooth. Odour slight; taste extremely bitter.

Microscopic identification:

1. **Transverse section:**
   (1) Stem of *Andrographis paniculata*: 1 column of epidermal cell, outer layer horny, some cells contain calcium carbonate crystals (cystolith); thick-angled tissues are more at the four corners of the stem. Cortical parenchyma cells contain chlorophyll. Endothelial layer consists of 1 column of slightly thickened cells. Phloem narrow, cell walls shrunk, arranged closely. Xylem well developed, consists of ductal, wood fiber and pith cord cells. Parenchyma cells large, and some contain fine oxalate needles, scattered or clustered.
   (2) Leaf of *Andrographis paniculata*: Upper epidermis consists of 1 column of subsquare or rectangular cells, some contain round, long elliptical to rod-shaped cystolith or glandular scales. Grid-like structure 1 column of long columnar cells, thick tissue seen near the middle column of the epidermal cells; sponge tissue composed of 4~5 columns of loose parenchyma cells, voids visible. Outer vascular bundle of the main vascular bundle tough, groove shape; xylem located above, Phloem located below; lower epidermis consists of 1 column of square cells, some contain cystolith or glandular scales.
2. **Powder:** Yellowish-green. Non-glandular conical, consisting of 1~4 cells, top blunt or pointed, horny texture at the base. Epidermal cells irregular in shape, outer wall slightly thickened, keratinized. Stomatal direct axis or infinitive, size of the subsidiary cells is very different. crystal cells subsquare or rectangular, contain round, elliptical or rod-shaped cystolith. Catheter round, mainly threaded, textured and edged. Glandular head oblate, consists of 4, 6 or 8 cells, very short stem.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 20 mL of ethanol, ultrasonicate for 20 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 2 mL of methanol.
2. Reference drug solution: Take 1.0 g of the reference

drug and the method of preparation is the same as which is described above.

3. Reference standard solution: Weigh accurately a quantity of andrographolide and dehydroandrographolide in ethanol to produce a solution containing 1.0 mg per mL of each.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of petroleum ether (30~60 ℃), ethyl acetate, and ethanol (4:2:1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 254 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 13.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 13.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Andrographolide and dehydroandrographolide:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and water as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of andrographolide and dehydroandrographolide and dissolve in methanol to produce a solution containing 60 μg per mL of each.
   (3) Sample solution: Weigh accurately 0.2 g of the powdered sample and place it in a 15-mL centrifuge tube, then add accurately 10 mL of methanol, ultrasonicate for 30 minutes. Centrifuge for 10 minutes, transfer the supernatant to a 25-mL volumetric flask. Repeat the extraction of the residue one more time. Combine the supernatant and make up to volume with methanol, mix well, filter and use the filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (220 nm) and a column packing L1. The column temperature is maintained at 25℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of andrographolide and dehydroandrographolide should not be less than 2,000 of each.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~25	20→55	80→45

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Andrographolide or dehydroandrographolide (%) = 0.0025(r_U/r_S) (C_S) / (W)

r_U: peak area of andrographolide or dehydroandrographolide of sample solution

r_S: peak area of andrographolide or dehydroandrographolide of reference standard solution

C_S: concentration of andrographolide or dehydroandrographolide of reference standard solution (μg/mL)

W: weight of test sample (g) calculated with dried sample.

Storage: Store in a ventilated and dry place.
Usage: Heat-clearing medicinal (Heat-clearing and detoxicating medicinal).
Property and flavor: Cold; bitter.
Meridian tropism: Heart, lung, stomach, large intestine, and bladder meridians.
Effects: Clear heat and detoxicate, dry dampness to alleviate edema.
Administration and dosage: 6~9 g.

ANEMARRHENAE RHIZOMA
知母
Jhih Mu / Zhi Mu
Anemarrhena Rhizome

Anemarrhena rhizome is the dried rhizome of *Anemarrhena asphodeloides* Bunge (Fam. Liliaceae).
It contains not less than 30.0% of dilute ethanol-soluble extractives, not less than 40.0% of water extractives, not less than 0.7% of mangiferin and not less than 3.0% of timosaponin B_{II}.

Description: Flattened cylindrical, slightly curved, different thickness at the both ends, branched occasionally, 3~17 cm in length, 0.8~2.0 cm in diameter, with pale yellow leaf scars and root scars, commonly known as “Jin Se Tou”. The upper part exhibiting a deep longitudinal furrows and closely arranged annular nodes with dense and flat yellowish-brown tomenta, growing upward bilaterally; the other side crumpled, with dented or protruding dotted root scars. Texture hard, easily broken,

fracture yellowish-white, even. Odourless; taste sweetish and bitter, viscous on chewing.

Microscopic identification:

1. **Transverse section:**
   Rhizome of *Anemarrhena asphodeloides*: Cork composed of several layers of polygonal or flat-rectangular cells. Cortex scattered with some leaf-trace vascular bundles; endodermis indistinct. Stele scattered with numerous collateral vascular bundles surrounded by cells containing raphides of calcium oxalate. Root-trace vascular bundles tangentially arranged along the pericycle. Mucilage cells found everywhere, mostly distributed in cortex, containing raphides of calcium oxalate.
2. **Powder:** Pale yellow. Mucilage cells contain raphides of calcium oxalate. Mounting with glycerin-acetic acid TS, showing swollen cells, raphides of calcium oxalate surrounded by mucilage contents; while mounting with absolute ethanol TS, showing subrounded or oblong mucilage cells, up to about 340 μm in length, 56~160 μm in diameter, translucent, walls indistinct or relatively distinct, lumen containing raphides of calcium oxalate, 36~110 μm in length, relatively fine, some up to 7 μm thick, fine prism-like when broken. Fibers (leaf base) relatively slender, 8~14 μm in diameter, walls slightly thickened and lignified, pits sparse, lumen broad. Bordered-pitted, reticulate and spiral vessels 8~14 μm in diameter. Lignified sclerenchymatous cells (scales) subrectangular, long-polygonal or short fiber-like elongated, arranged alternately,16~48 μm in diameter, walls slightly thickened and lignified, pit canals relatively dense, lumen containing brownish-yellow contents. Cork cells varying in size, walls thin and usually overlapped. Epidermal cells of scales present.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes then filter, make up the filtrate to 10 mL and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and the supernatant of *n*-butanol, glacial acetic acid, and water (4:1:5) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with vanillin/H_2SO_4 TS and heat at 105°C until the spots become visible. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:

1. Loss on drying: Not more than 12.0% dry at 105°C for 5 hours (General rule 6015).
2. Total ash: Not more than 6.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 400 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 5.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Mangiferin:
   (1) Mobile phase: A solution of acetonitrile and 0.2% glacial acetic acid (15:85). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of mangiferin and dissolve in dilute ethanol to produce a solution containing 0.5 mg per mL.
   (3) Sample solution: Weigh accurately 0.1 g of powdered sample, and place it in a conical flask with stopper, add accurately 25 mL of dilute ethanol then weigh, ultrasonicate for 30 minutes, cool, weigh again, replenish the loss of the weight with dilute ethanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (258 nm) and a column packing L1. The number of theoretical plates of the peak of mangiferin should not be less than 6,000.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Mangiferin (%)=0.0025(r_U/r_S) (C_S) / (W)
   r_U: peak area of mangiferin of sample solution
   r_S: peak area of mangiferin of reference standard solution
   C_S: concentration of mangiferin of reference standard solution (μg/mL)
   W: weight of test sample (g) calculated
2. Timosaponin B_{II}:
   (1) Mobile phase: A solution of acetonitrile and water (25:75). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of timosaponin B_{II} and dissolve in 30% acetone to produce a solution containing 0.50 mg and 3.0 mg per mL.
   (3) Sample solution: Weigh accurately 0.15 g of powdered sample, and place it in a conical

flask with stopper, add accurately 25 mL of 30% acetone then weigh, ultrasonicate for 30 minutes, cool, weigh again, replenish the loss of the weight with 30% acetone, mix well, filter and use the successive filtrate.

(4) Chromatographic system: It is equipped with an evaporative light-scattering detector (ELSD) and a column packed with L7. The number of theoretical plates of the peak of timosaponin B_{II} should not be less than 10,000.

(5) Procedure: Inject accurately 10 μL of the reference standard solution and sample solution into the apparatus, and use a calibration equation of logarithm alteration of 2 external standards calculate the content.

3. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
4. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from insects.
Usage: Heat-clearing medicinal (Heat-clearing and fire-purging medicinal).
Property and flavor: Cold; bitter and sweet.
Meridian tropism: Lung, stomach, and kidney meridians.
Effects: Clear heat and purge fire, moisten dryness.
Administration and dosage: 6~12 g.

ANGELICAE DAHURICAE RADIX
白芷
Bai Jhih / Bai Zhi
Dahurian Angelica Root

Dahurian angelica root is the dried root of *Angelica dahurica* (Hoffm.) Benth. & Hook.f. ex Franch. & Sav., *Angelica dahurica* (Hoffm.) Benth. & Hook.f. ex Franch. & Sav. cv. 'Hangbaizhi'or *Angelica dahurica* Benth. & Hook.f. var. *formosana* Yen (Fam. Umbelliferae).
It contains not less than 13.0% of dilute ethanol-soluble extractives, not less than 13.0% of water extractives and not less than 0.08% of imperatorin.

Description:Long-conical, t hick at the upper part and thin at the lower part, 10~25 cm in length, 1.5~2.5 cm in diameter, apex with dented and concentric-ring reticulated stem scars. Externally grayish-brown or yellowish-brown, slightly glossy, with longitudinal wrinkles, scattered with transverse lenticel-like protruded commonly known as "Ge Da Ding" and rootlet scars. Texture compact, fracture grayish-white, starchy, scattered with numerous brown oil dots (secretory cavities) in bark, cambium ring rounded, wood occupying a third of cross section. Odour strongly aromatic; taste pungent and slightly bitter.
Root of *Angelica dahurica* var. *formosana*: Similar to *Angelica dahurica* (Hoffm.) Benth. et Hook.f. ex Franch. et Sav. Transverse lenticel-like protruded arranged in 4 longitudinal row, forming subconical root with four longitudinal ridges. Cambium ring slightly square, wood occupying half of cross section.

Microscopic identification:
1. **Transverse section:**
   (1) Angelicae Dahuricae Radix: Cork composed of 5~10 or more layers of cells. Cortex and phloem scattered with secretory canals, parenchymatous cells contain starch granules, rays distinct. Xylem slightly round, vessels arranged radially.
   (2) Root of *Angelica dahurica* var. *formosana*: Similar to root of *Angelica dahurica* in sectional view, but xylem slightly squared, rays more, vessels arranged sparsely.
2. **Powder:** Pale grayish-white. Starch granules numerous, simple granules subspheroidal or polygonal, 3~16 μm in diameter; compound granules relatively large, mostly composed of more than 10 components. Reticulate vessels mostly 13~18 μm in diameter, occasionally spiral vessels also present. Commonly with secretory canals fragments, contain yellowish-brown secretions. Cork cells subpolygonal, brownish-yellow. Clusters of calcium oxalate existed in parenchymatous cells.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 1 mL of methanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of imperatorin and isoimperatorin and dissolve in ethyl acetate to produce a solution containing 1.0 mg per mL of each.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of petroleum ether (30~60℃) and ethyl ether (1:1) as the developing solvent. Apply 2 μL of the sample solution and reference drug solution and 5 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 14.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 7.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).

4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 5.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Imperatorin:
   (1) Mobile phase: A solution of methanol and water (55:45). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of imperatorin and dissolve in methanol to produce a solution containing 5 μg per mL.
   (3) Sample solution: Weigh accurately 0.4 g of powdered sample and place it in a 50-mL centrifuge tube, then add accurately 45 mL of methanol, ultrasonicate for 30 minutes. Filter with filter paper, use the filtrate. Repeat the extraction of the residue one more time. Combine the filtrate, transfer to 100-mL volumetric flask and make up to volume with methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (300 nm) and a column packing L1. The column temperature is maintained at 35℃. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of imperatorin should not be less than 5,000.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   Imperatorin: (%)= 0.01(r_U/r_S) (C_S) / (W)

   r_U: peak area of imperatorin of sample solution
   r_S: peak area of imperatorin of reference standard solution
   C_S: concentration of imperatorin of reference standard solution (μg/mL)
   W: weight of test sample (g) calculated with dried sample.
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from insects.

Usage: Exterior-releasing medicinal (Pungent-warm exterior-releasing medicinal).
Property and flavor: Warm; pungent.
Meridian tropism: Stomach, large intestine, and lung meridians.
Effects: Release the exterior to dissipate cold, dispel wind and eliminate dampness, disperse swelling and expel pus, open orifices and relieve pain.
Administration and dosage: 3~11.5 g.

【Decoction pieces】

ANGELICAE DAHURICAE RADIX

It contains not less than 13.0% of dilute ethanol-soluble extractives, not less than 13.0% of water extractives and not less than 0.08% of imperatorin.
Raw medicinal materials are processed to remove remove impurities, clean selection, soak briefly, soften thoroughly, cut into thin slices, and dry, mostly crosscut rounded thick slices, externally pale brown, cut surface greyish-white, starchy and smooth, has many distinct and brownish cambium ring, scattered with brown oil dots. Odour aromatic; taste pungent and slightly bitter.

Thin layer chromatographic identification test: The method is the same as that for crude herb.
Impurities and other requirements: Methods and specifications are the same as those for crude herb.
Assay: The method is the same as that for crude herb.
Storage: The method is the same as that for crude herb.
Usage: Exterior-releasing medicinal (Pungent-warm exterior-releasing medicinal).
Property and flavor: Warm; pungent.
Meridian tropism: Stomach, large intestine, and lung meridians.
Effects: Release the exterior to dissipate cold, dispel wind and eliminate dampness, disperse swelling and expel pus, open orifices to relieve pain.
Administration and dosage: 3~11.5 g.

ANGELICAE PUBESCENTIS RADIX
獨活
Du Huo / Du Huo
Pubescent Angelica Root

Pubescent angelica root is the dried root of *Angelica pubescens* Maxim. f. *biserrata* R.H.Shan & C.Q.Yuan (Fam. Umbelliferae).
It contains not less than 30.0% of dilute ethanol-soluble extractives, not less than 30.0% of water extractives and not less than 0.5% of osthol.

Description: Root stock and main root stout, slightly cylindrical, 1.5~4 cm in length, 1.5~3.5 cm in diameter, the lower part branched and curved, 12~30 cm in length, 0.5~1.5 cm in diameter. Externally grayish-brown, with irregularly longitudinal wrinkles and transverse crack,

transverse elliptic lenticels and slightly protuberant scars of rootlets present. Root stock with annular striations, apex truncated, with numerous annular scars of petioles and dented scars of stems in the center. Texture hard, fracture grayish-white, cambium ring brown, bark scattered with numerous brown oil cavities, ray arranged densely; the fracture of root stock with larger pith and oil cavities. Odour characteristic and aromatic; taste bitter and pungent, numb.

Microscopic identification:

1. **Transverse section:**
   Root of *Angelica pubescens*: Cork with cell walls slightly lignified. Cortex narrow, scattered with a few of oblong oil ducts, 32~72 μm in length, up to 120 μm in width, surrounded by 6~8 secretory cells. Phloem occupied about 1/2 portion of the radius of root, oil ducts 3~8 arranged in a ring, round or oblong, 24~80 μm in diameter, oil ducts at the outer part up to about 160 μm in width, extremely small near the cambium, surrounded by 6~10 secretory cells; phloem rays relatively straight, 3~6 layers of cells wide. Cambium in a ring. Xylem vessels few, polygonal, 10~64 μm in diameter, singly scattered or 2~3 in groups, arranged sparsely and radially. Parenchymatous cells contain starch granules, 2~10 μm in diameter.
2. **Powder:** Pale yellow or pale brown. Simple starch granules subrounded or oblong, hilum and striations indistinct; compound granules composed of several dozens of components, easily discrete. Oil ducts mostly broken, in transverse view, surrounded by the suboblong secretory cells, 9~22 μm in diameter, lumens mostly contain yellowish-green or pale yellowish-brown secretions and oil droplets; secretory cells slender in longitudinal view. Reticulate and spiral vessels 14~81 μm in diameter. Cork cells polygonal or elongated-polygonal in surface view, wall slightly thickened, curved and lignified, some lumens contain brown contents; subrectangular in sectional view. Phelloderm cells and Subrounded or subrectangular parenchymatous cells present in cork tissue.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 15 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of osthol and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane and ethyl acetate(2:1) as the developing solvent. Apply 5 μL of the sample solution and reference drug solution and 2 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:

1. Total ash: Not more than 10.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 4.0% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Osthol:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and water as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of osthol and dissolve in methanol to produce a solution containing 20 μg per mL.
   (3) Sample solution: Weigh accurately 0.2 g of the powdered sample and place it in a 50-mL centrifuge tube, add 40 mL of methanol, ultrasonicate for 30 minutes, centrifuge for 5 minutes, filter with filter paper. Use the filtrate, transfer to 50-mL volumetric flask, make up to volume with methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (320 nm) and a column packing L1. The column temperature is maintained at 30°C. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of osthol should not be less than 8,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~25	52	48
25~35	52→100	48→0

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Osthol (%)=0.005(r_U/r_S) (C_S) / (W)
   r_U: peak area of osthol of sample solution
   r_S: peak area of osthol of reference standard solution

Cs: concentration of osthol of reference standard solution (μg /mL)
W: weight of test sample (g) calculated with dried sample.

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from mold, insects and oil seeping.
Usage: Dampness-dispelling medicinal (Wind-dampness-dispelling medicinal).
Property and flavor: Warm; pungent and bitter.
Meridian tropism: Kidney and bladder meridians.
Effects: Dispel wind and eliminate dampness, relieve impediment pain.
Administration and dosage: 3~11.5 g.

【Decoction pieces】

ANGELICAE PUBESCENTIS RADIX

It contains not less than 30.0% of dilute ethanol-soluble extractives, not less than 30.0% of water extractives and not less than 0.5% of osthol.
Raw medicinal materials are processed to remove impurities, clean selection, soften thoroughly, cut into thin slices, and dry, or dry at a lower temperature , mostly irregular thin slices, externally brown or greyish-brown, with wrinkles. Cut surface yellowish-white or pale greyish-brown in bark part, scattered with numerous brown oil spots, yellowish-brown in wood part, cambium ring brown. Texture hard and fragile. Odour characteristic and aromatic, taste bitter and pungent, slightly numbing.

Thin layer chromatographic identification test: The method is the same as that for crude herb.
Impurities and other requirements: Methods and specifications is the same as that for crude herb.
Assay: The method is the same as that for crude herb.
Storage: The method is the ame as that for crude herb.
Usage: Dampness-dispelling medicinal (Wind-dampness-dispelling medicinal).
Property and flavor: Warm; pungent and bitter.
Meridian tropism: Spleen and bladder meridians.
Effects: Dispel wind and eliminate dampness, relieve impediment pain.
Administration and dosage: 3~11.5 g.

ANGELICAE SINENSIS RADIX
當歸
Dang Guei / Dang Gui
Chinese Angelica Root

Chinese angelica root is the dried root of *Angelica sinensis* (Oliv.) Diels (Fam. Umbelliferae).

It contains not less than 35.0% of dilute ethanol-soluble extractives, not less than 30.0% of water extractives and not less than 0.03% of ferulic acid.

Description: Root stocks, main roots, branching roots and whole commonly known as “Guei Tou”, “Guei Shen”, “Guei Wei” and “Cyuan Guei” respectively. Slightly cylindrical, 15~25 cm in length. Externally yellowish-brown to dark brown, with longitudinally wrinkles and transverse lenticels. The upper part swollen, 1.5~4 cm in diameter, obtuse, remained with leaf sheaths and stem base; main roots stout, 1~3 cm in length, 1.5~3 cm in diameter; the lower part with 3~5 or more branched, the upper portion thick and the lower portion thin, mostly twisted, with a few rootlet scars. Texture hard, softened when moistened, fracture yellowish-white or pale yellowish-brown, bark thick, scattered with brown oil cavities, cambium ring yellowish-brown, wood paler in color. The center fracture of root stocks usually with pith and cavities. Odour strongly aromatic and characteristic; taste sweet, pungent, slightly bitter and numb.

Microscopic identification:

1. **Transverse section:**
   Lateral roots of *Angelica sinensis*: Cork composed of 4~7 layers of cells. Cortex narrow, composed of several rows of tangentially elongated cells. Phloem relatively broad, scattered with numerous subrounded oil cavities (secretory cavities), 25~160 μm in diameter, surrounded by 6~9 secretory cells, oil cavities relatively small near cambium. Cambium in a ring. Xylem rays broad, up to 10 layers of cells wide, vessels singly scattered or 2~3 in groups. Parenchymatous cells contain starch granules.
2. **Powder**: Pale yellow. Phloem parenchymatous cells fusiform, single cell elongated-fusiform, with 1~2 thin septa, walls usually with obliquely trellis striations. Oil cavities or its fragments visible, containing volatile oil droplets. Scalariform and reticulate vessels 13~80 μm in diameter, bordered-pitted and spiral vessels also found. Cork cells and starch granules visible, xylem fibers occasionally present.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 15 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of ligustilide and dissolve in methanol to produce a solution containing 1 μL per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane and ethyl acetate (4:1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the

top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Total ash: Not more than 8.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
3. Sulfur dioxide: Not more than 400 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 5.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Ferulic acid:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and a solution of 0.05% phosphoric acid as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of ferulic acid, transfer to an amber volumetric flask, and dissolve in 70% methanol to produce a solution containing 3 μg per mL.
   (3) Sample solution: Weigh accurately 0.2 g of powdered sample, add 25 mL of 70% methanol, heat under reflux for 30 minutes, cool and filter, transfer to a 50-mL volumetric flask, repeat the extraction of the residue one more time. Combine the filtrate and make up to volume with 70% methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (320 nm) and a column packing L1. The column temperature is maintained at 35℃. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of ferulic acid should not be less than 5,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~10	15	85
10~20	15→20	85→80
20~30	20→38	80→62
30~40	38→60	62→40
40~50	60→63	40→37
50~60	63→100	37→0

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   Ferulic acid (%)=0.005 (r_U/r_S) (C_S) / (W)

   r_U: peak area of ferulic acid of sample solution
   r_S: peak area of ferulic acid of reference standard solution
   C_S: concentration of ferulic acid of reference standard solution (μg/mL)
   W: weight of test sample (g) calculated with dried sample.
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from mold and insects.
Usage: Tonifying and replenishing medicinal (Blood-tonifying medicinal).
Property and flavor: Warm; sweet and pungent.
Meridian tropism: Liver, heart, and spleen meridians.
Effects: Tonify and harmony blood, activate blood and regulate menstruation to relieve pain, moisten intestine and relax the bowels.
Administration and dosage: 5~15 g.

【Decoction pieces】

ANGELICAE SINENSIS RADIX

It contains not less than 35.0% of dilute ethanol-soluble extractives, not less than 30.0% of water extractives and not less than 0.03% of ferulic acid.
Raw medicinal materials are processed to remove impurities, clean selection, soften thoroughly, cut into thin slices, and dry, mostly irregular, rounded, subrounded or sub-“Cyuan Guei” form. Surface yellowish-white, a pale brown ring in the middle, numerous brown oily dots visible, texture flexible, odour strongly aromatic.

Thin layer chromatographic identification test: The method is the same as that for crude herb.
Impurities and other requirements: Methods and specifications are the same as those for crude herb.
Assay: The method is the same as that for crude herb.
Storage: The method is the same as that for crude herb.
Usage: Tonifying and replenishing medicinal (Blood-tonifying medicinal).
Property and flavor: Warm; sweet and pungent.
Meridian tropism: Liver, heart, and spleen meridians.
Effects: Tonify and harmony blood, activate blood and regulate menstruation to relieve pain, moisten intestine and relax the bowel.
Administration and dosage: 5~15 g.

ANISI STELLATI FRUCTUS
八角茴香
Ba Jiao Huei Siang / Ba Jiao Hui Xiang
Star Anise Fruit

Star anise fruit is the dried ripe fruit of *Illicium verum* Hook.f. (Fam. Magnoliaceae).
It contains not less than 18.0% of dilute ethanol-soluble extractives, not less than 16.0% of water extractives, not less than 4.0% (v/w) of volatile oil and not less than 4.0% of *trans*-anethole.

Description: Mostly aggregate fruit composed of 8 follicles radiated arranged from the central axis, the stalk curved as hook like, 3~4 cm in length. Follicles boats shaped, 5~15 mm in length, about 5 mm in width, 5~10 mm in height, the upper part mostly dehiscent, apex blunt, outer surface reddish-brown with numerous wrinkles, inner surface brown, lustrous. Each follicle containing a flattened ovate seed, 7 mm in length, 4 mm in width, 2 mm thick, testa reddish-brown, lustrous, one end with a sunken hilum and obvious micropyle, the other end with chalaza, raphe in the center slender. Endosperm white, oily. Odour aromatic; taste pungent and sweet.

Microscopic identification:

1. **Transverse section:**
   Fruit of *Illicium verum*: Exocarp composed of 1 row of epidermal cells covered with cuticle. Mesocarp composed of collenchymatous cells, inside showing parenchymatous cells with vascular bundles and oil cells. Endocarp composed of 1 row of palisade-shaped cells. The outer layer of testa composed of 1 row of rectangular stone cells, arranged densely, inside showing several layers of parenchymatous cells. Endosperm contains aleurone grains and fatty oil.
2. **Powder:** Reddish-brown. Epidermal cells of exocarp polygonal. Stone cells of endocarp subsquare or polygonal, 90~400 μm in length, 40~120 μm in diameter, wall thickened with striations and pit canals. Palisade-shaped cells of endocarp 120~450 μm in length, 50~80 μm in width, walls thin and lignified, with pits. Stone cells of testa square or polygonal, pale yellow, 120~200 μm in length, 50~80 μm in width, containing brown contents. Fibers fusiform, lignified, with pits. Endosperm cells polygonal, containing aleurone grains and fatty oil.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 15 mL of petroleum ether (30~60℃) and ethyl ether (1:1), stopper tightly, shake for 15 minutes and filter. Evaporate the filtrate to dryness, and dissolve the residue in 2 mL of absolute ethanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of anisaldehyde and dissolve in 1 mL of absolute ethanol to produce a solution containing 10 μL per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of petroleum ether (30~60℃), acetone, and ethyl acetate (16:4:1). Apply 2~5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with dinitrophenyl-hydrazine TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Total ash: Not more than 9.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).
8. Aflatoxins
   (1) Aflatoxins (sum of B_1, B_2, G_1 and G_2): Not more than 10.0 ppb (General rule 6307).
   (2) Aflatoxin B_1: Not more than 5.0 ppb (General rule 6307).

※Note: "When this TCM herb is sold commercially, the limits of heavy metals, sulfur dioxide and aflatoxins should follow the food standard."

Assay:

1. *trans*-Anethole:
   (1) Mobile phase: A solution of 0.1% formic acid in acetonitrile as the mobile phase A, and a solution of 0.1% formic acid as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of *trans*-anethole, and dissolve in methanol to produce a solution containing 1.0 mg per mL.
   (3) Sample solution: Weigh accurately 1.0 g of the powdered sample and place it in a conical flask, then add accurately 12.5 mL of methanol, ultrasonicate for 30 minutes, filter to 25 mL volumetric flask with filter paper. Repeat the extraction of the residue one more time. Combine the extracts and make up to volume with methanol, mix well, filter and use the successive filtrate.

(4) Chromatographic system: The liquid chromatography is equipped with an UV detector (254 nm) and a column packing L1. The column temperature is maintained at 35 ℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~2	10	90
2~30	10→100	90→0

(5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

***trans*-Anethole (%)=2.5 (r_U/r_S) (C_S) / (W)**

r_U: peak area of *trans*-anethole of sample solution

r_S: peak area of *trans*-anethole of reference standard solution

C_S: concentration of *trans*-anethole of reference standard solution (mg/mL)

W: weight of test sample (g) calculated with dried sample.

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).
4. Volatile oil: Carry out the method for determination of volatile oil (General rule 6013).

Storage: Store in a cool and dry place, and protect from moisture.
Usage: Interior-warming medicinal.
Property and flavor: Warm; pungent.
Meridian tropism: Liver, kidney, spleen, and stomach meridians.
Effects: Regulates qi to relieve pain.
Administration and dosage: 3~6 g

AQUILARIAE LIGNUM RESINATUM
沉香
Chen Siang / Chen Xiang
Chinese Eaglewood

Chinese eaglewood is the resin containing wood of *Aquilaria sinensis* (Lour.) Spreng. (Fam. Thymelaeaceae). It contains not less than 10.0% of the ethanol-soluble extractives.

Description: Irregular lumps, flakes, slices or helmet-shaped, varying in size, 5~20 cm in length, 2~5 cm in width, about 1 cm thick. Externally bumpy, pale yellowish-white, scattered with blackish-brown alternating with yellow striations, with scars of knife cutting, holes occasionally present. Surface of holes and dent mostly rotten wood-like. Texture relatively compact, uneasily broken, fracture spiny, brown. Odour aromatic; taste bitter. Oil leaking, smoke and extreme aromatic when burned.

Microscopic identification:

1. **Transverse section:**
   Resin-containing wood of *Aquilaria sinensis*: Vessels subpolygonal, some containing brown resins. Xylem fibers with walls slightly thickened and lignified. Interxylary phloem usually intersect with rays, elongated-elliptical or strip-shaped, cell walls thin and unlignified, lumen filled with brown resins, scattered with few fibers, some parenchymatous cells contain prisms of calcium oxalate. Rays 1~2 rows of cells wide, containing resins.
2. **Powder:** Blackish-brown. Fiber tracheids mostly in bundles, long-fusiform. Xylem rays 1~2 rows of cells wide; parenchymatous cells of interxylary phloem contain yellowish-brown contents, walls unlignified. Prisms of calcium oxalate rare, tetrahedral. Resin masses also present.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 0.5 g of powdered sample to 30 mL of ethyl ether, ultrasonicate for 1 hour, evaporate the filtrate to dryness, and dissolve the residue in 2 mL of chloroform.
2. Reference drug solution: Take 0.5 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of toluene and acetone (9:1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:

1. Loss on drying: Not more than 10.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 9.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
Ethanol-soluble extractives: Carry out the method for determination of hot extraction method (General rule 6011).

Storage: Store in a cool and dry place, and protect from moisture.
Usage: Qi-regulating medicinal.
Property and flavor: Warm; pungent and bitter.
Meridian tropism: Spleen, stomach, and kidney meridians.
Effects: Move qi to relieve pain, downbear counterflow to stop vomiting, promote qi absorption to calm panting.
Administration and dosage: 1~5 g.

ARCTII FRUCTUS
牛蒡子
Niou Bang Zih / Niu Bang Zi
Great Burdock Achene

Great burdock achene is the dried ripe fruit of *Arctium lappa* L. (Fam. Compositae).
It contains not less than 10.0% of dilute ethanol-soluble extractives, not less than 6.0% of water extractives and not less than 5.0% of arctiin.

Description: Achenes, flattened and long-ovate, slightly curved, 6~7 mm in length, 2~3 mm in width. Externally grayish-brown, with several longitudinal ribs and black spots. One side obtuse-rounded, slightly broad, apex with a circular protuberant stylopodium; the other side slightly narrowed and curved, apex with a pale color spots. Pericarp hard, endosperm 2, grayish-white or yellowish-white, oily. Odour slight; taste slightly pungent and bitter.

Microscopic identification:
1. **Transverse section:**
   Fruit of *Arctium lappa*: Exocarp composed of irregular parenchymatous cells, covered with cuticle. Mesocarp varies in thickness, walls thickened and slightly lignified, brownish-yellow, with small collateral vascular bundles. Endocarp narrow, composed of yellowish-brown colored decadent cell layer, fill with a row of prisms of calcium oxalate, cell boundary instinct. Outermost layer of testa composed of palisade cells, 75~120 μm in length, 10~30 μm in diameter, walls thickened and with distinct striations. Nutritive layer consists of several layers of parenchymatous cells decadently instinct, innermost layer with 5 μm thick cuticles. Endosperm cells contain fatty oil. Cotyledon cells filled with aleurone grains and fatty oil, clusters and prism of calcium oxalate also present.
2. **Powder:** Grayish-white to grayish-brown. Exocarp cells composed of dense parenchymatous cells, containing brown contents. Mesocarp cells fusiform, reticulate cell walls distinct, 10~20 μm in diameter. Endocarp cells brownish-yellow, 5~20 μm in diameter, containing abundant prisms of calcium oxalate. Palisade cells of testa arranged densely, thick-walled, 50~120 μm in length, 10~30 μm wide. Parenchymatous cells of cotyledon filled with clusters of calcium oxalate, 5~10 μm in diameter, containing fatty oil droplets.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of arctiin and dissolve in ethanol to produce a solution containing 5.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, methanol, and water (12:2:1) as the developing solvent. Apply 8 μL of each of the sample solution and reference drug solution and 5 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 10.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 7.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
1. Arctiin:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and a solution of 0.1% formic acid as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of arctiin and dissolve in methanol to produce a solution containing 0.5 mg per mL.
   (3) Sample solution: Weigh accurately 10 mg of the powdered sample in a 50-mL centrifuge

tube, add 45 mL of methanol, ultrasonicate for 30 minutes, centrifuge for 15 minutes, use the supernatant. Repeat the extraction of the residue one more time. Combine the filtrate, transfer to a 100-mL volumetric flask, make up to volume with methanol, mix well, filter and use the successive filtrate.

(4) Chromatographic system: The liquid chromatography is equipped with an UV detector (280nm) and a column packing L1. The column temperature is maintained at room temperature. The flow rate is about 1 mL/min.The number of theoretical plates of the peak of arctiin should not be less than 5000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~10	25→45	75→55
10~20	45→70	55→30

(5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Arctiin: (%)= 10(r_U/r_S) (C_S) / (W)

r_U: peak area of arctiin of sample solution

r_S: peak area of arctiin of reference standard solution

C_S: concentration of arctiin of reference standard solution (mg/mL)

W: weight of test sample (g) calculated with dried sample.

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place, and protect from moisture.

Usage: Exterior-releasing medicinal (Pungent-cold exterior-releasing medicinal).

Property and flavor: Cold; pungent and bitter.

Meridian tropism: Lung and stomach meridians.

Effects: Disperse wind-heat, detoxicate and outthrust rashes, soothe throat and disperse swelling.

Administration and dosage: 5~12 g.

ARECAE PERICARPIUM
大腹皮
Da Fu Pi / Da Fu Pi
Areca Nut

Areca nut is the dried ripe pericarp of *Areca catechu* L. (Fam. Palmae).

It contains not less than 11.0% of dilute ethanol-soluble extractives and not less than 11.0% of water extractives.

Description: Ellipsoidal or gourd-shaped, 5~6.5 cm in length, 3 cm in width, 0.8~1 cm thick. Externally yellowish-white to grayish-yellow, with loose fiber longitudinally arranged. Exocarp fibers loose. Mesocarp fibers maned-like. Endocarp dented, brown or dark brown, smooth and hard shell-shaped. Texture light in weight and tenacious, easily tore longitudinally. Odourless; taste weak.

Microscopic identification:

Powder: Yellowish-white or yellowish-brown. Exocarp cells polygonal or elongated-polygonal in surface view, up to 52.8 μm in length, 9~15 μm in diameter, walls slightly moniliform thickened. Fibers of mesocarp mostly in bundles, fine long strip-shaped, straight or slightly curved, occasionally wavy at one side, the terminal slightly blunt, about 10 μm in diameter, walls thickened and lignified, with distinct pit canals; fiber bundles surrounded by cells containing silica bodies, silica bodies 6~9 μm in diameter, the cells containing silica bodies with thickened and lignified walls. Stone cells of mesocarp subrounded, subrectangular or elongated-oval, 22~50 μm in diameter, wall slightly thickened, lignified or slightly lignified, with distinct pits and pit canals, occasionally with distinct striations. Endocarp cells are irregular polygon, round or oval, 9~24 μm in diameter, walls thickened and lignified, with distinct pit canals.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 50 mL of ethanol, ultrasonicate for 45 minutes, filter and evaporate to dryness, and dissolve the residue in 1 mL of methanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of arecoline hydrobromide and dissolve in methanol to produce a solution containing 0.1 mg per mL.
4. Procedure: Use silica gel F254 as the coating substance and a solution of ethyl acetate, methanol, and 25%(v/v) ammonia solution (8∶1∶0.2) as the developing solvent. Apply 5 μL of the sample solution and reference drug solution and 2 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Expose to iodine vapor for 30 minutes. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 11.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 6.0% (General rule 6007).

3. Acid-insoluble ash: Not more than 2.5 % (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).
9. Aflatoxins
   (1) Aflatoxins (sum of B_1, B_2, G_1 and G_2): Not more than 10.0 ppb (General rule 6307).
   (2) Aflatoxin B_1: Not more than 5.0 ppb (General rule 6307)

Assay:
1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place.
Usage: Qi-regulating medicinal.
Property and flavor: Mild warm; pungent.
Meridian tropism: Spleen, stomach, large intestine, and small intestine meridians.
Effects: Direct qi downward and expands center, induce diuresis to alleviate edema.
Administration and dosage: 4.5~11.5 g.

ARECAE SEMEN
檳榔
Bin Lang / Bin Lang
Areca Nut

Areca nut is the dried ripe seed of *Areca catechu* L. (Fam. Palmae).
It contains not less than 5.0% of dilute ethanol-soluble extractives, not less than 5.0% of water extractives and not less than 0.2% of arecoline.

Description: Flattened conical or conical, apex obtuse, base flattened and broad, 1.5~3.5 cm in height, base 1.5~3 cm in diameter. Externally pale yellowish-brown or dark brown, with slightly dented reticulate furrows, occasionally with silvery endocarp patches or fibrous mesocarp, and a round concave (micropyle) in the center of the base, by side with a large and pale hilum. Texture hard, uneasily broken; fracture showing marble-like striations, forming from reddish-brown testa and perisperm insert into whitish endosperm; in transverse section, a small and shrunken embryo within micropyle. Odour slight; taste slightly bitter and astringent.

Microscopic identification:
1. **Transverse section:**
   Seed of *Areca catechu*: Outer layers of testa composed of several layers of flattened stone cells, elongated tangentially, stone cells vary in shape and size, containing reddish-brown contents, usually with intercellular spaces; inner layers of testa composed of rectangular or irregular cells, containing reddish-brown contents, wall slightly thickened, scattered with few vascular bundles, cells arranged densely, without intercellular spaces. The inner layers of testa and perisperm usually inserted into the endosperm, forming a crisscross tissue. Endosperm composed of white and polygonal cells, with thickened walls, pits large and distinct, moniliform, containing abundant oil droplets and aleurone grains.
2. **Powder:** Brownish-purple. Fragments of endosperm cells abundant, colorless, intact cells irregular polygonal or subsquare, wall 6~11 μm thick, with large subrounded pits, 8~19 μm in diameter. Perisperm cells subrectangular or subpolygonal, wall relatively thickened, with few fine pits, lumen mostly filled with reddish-brown or dark brown contents. Stone cells of testa parameciu-shaped or fusiform, 24~64 μm in diameter. Vessels spiral or reticulate, occasionally visible, 5~20 μm in diameter.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 2.0 g of powdered sample to 10 mL of 80% methanol, ultrasonicate for 1 hour, centrifuge, filter and use the filtrate.
2. Reference drug solution: Take 2.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of arecoline hydrobromide and arecaidine hydrochloride, dissolve in methanol to produce a solution containing 1.0 mg per mL of each.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of dichloromethane, methanol, and ammonia solution (6:2:0.5) as the developing solvent. Apply 5 μL of each of the sample solution and reference drug solution and 2 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Expose to iodine vapor for 20 minutes until the spots or bands become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 10.0% dry at 105°C for 5 hours (General rule 6015).
2. Total ash: Not more than 3.0% (General rule 6007).

3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).
9. Aflatoxins
   (1) Aflatoxins (sum of B_1, B_2, G_1, and G_2): Not more than 10.0 ppb (General rule 6307).
   (2) Aflatoxin B_1: Not more than 5.0 ppb (General rule 6307).

Assay:

1. Arecoline:
   (1) Mobile phase: A solution of acetonitrile and 0.2% phosphoric acid solution (2 in 1,000) (adjust pH value to 3.8 with concentrated ammonia solution) (55:45). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of arecoline hydrobromide and dissolve in mobile phase to produce a solution containing 30 μg per mL (the weight of arecoline is equivalent to 1/1.5214 of the weight of arecoline hydrobromide).
   (3) Sample solution: Weigh accurately 0.5 g of the powdered sample and place it in a conical flask with stopper, accurately add 25 mL of 50% methanol, ultrasonicate for 30 minutes, filter and transfer the solution to 50-mL volumetric flask. Repeat the extraction of the residue one more time, wash the residue with a quantity of 50% methanol. Combine the filtrate and make up to volume with 50% methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (210 nm) and a column packing L9 (SCX-strong cation exchange resin). The column temperature is maintained at 25℃. The flow rate is about 1.2 mL/min.The number of theoretical plates of the peak of arecoline should not be less than 3,000.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   Arecoline (%)=(0.005 / 1.5214) (r_U/r_S) (C_S) / (W)

   r_U: peak area of arecoline of sample solution
   r_S: peak area of arecoline of reference standard solution
   C_S: concentration of arecoline reference standard solution (μg /mL)
   W: weight of test sample (g) calculated with dried sample.
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place, and protect from insects.

Usage: Worm-expelling medicinal.

Property and flavor: Warm; bitter and pungent.

Meridian tropism: Stomach and large intestine meridians.

Effects: expel worms and disperse accumulation, move qi to induce diuresis.

Administration and dosage: 3~11.5 g.

ARISAEMATIS RHIZOMA
天南星
Tian Nan Sing / Tian Nan Xing
Jackinthepulpit Tuber

Jackinthepulpit tuber is the dried tuber of *Arisaema heterophyllum* Blume, *Arisaema erubescens* (Wall.) Schott or *Arisaema amurens*e Maxim. (Fam. Araceae).
It contains not less than 2.5% of dilute ethanol-soluble extractives and not less than 5.0% of water extractives.

Description:

1. Tuber of *Arisaema heterophyllum*: Slightly compressed-globose, 1.5~4.5 cm in diameter. Center with dented stem scars, encircled with 1~2 rows of sparse and coarse root scars, some surrounded by small lateral buds or has been grind.
2. Tuber of *Arisaema erubescens*: Oblate, 2~7 cm in diameter, externally pale yellow to pale brown, milky to pale yellow milky when peeled. Apex relatively flat, center with a round dented stem scars and brown bud scales, encircled with numerous pitted fibrous root scars. Bottom round and obtuse. Texture hard, fracture whitish, starchy. Odour slight; taste numb and pungent on chewing.
3. Tuber of *Arisaema amurens*e: Oblate, 1.5~4 cm in diameter, center with large and relatively flat stem scars, encircled with numerous irregular pitted fibrous root scars, some surrounded by small lateral buds.

Microscopic identification:

1. **Transverse section:**
   (1) Tuber of *Arisaema heterophyllum*: The outermost layer composed of brownish-yellow cork cells, some cork covered with brownish-black and indistinct cell form of dead layers. Cork composed of several layers of cells, flat-rectangular shaped, thin-walled, arranged dense and neat, with curved

undulation. Cortex composed of parenchymatous cells, with raphides of calcium oxalate; parenchymatous cells of outer part of cortex, irregularly flat-rectangular, and the inner part of cortex irregularly round. Secretory cavities enclosed in circle in the center of cortex, containing secretory oil droplets. Vascular bundles scattered among parenchymatous cells of cortex. Xylem mainly composed of vessels and xylem parenchymatous cells; vessels mainly annular and spiral, 3~32 μm in diameter, lignified. Starch granules scattered in parenchymatous cells, mainly individual, 3~12 μm in diameter, mostly subrounded, hilum rare; commonly with compound granules composed of 2~12 components are usually visible.

(2) Tuber of *Arisaema erubescens*: Cork composed of 6~20 layers of cork cells, cells tangentially elongated, arranged densely, cells containing brown mucilage contents scattered interruptedly near parenchyma; inner parenchymatous cells (some cells extruded) filled with starch granules, 20~92 μm in diameter. Secretory canals exist in parenchyma near cork with brown mucilage contents. Mucilage cells scattered in parenchymatous cells, or aggregated in group, subrounded or oblong, 60~280 μm in diameter, containing raphides of calcium oxalate, usually in bundles, 10~75 μm in length, distinct in length variations. Parenchymatous cells among vascular bundles contain brown granules aggregated in masses. Vascular bundles amphivasal, varying in direction or only few vessels. Vessels annular or spiral, 8~50 μm in diameter. Parenchymatous cells near vessels contain crystals of tiny-square calcium oxalate, polygonal or triangle.

(3) Tuber of *Arisaema amurens*e: Cork composed of 6~15 layers of cells. Parenchymatous cells near cortex contain less starch granules, between cells scattered with relative density of raphides of calcium oxalate contained mucilage cells. Parenchyma near vascular bundles usually scattered with mucilage cells containing brown granules.

2. **Powder:**

(1) Tuber of *Arisaema heterophyllum*: Pale yellowish-white. Starch granules mostly compound; simple granules round, subtriangle or irregular, 2~20 μm in diameter, occasionally up to 22 μm; compound granules composed of 2~12 components, mostly composed of 2~4 or 5~7 components; hilum dotted, stellated, cleft-shaped or Y-shaped. More existence of raphides of calcium oxalate than Tiananxing, annular vessels and brown mucilage masses also present.

(2) Tuber of *Arisaema erubescens*: Pale yellowish-white. The major portion of the powder is occupied by starch granules, mostly in individual with rare compound; simple granules subrounded or oblong, 2~20 μm in diameter; compound granules mostly composed of 2~3 components, uncommonly composed of 4~5 components, 15~25 μm in diameter; hilum asteroidal, dotted, cleft-shaped, V-shaped or cruciate, large granules with faint striations and scattered raphides of calcium oxalate. Annular and spiral vessels, brown mucilage contents, brown granules and prisms of calcium oxalate also present.

(3) Tuber of *Arisaema amurens*e: Pale yellowish-white. Starch granules mostly compound; simple granules spheroid, oblong or irregular, 2~28 μm in diameter; compound granules composed of 2~10 components, mostly composed of 2~4 components; hilum dotted, stellated or cleft-shaped. Raphides of calcium oxalate relatively numerous, annular vessels and brown granules also present.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Take 3.0 g of powdered sample and add 10 mL of ethanol, ultrasonicate for 30 minutes, filter and make up to 10 mL.
2. Reference drug solution: Take 3.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-butanol, glacial acetic acid, and water (7:1:2) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with *p*-anisaldehyde/H_2SO_4 TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:

1. Loss on drying: Not more than 15.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 4.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 0.5% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).

7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from mold and insects.
Usage: Phlegm-dispelling medicinal (Dampness and phlegm eliminating medicinal).
Property and flavor: Warm; bitter and pungent; toxic.
Meridian tropism: Lung, liver, and spleen meridians.
Effects: Dry dampness to resolve phlegm, dispel wind to arrest convulsions, dissipate binds to alleviate edema.
Administration and dosage: 3~10 g, generally processed before application; used an appropriate amount for external use.
Precaution and warning: Unprocessed one toxic, use cautiously during pregnancy.

ARMENIACAE SEMEN AMARUM
苦杏仁
Ku Sing Ren / Ku Xing Ren
Bitter Apricot Seed

Bitter apricot seed is the dried ripe seed of *Prunus armeniaca* L. var. *ansu* Maxim., *Prunus sibirica* L., *Prunus mandshurica* (Maxim.) Koehne or *Prunus armeniaca* L. (Fam. Rosaceae).
It contains not less than 7.0% of water extractives and not less than 3.0% of amygdalin.

Description: Different species with similar appearance. Flattened-cordate, 10~19 mm in length, 7~15 mm in width, 5~7 mm thick. Apex slightly acute, base obtuse, unsymmetrical. Testa thin, brown to dark brown, with irregular wrinkles, nearly apex with a short-liner hilum, base with elliptical chalaza, raphe dark color, slightly furrowed, connecting with hilum and chalaza, with numerous dark brown veins. Testa peeled by using warm water, showing cotyledons 2, white, oily, with smaller radicle and embryo at the apex. Odourless; taste bitter.

Microscopic identification:
1. **Transverse section:**
   Armeniacae semen amarum: Epidermis of testa composed of 1 layer of thin cells, scattered with subrounded orange-yellow stone cells, inside showing several layers of parenchymatous cell, scattered with fine vascular bundles. Perisperm composed of 1 layer of fallen parenchymatous cells. Endosperm composed of 1 to several layers of square cells, containing aleurone grains and fatty oil. Cotyledon composed of polygonal parenchymatous cells, containing aleurone grains and fatty oil.
2. **Powder:** Yellowish-white. Stone cells of testa singly scattered or in a group, mostly conchoidal in lateral view; subrounded or subpolygonal in surface view. Parenchymatous cells of outer epidermis of testa yellowish-brown, mostly shrunken and connected with stone cells, with indistinct cell boundaries. Cotyledon cells contain aleurone grains and oil droplets, fine clusters of calcium oxalate also visible. Endosperm cells subpolygonal, containing aleurone grains.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of amygdalin and dissolve in methanol to produce a solution containing 2.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, methanol, and water (7:3:1) as the developing solvent. Apply 10 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 10.0% dry at 105 ℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 5.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).
9. Aflatoxins
   (1) Aflatoxins (sum of B_1, B_2, G_1 and G_2): Not more than 10.0 ppb (General rule 6307).
   (2) Aflatoxin B_1: Not more than 5.0 ppb (General rule 6307)

Assay:

1. Amygdalin:
   (1) Mobile phase: A solution of acetonitrile and 0.1% phosphoric acid (8:92). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of amygdalin and dissolve in methanol to produce a solution containing 40 μg per mL.
   (3) Sample solution: Weigh accurately 0.25 g of powdered sample, and place it in a conical flask with stopper, add accurately 25 mL of methanol, stopper tightly and weigh, ultrasonicate for 30 minutes, cool, weigh again, replenish the loss of the weight with methanol, mix well and filter. Take 5 mL of the successive filtrate in a 50-mL volumetric flask, make up to volume with 50% methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (207 nm) and a column packing L1. The column temperature is maintained at 25℃. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of amygdalin should not be less than 7,000.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Amygdalin (%)=0.025(r_U/r_S) (C_S) / (W)
   r_U: peak area of amygdalin of sample solution
   r_S: peak area of amygdalin of reference standard solution
   C_S: concentration of amygdalin of reference standard solution (μg/mL)
   W: weight of test sample (g) calculated with dried sample.
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from insects.
Usage: Phlegm-dispelling medicinal (Cough-suppressing and panting-calming medicinal).
Property and flavor: Mild warm; bitter.
Meridian tropism: Lung and large intestine meridians.
Effects: Suppress cough and to calm panting, moisten the intestine and relax the bowel.
Administration and dosage: 3~11.5 g.
Precaution and warning: Unprocessed one toxic, avoid hydrocyanism.

ARNEBIAE RADIX
紫草
Zih Cao / Zi Cao
Arnebia Root

Arnebia root is the dried root of *Arnebia euchroma* (Royle) I.M.Johnst. or *Arnebia guttata* Bunge (Fam. Boraginaceae).
It contains not less than 2.0% of dilute ethanol-soluble extractives, not less than 3.0% of water extractives and not less than 0.3% of acetylshikonin.

Description:

1. Root of *Arnebia euchroma* (Soft Arnebia Root): Conical or cylindrical, twisted, 6~15 cm in length, 1~2 cm in diameter. Externally purplish-red or purplish-black, with longitudinal wrinkles. Bark easily exfoliated and exposed yellowish-white wood. Apex bearing with scars or base of stem. Texture lax and soft, easily broken, fracture purple, with several layers overlapped, scattered with yellowish-white dots of vessels and fibers. Odour slightly stinking; taste slightly bitter and astringent.
2. Root of *Arnebia guttata*: Conical or cylindrical, twisted, 4~12 cm in length, 0.5~2.5 cm in diameter. Externally purplish-brown, starchy, with irregular longitudinal wrinkles. Bark thin and easily exfoliated. Root stock swollen, bearing with remained stem, strigose and white glandular-punctate. Texture hard and fragile, easily broken, fracture uneven, bark purplish-red; wood yellowish-white, vascular bundle arranged radially. Odour aromatic; taste slightly sweet and astringent.

Microscopic identification:

1. **Transverse section:**
   (1) Root of *Arnebia euchroma* (Soft Arnebia Root): Cork several layered, tissue in the center mostly broken. Phloem narrow, xylem arranged radially, vessels 2~4 rows. Cork cells and parenchymatous cells contain purple pigments, cells became red in color after treatment with a solution of chloral hydrate.
   (2) Root of *Arnebia guttata*: Cork composed of 2~10 rows of cork cells. Cortex narrow, parenchymatous cells small. Stele irregular in shape. Xylem broad, usually with xylem fiber groups in the center, vessels singly scattered or in bundles, rays narrow.
2. **Powder:**
   (1) Root of *Arnebia euchroma* (Soft Arnebia Root): Purplish-red. Cork cells polygonal or subsquare, filled with purplish-red pigments, strip-shaped or lumpy. Cells became yellowish-brown in color after treatment with a solution of chloral hydrate. Reticulate, bordered-pitted and spiral vessels visible, 7~100 μm in diameter. Non-glandular hairs unicellular, 10~50 μm in diameter, usually with longitudinal striations, purplish-red

contents occasionally visible.

(2) Root of *Arnebia guttata*: Purplish-red. Cork cells polygonal or square, containing purplish-red granular pigments. Parenchymatous cells square or fusiform. Fibers singly scattered or in bundles, long-fusiform, yellowish-green, 10~20 μm in diameter. Reticulate, bordered-pitted and spiral vessels visible. Non-glandular hairs unicellular, 10~30 μm in diameter, wall thick, mostly broken.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of ethyl acetate, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Weigh accurately a quantity of acetylshikonin and dissolve in ethyl acetate to produce a solution containing 0.5 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane, ethyl acetate, and formic acid (9:2:0.2) as the developing solvent. Apply 8 μL of each of the sample solution and reference drug solution and 5 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Total ash: Not more than 16.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 7.0% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 5.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Acetylshikonin:
   (1) Mobile phase: A solution of acetonitrile and 0.1% formic acid (70:30). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of acetylshikonin, and dissolve in methanol to produce a solution containing 80 μg per mL.
   (3) Sample solution: Weigh accurately 0.5 g of the powdered sample and place it in a 50-mL conical flask, then add accurately 25 mL of acetone, ultrasonicate for 30 minutes, filter to a 25-mL volumetric flask with filter paper and make up to volume with acetone, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (516 nm) and a column packing L1. The column temperature is maintained at room temperature. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of acetylshikonin should not be less than 8,000.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   Acetylshikonin (%)=0.0025(r_U/r_S) (C_S) / (W)

   r_U: peak area of acetylshikonin of sample solution

   r_S: peak area of acetylshikonin of reference standard solution

   C_S: concentration of acetylshikonin of reference standard solution (μg/mL)

   W: weight of test sample (g) calculated with dried sample.
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place, and protect from moisture.
Usage: Heat-clearing medicinal (Heat-clearing and blood-cooling medicinal).
Property and flavor: Cold; sweet and salty.
Meridian tropism: Heart and liver meridians.
Effects: Clear heat to cool the blood, resolve macule to detoxify, activate blood to outthrust rashes.
Administration and dosage: 5~11.5 g; used an appropriate amount for external use.

ARTEMISIAE ANNUAE HERBA
青蒿
Cing Hao / Qing Hao
Sweet Wormwood Herb

Sweet wormwood herb is the dried aeiral part of *Artemisia annua* L. (Fam. Compositae).
It contains not less than 6.0% of dilute ethanol-soluble extractives and not less than 6.0% of water extractives.

Description: Stems cylindrical, frequently branched at the upper part, 30~80 cm in length, 0.2~0.6 cm in diameter.

Externally yellowish-green or brownish-yellow, with longitudinal ridges. Texture slightly hard, fracture yellowish-white, with pith in the center, white. Leaves alternate, dark green or brownish-green, mostly crumpled or broken, 3-pinnatiparted as whole, the segments and smaller segments short round or oblong, both surfaces pubescent. Odour characteristically aromatic; taste slightly bitter, with a cooling sensation.

Microscopic identification:

1. **Transverse section:**
   Leaf of *Artemisia annua*: Epidermal cells irregular, vertical wall is wavy, epidermal cells on the ridge are narrow rectangles. Stomata infinitive. Epidermis is densely covered with T-hair and glandular hairs. T hair stalk cells for 3 ~7, up to 4 ~ 5, sclerenchyma cells 240~816 μm in length. Hair with only stalk cells is often seen near the midrib; sometimes visible linear single-celled hairs.
2. **Powder:**
   (1) Stem of *Artemisia annua*: Brownish yellow. It has a specific aroma and tastes bitter. The Vessels is mainly composed of spiral, bordered-pitted and scalariform vessels . 12~65 μm in diameter. Thin fiber wall, long spindle-shaped, with a twill hole, 5~20 μm in diameter.
   (2) Leaf of *Artemisia annua*: Grayish green, epidermal cells irregular. surface is densely covered with T-hairs, and the number of T-shaped cells is 3 ~7. sclerenchyma cells up to 816 μm long. glandular hair is sparsely scattered.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, methanol, and water (10:2:1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:

1. Loss on drying: Not more than 15.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 10.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 3.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place.
Usage: Heat-clearing medicinal (Deficiency heat-clearing medicinal).
Property and flavor: Cold; bitter and pungent.
Meridian tropism: Liver and gallbladder meridians.
Effects: Clear deficiency heat and release summerheat, relieve bone steaming fever, interrupt malaria.
Administration and dosage: 6~12 g, added when the decoction is nearly done, not decocted for a long time.

ARTEMISIAE ARGYI FOLIUM
艾葉
Ai Ye / Ai Ye
Argy Wormwood Leaf

Argy wormwood leaf is the dried leaf of *Artemisia argyi* H.Lév. & Vaniot (Fam. Compositae).
It contains not less than 15.0% of dilute ethanol-soluble extractives and not less than 14.0% of water extractives.

Description: Crumpled or broken, with short petiole, ovate-ellipsoidal as whole, pinnatiparted, segments ellipsoidal-lanceolate, margin irregularly dentate; upper surface grayish-green or dark yellowish-green, sparsely pubescent and glandular-punctate, lower surface densely grayish-white tomenta. Texture soft. Odour delicately aromatic; taste bitter.

Microscopic identification:

1. **Transverse section:**
   Leaf of *Artemisia argyi*: Epidermis composed of 1 layer of cells, covered with cuticles. Non-glandular hairs and glandular hairs present on the upper and lower surface of epidermis, non-glandular hairs especially abundant on the lower epidermis. Non-glandular hairs 2 types: T-shaped and uniseriate, both often broken. Palisade tissue and spongy tissue each comprises half of the mesophyll, some cells containing clusters of calcium oxalate; palisade tissue composed of 1~2 layers of rectangular cells,

arranged radially. Midvein 1 distinctly protruded, collenchyma tissue existed in the inner side of both upper and lower epidermis. Vascular bundles collateral, with sclerenchymatous cells on the upper and lower parts of the vascular bundle; phloem cells relatively small, varing in shape; xylem subrounded or oblong, 3~7 arranged in line, lignified to extremely lignified. Parenchymatous cells usually contain pale yellow or light yellow contents.

2. **Powder:** Greenish-brown. Non-glandular hairs in 2 types, first type T-shaped, with elongated and bent apical cell and 2~4 celled stalk, unequal arms 2; second type uniseriate, 3~5 celled, with very long and twisted apical cell, frequently broken. Glandular hairs composed of 4~6 oppositely overlapped cells, without stalk, paramecium-like in surface view. Clusters of calcium oxalate 3~7 μm in diameter, existing in mesophyll.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 1 mL of methanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of petroleum ether (30~60℃), toluene, and acetone (10:8:0.5) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with vanillin/H_2SO_4 TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:

1. Loss on drying: Not more than 12.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 12.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 4.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place, and protect from moisture.
Usage: Blood-regulating medicinal (Hemostatic medicinal).
Property and flavor: Warm; pungent and bitter.
Meridian tropism: Liver, spleen, and kidney meridians.
Effects: Warm the meridian to hemostatic, dissipate cold and relieve pain, prevent abortion.
Administration and dosage: 3~10 g; used an appropriate amount for external use. It can be used for moxibustion or decocted for fuming-washing therapy.

ARTEMISIAE HERBA
茵陳
Yin Chen / Yin Chen
Oriental Wormwood Herb

Oriental wormwood herb is the dried aerial part of *Artemisia scoparia* Waldst. & Kit. or *Artemisia capillaris* Thunb. (Fam. Compositae). The drug collected in spring is commonly known as “Mian Yin Chen” and that collected in autumn with flower buds is commonly known as “Yin Chen Hau”.
It contains not less than 7.0% of dilute ethanol-soluble extractives and not less than 8.0% of water extractives.

Description:

1. Mian Yin Chen: Mostly crumpled into masses, grayish-white or grayish-green, densely covered with white pubescences throughout, soft like nap. Stems thin and small, generally 1.5~2.5 cm in length, l.5~3 mm in diameter, the upper or lower part with petioled leaves. Leaves soft, crumpled and curved, lamina 0.5~2 cm in length, 2~3 pinnatiparted, lobes liner-shaped, entire. Texture fragile, easily broken. Odour slightly aromatic; taste slightly bitter.
2. Yin Chen Hau: Stem cylindrical, frequently branched, 30~100 cm in length, 2~8 mm in diameter. Externally pale purple or purple, striated longitudinally, pubescent; texture light in weight and fragile, fracture whitish. Leaves densely gathered, or mostly fallen off. Basal leaves 2~3 pinnatiparted, lobes stripe-shaped or finely stripe-shaped, densely covered with white pubescences on both surfaces; cauline leaves 1~2 pinnatiparted, amplexicaul at the base, lobes filamentous. Heads ovate, mostly gathered in conical, 1.2~1.5 mm in length, 1~1.2 mm in diameter, short petioled; involucres 3~4 layers, ovate, phyllaries 3-lobed; the outer pistillate flowers 6~10, up to 15, the inner

bisexual flowers 2~10. Achenes oblong, yellowish-brown. Odour aromatic; taste slightly bitter.

Microscopic identification:
Powder:
Leaf of Yin Chen Hau: Grayish-green. Walls of upper epidermal cells relatively straight, walls of lower epidermal cells undulately curved; both the upper and lower epidermis with anomocytic stomata. Leaf lobes obtuse or slightly narrow at the apex, epidermal cells relatively small, stomata rare. Glandular hairs rare, the apex sole-shaped, composed of 6~8 pairly overlapped cells, 5~26 μm in diameter, with unequal arms, wall thick and lignified, the base 1~3 cells, extremely flat and short. T-shaped non-glandular hairs abundant, mostly broken in fiber-shaped, intact ones with extremely long apex cells, up to 2 mm in length, 5~6 μm in diameter.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 0.5 g of powdered sample to 10 mL of methanol, shake for 3 minutes, stand, filter and use the filtrate.
2. Reference drug solution: Take 0.5 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane and acetone (1:1) as the developing solvent. Apply appropriate amount of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:
1. Loss on drying: Not more than 13.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 30.0% of Mian Yin Chen, not more than 10% of Yin Chen Hau (General rule 6007).
3. Acid-insoluble ash: Not more than 15.0% of Mian Yin Che, not more than 3.0% of Yin Chen Hau (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.5 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place, and protect from mold and insects.
Usage: Dampness-dispelling medicinal (Dampness-draining diuretic medicinal).
Property and flavor: Mild cold; bitter.
Meridian tropism: Spleen, stomach, liver, and gallbladder meridians.
Effects: Clear heat and drain dampness, drain bile and reduces jaundice.
Administration and dosage: 6~30 g.

ARTEMISIAE LACTIFLORAE HERBA
劉寄奴
Liou Ji Nu/Liu Ji Nu
Diverse Wormwood Herb

Diverse wormwood herb the dried aerial part of *Artemisia lactiflora* Wall. ex DC. (Fam. Compositae), commonly known as “Nan Liou Ji Nu”.
It contains not less than 8.0% of dilute ethanol-soluble extractives and not less than 11.0% of water extractives and not less than 0.03% of 7-methoxycoumarin.

Description: Cylindrical, yellowish-brown or brownish-green with fine longitudinal edges. The quality is firm, the cross section is fibrous, yellowish-white, with a white loose pith in the middle. Leaves alternate, shrunken or detached, long oval-shaped after spreading, leaf margin serrate, brownish green on top, grayish-green underneath, densely covered with white hair, crispy, easily broken or detached. Odour aroma, light taste.

Microscopic identification:
1. **Transverse section:**
   (1) Stem of *Artemisia lactiflora*: Epidermis consists of 1 layer of subrounded or subrectangular cells, with glandular and non-glandular hairs present. Non-grandular hairs are T-shaped, many broken off and the handle area easily fall off. Sclerenchyma consists around 10 layers of cell, mainly at the corner or edges of stem. Cortex consists of 1~2 layers of subround or oblong parenchymatous cells. The vascular bundles are in a vertical shape, and there are 10~20 vascular bundles arranged in a ring shape; Pericycle fibres arranged in an interrupted ring, located in the outer side of vascular bundles. Vascular bundles collateral, phloem relatively narrow. Xylem vessels singly scattered or sometimes 2~3 in groups. Pith broad, sometimes broken

or hollowed, parenchymatous cells arranged loosely and clusters of calcium oxalate present

(2) Leaf of *Artemisia lactiflora*: The upper and lower epidermis are each composed of one tangentially elongated cell, and the outer wall is serrated. Palisade tissue contains 1 layer of oblong cells. Spongy tissue 3~5 layers of irregular shaped cells arranged loosely, sometimes contains clusters of calcium oxalate. Collenchymatous cells exist between the inner side of upper and lower epidermal cells. The vascular bundles are vertical and have 2~4 columns of fibers on the upper and lower sides; the xylem is wider; the phloem is narrower.

2. **Powder:** Yellowish-brown. The top surface of the glandular hairs is oval, 6 or 8 cells. Non-glandular hairs are slender and sometimes contain pale yellowish-brown material. The pollen grains are subround, with three-hole grooves, the surface has fine grained carvings. The secretory tract is located next to the veins, and the yellow strips of secretions often come out. The epithelial cells of the bracts are round to rectangular, sometimes containing yellowish-brown, subrounded spaces. Stem epidermal cells are subrectangular or subpolyhoid, sometimes containing pale yellow or reddish brown, with stomata. The vertical wall of the epidermis cells of the leaves is slightly curved, and the pores are slightly raised. The calcium oxalate clusters are small, exist in the pith of the stem and in the palisade cells of the leaves; they are pale yellowish-white under a polarizing microscope. The fiber is bundled and has a thick wall; it is colorful under a polarizing microscope. Most of the catheters are scalariform, spiral and reticulate catheters.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 1 hour, filter, evaporate the filtrate to dryness, and dissolve the residue in 1 mL of methanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of 7-methoxycoumarin and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of toluene, ethyl formate, and formic acid (5:4:1) as the developing solvent. Apply 2 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 10.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 10.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 0.5% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:

1. 7-Methoxycoumarin
   (1) Mobile phase: Acetonitrile as the mobile phase A, and water as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of 7-methoxycoumarin and dissolve in 50% ethanol to produce a solution containing 2 μg per mL.
   (3) Sample solution: Weigh accurately 0.2 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 20 mL of 50% ethanol, ultrasonicate for 30 minutes, centrifuge for 10 minutes. Transfer the supernatant to a 50-mL volumetric flask. Repeat the extraction of the residue one more time, combine the supernatant, and make up to volume with 50% ethanol, mix well, filter and use the filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (320 nm) and a column packing L1. The column temperature is maintained at 35℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of 7-methoxycoumarin should not be less than 9,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~15	30→60	70→40
15~20	60→95	40→5
20~25	95	5

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

7-methoxycoumarin (%)=0.005(r_U/r_S)(C_S)/(W)

r_U: peak area of 7-methoxycoumarin of sample solution

r_S: peak area of 7-methoxycoumarin of reference standard solution

C_S: concentration of 7-methoxycoumarin of reference standard solution (μg /mL)

W: weight of test sample (g) calculated with dried sample.

Storage: Store in a cool and dry place, and protect from insects.
Usage: Blood-regulating medicinal (Blood-activating and stasis-dispelling medicinal).
Property and flavor: Warm; bitter.
Administration and dosage: 6~9 g.

ASARI RADIX
細辛
Si Sin / Xi Xin
Asarum Root

Asarum root is the dried root of *Asarum heterotropoides* F.Schmidt f. *mandshuricum* (Maxim.) Kitag., *Asarum sieboldii* Miq. or *Asarum sieboldii* Miq. var. *seoulense* Nakai (Fam. Aristolochiaceae).
It contains not less than 8.0% of dilute ethanol-soluble extractives, not less than 8.0% of water extractives, not less than 1.0% of volatile oil and should not contain aristolochic acid.

Description:

1. Root of *Asarum heterotropoides*: Usually rolled a mass. Rhizomes irregular cylindrical, short-branched, 1~10 cm in length, 2~4 mm in diameter; externally grayish-yellow, with ringed nodes, internodes 2~3 mm in length, with dish-like stem scars at the top of branches. Roots densely occurring at nodes, 5~20 cm in length, up to 1 mm in diameter; externally brownish-yellow, smooth or longitudinally wrinkled, with fibrous roots or root scars at the lower part.
2. Root of *Asarum sieboldii*: Rhizomes 5~20 cm in length, 1~2 mm in diameter, internodes 0.2~1 cm in length.
3. Root of *Asarum sieboldii* var. *seoulense*: Rhizomes 1~5 mm in diameter, internodes 0.1~1 cm in length.

Microscopic identification:

1. **Transverse section:**
   Root of *Asarum heterotropoides*: Epidermis composed of 1 layer of cells, partially remained. Cortex broad, scattering numerous oil cells; exodermis composed of 1 layer of cells, cells subrectangular, walls suberized and slightly lignified; endodermis obvious, Casparian dots visible. Pericycle composed of 1~2 layers of cells. Primary xylem diarch to tetrarch. Phloem bundles each with 1~3 larger parenchymatous cells in the center but whose long diameter much shorter than that of the largest vessel; alternately, no large cells in phloem bundles. Parenchymatous cells containing starch granules.
2. **Powder:** Pale yellow. Odour strongly aromatic; taste bitter and pungent, with a strong and lasting numb feeling. Epidermal cells of root subrectangular or subrectangular-polygonal, wall thin and undulating. Epidermal cells of root in longitudinal view, pale yellow secretory cells occasionally visible in tissue, cells subrectangular, subsquare or subpolygonal. Parenchymatous cells of cortex in longitudinal view with distinct intercellular spaces, sandy crystals of calcium oxalate visible, filled with abundant starch granules. Vessels 20~100 μm in diameter, mainly reticulate, spiral, scalariform or annular, bordered-pitted vessels occasionally visible. Starch granules extremely numerous, simple granules subrounded, 2~14 μm in diameter, hilum dotted, V-shaped, cleft-shaped or Y-shaped, striations indistinct; compound granules varying in size, composed of 2~6 components. Stone cells rare in rhizome tissue, subrectangular, subsquare or elongated-polygonal, 18~50 μm in diameter.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of ethanol, ultrasonicate for 5 minutes, stand, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of methyleugenol and dissolve in ethanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane, toluene, and acetone (3:2:1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with *p*-anisaldehyde/H_2SO_4 TS and heat at 105°C until the spots become visible. Examine under visible light. The purplish-brown spots in the chromatogram obtained with the sample solution correspondings in R_f values and color to the spots in the chromatogram obtained with the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Total ash: Not more than 14.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 7.0% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 5.0 ppm (General rule 2211, 6301).

5. Cadmium (Cd): Not more than 1.5 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 10.0 ppm (General rule 2251, 6301).
8. Pesticide residues:
   (1) The total DDT content: Not more than 0.2 ppm (General rule 6305).
   (2) The total BHC content: Not more than 0.2 ppm (General rule 6305).
9. Should not contain aristolochic acid:
   (1) Mobile phase: Take 7.8 g of sodium dihydrogen phosphate ($NaH_2PO_4 \cdot 2H_2O$), weighed accurately, and place it in a 1,000 mL-volumetric flask. Pipette 2 mL of phosphoric acid solution and transfer it into the previous flask, adding adequate amount of deioned water to make 1000 mL of 0.05M NaH_2PO_4. A solution of acetonitrile and 0.05 M sodium dihydrogen phosphate solution (2 mL of phosphoric acid) (9:11), is used as the mobile phase. The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Accurately weigh X mg of aristolochic acid (It is equivalent to 10 mg of aristolochic acid I, X=10×100/F, F refers to the purity of reference standard aristolochic acid I, which is marked on its packed container in %) and dissolve in 75% methanol to 200 mL. Measure accurately 2 mL of the mixture and add 75% methanol to produce a 200 mL solution.
   (3) Sample solution: Weigh accurately 2.0 g of the powdered sample, transfer to a round bottom flask, add 50 mL of a solution of 75% methanol in water, ultrasonicate for 20 minutes, filter and use the filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (400 nm) and a column (4.6 mm × 25 cm) packing L1 (5 μm). The column temperature is maintained at 25~40℃. The flow rate is about 1.0 mL/min.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and record the chromatogram. If the chromatogram obtained with the sample solution didn't corresponding in the retention time of aristolochic acid I to the chromatogram obtained with the reference standard solution, the sample is acceptable. If the chromatogram obtained with the sample solution corresponding in the retention time of aristolochic acid I to the chromatogram obtained with the reference standard solution, the sample should be retested under different conditions; when the chromatogram obtained with the sample solution didn't corresponding in the retention time of aristolochic acid I to the chromatogram obtained with the reference standard solution, the sample should be acceptable.

Assay:
1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).
3. Volatile oil: Carry out the method for determination of volatile oil (General rule 6013).

Storage: Store in a ventilated and dry place, and protect from moisture.
Usage: Exterior-releasing medicinal (Pungent-warm exterior-releasing medicinal).
Property and flavor: Warm; pungent.
Meridian tropism: Heart, lung, and kidney meridians.
Effects: Dispel wind and dissipate cold, open orifices and relieve pain, warms lung to resolve phlegm.
Administration and dosage: 1~4 g.
Precaution and warning: Avoid overdosing when applied alone.

ASPARAGI RADIX
天門冬
Tian Men Dong / Tian Men Dong
Asparagus Root

Asparagus root is the dried root tuber of *Asparagus cochinchinensis* (Lour.) Merr. (Fam. Liliaceae), commonly known as "Tian Dong".
It contains not less than 50.0% of dilute ethanol-soluble extractives and not less than 50.0% of water extractives.

Description: Long fusiform, 5~23 cm in length, 0.5~2.2 cm in diameter. Externally yellowish-white or pale yellowish-brown, translucent, smooth, with deep and shallow wrinkles, some with patches of the grayish-brown bark. Texture hard, fracture even, horny, stele yellowish-white in the center, softened when moistened, with elasticity. Odour slight; taste slightly sweet and sticky.

Microscopic identification:
1. **Transverse section:**
   Root tuber of *Asparagus cochinchinensis*: Occasionally with remains of velamen. Cortex broad, with stone cells arranged in an interrupted ring on the outer part, 2~4 layers thick. Stone cells subrounded, subpolygonal or square, walls vary in thickness, with fine and dense pits and distinct pit canals. Casparian strip of endodermis distinct. Pericycle consists of 1~2 layers of parenchymatous cells; xylem strands and phloem strand content 35~100 of each, respectively, arranged alternately, a few vessels

developing towards the large pith. Parenchymatous cells scattered with mucilage cells, containing raphides of calcium oxalate, mostly distributed near the stone cell ring, arranged almost in a ring near endoderm, but rare in pith.

2. **Powder:** Grayish-yellow. Stone cells rectangular, strip-shape, subrounded or long-fusiform, 85~600 μm long, 30~90 μm in diameter, the wall 5~37 μm thick; pits and pit canals indistinct; pits fine and dense, pit canals fine and short, occasionally with extremely thick walls. Raphides of calcium oxalate scattered or existed in mucilage cells, 40~100 μm long. Bordered-pitted and scalariform bordered-pitted vessels up to 110 μm in diameter. Xylem parenchymatous cells, fiber tracheids and endodermis cells also present.

Identification:
Check α-amino carboxylic acid: Take a quantity of powdered sample in a micropipette, add drops of saturated sodium hypochlorite solution, and heat slowly, add drops of fuchsin-sulfurous acid TS (add SO_2 to 1% fuchsin solution until the color fades), if a red color is produced and indicates the presence of asparagine.

Impurities and other requirements:
1. Total ash: Not more than 4.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
3. Sulfur dioxide: Not more than 400 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 5.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from mold and insects.
Usage: Tonifying and replenishing medicinal (Yin-tonifying medicinal).
Property and flavor: Cold; sweet and bitter.
Meridian tropism: Lung and kidney meridians.
Effects: Clear lung and downbear fire, enrich yin to moisten dryness.
Administration and dosage: 6~12 g

ASTERIS RADIX ET RHIZOMA
紫菀
Zih Wan / Zi Wan
Tatarian Aster Root and Rhizome

Tatarian aster root and rhizome is the dried root and rhizome of *Aster tataricus* L.f. (Fam. Compositae).
It contains not less than 38.0% of dilute ethanol-soluble extractives, not less than 40.0% of water extractives and not less than 0.15% of shionone.

Description: Rhizomes in irregular masses, varying in size; externally grayish-brown; root stock small, apex with remains of stems and leaves, fibrous; texture hard. Numerous rootlet fasciculated on rhizomes, 3~15 cm in length, frequently braided; externally purplish-red or grayish-red, with longitudinal wrinkles; texture flexible. Odour slightly aromatic; taste sweet and slightly bitter.

Microscopic identification:
1. **Transverse section:**
   Root of *Aster tataricus*: Epidermal cells frequently withered or occasionally fallen off, containing purplish-red pigments. Hypodermal cells flat, slightly elongated tangentially, some cells containing purplish-red pigments, wall thin. Cortex broad, composed of parenchymatous cells, cells subrounded, intercellular spaces distinct, with 4~6 secretory canals. Endodermis distinct. Stele small, xylem slightly polygonal, vascular bundles arranged radially, rays distinct, pith large. Parenchymatous cells contain inulin.
2. **Powder:** Yellowish-brown. Cork cells rectangular, occasionally polygonal or subsquare. Sclerenchymatous cells rectangular or oblong, wall slightly thickened. Hypodermal cells subrectangular, containing purplish-red pigments. Vessels mainly pitted and scalariform, about 12~55 μm in diameter. Fibers acute at both ends, 10~36 μm in diameter, wall thin, with obliquely pits, slightly lignified. Parenchymatous cells contain inulin and clusters of calcium oxalate; inulin fan-shaped.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
   Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane and ethyl acetate (5:2) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with *p*-anisaldehyde/H_2SO_4 TS and heat at 105°C until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution

corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:

1. Total ash: Not more than 12.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 7.0% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Shionone:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and water as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of shionone, and dissolve in methanol to produce a solution containing 50 μg per mL.
   (3) Sample solution: Weigh accurately 0.5 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 10 mL of methanol, ultrasonicate for 30 minutes. Centrifuge for 10 minutes, transfer the supernatant to a 25-mL volumetric flask. Repeat the extraction of the residue one more time. Combine the supernatant and make up to volume with methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (200 nm) and a column packing L1. The column temperature is maintained at 25℃. The flow rate is about 1 mL/min.Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of shionone should not be less than 3,500.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~10	80→90	20→10
10~30	90→95	10→5

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Shionone (%)=0.0025(r_U/r_S) (C_S) / (W)
   r_U: peak area of shionone of sample solution
   r_S: peak area of shionone of reference standard solution
   C_S: concentration of shionone of referencestandard solution (μg/mL)
   W: weight of test sample (g) calculated with dried sample.
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from mold and insects.
Usage: Phlegm-dispelling medicinal (Cough-suppressing and panting-calming medicinal).
Property and flavor: Warm; pungent and bitter.
Meridian tropism: Lung meridians.
Effects: Resolve phlegm to suppress cough.
Administration and dosage: 5~11.5 g.

ASTRAGALI COMPLANATI SEMEN
沙苑蒺藜
Sha Yuan Ji Li / Sha Yuan Ji Li
Flastem Milkvetch Seed

Flastem milkvetch seed is the dried ripe seed of *Astragalus complanatus* R.Br. ex Bunge (Fam. Leguminosae). It is commonly “Sha Yuan Zi”.
It contains not less than 13.0% of dilute ethanol-soluble extractives, not less than 16.0% of water extractives and not less than 0.06% of complanatuside.

Description: Reniform, slightly flattened, about 2 mm in length, about 1.5 mm in width. Externally grayish-brown or greenish-brown, smooth, with a pale color hilum located on one slightly dented edge. Texture hard. 2 cotyledons, pale yellow, radicle curved. Odour slight; taste weak and beany flavored on chewing.

Microscopic identification:

1. **Transverse section:**
   Seed of *Astragalus complanatus*: Epidermal palisade cells of testa composed of 1 layer of cells, and 2 layers of cells in hilum region, 35~55 μm in radial length, about 7 μm in tangential length, lateral walls gradually thickened outward, outer walls thickened with longitudinal striations; a light line bearing at 1/5~1/8 part close to surface, covered with cuticle, about 1.5 μm thick. 1 layer brace cells short dumbbell-shaped, 20~25 μm in radial length, 15~25 μm in tangential length of the upper part, 25~45 μm in tangential length of the lower part, containing longitudinal and thick striations. Nutritive layer composed of several layers of parenchymatous cells, mostly shrunken, cell boundary indistinct. Cotyledon cells contain fatty oil.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 0.5 g of powdered sample to 5 mL of 50% ethanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 0.5 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of complanatoside and dissolve in 50% ethanol to produce a solution containing 0.1 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, formic acid, and water (4:1:1) as the developing solvent. Apply 2 μL of each of the sample solution and reference drug solution and 1 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 12.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 5.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Complanatuside:
   (1) Mobile phase: A solution of acetonitrile and 0.2% formic acid (20:80). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of complanatuside and dissolve in 50% ethanol to produce a solution containing 20 μg per mL.
   (3) Sample solution: Weigh accurately 0.5 g of powdered sample and place it in a conical flask with a stopper, then add accurately 25 mL of 50% ethanol, heat under reflux for 30 minutes, cool, filter to 25-mL volumetric flask and make up to volume with 50% ethanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (265 nm) and a column packing L1. The column temperature is maintained at 35℃. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of complanatuside should not be less than 8,000.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   Complanatuside (%)=0.0025(r_U/r_S) (C_S) / (W)

   r_U: peak area of complanatuside of sample solution

   r_S: peak area of complanatuside of reference standard solution

   C_S: concentration of complanatuside of reference standard solution (μg/mL)

   W: weight of test sample (g) calculated with dried sample.
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place.
Usage: Tonifying and replenishing medicinal (Yang-tonifying medicinal).
Property and flavor: Warm; sweet.
Meridian tropism: Liver and kidney meridians.
Effects: Tonify kidney and secure essence, emolliate the liver to improve vision.
Administration and dosage: 9~15 g.

ASTRAGALI RADIX
黃耆
Huang Ci / Huang Qi
Astragalus Root

Astragalus root is the dried root of *Astragalus mongholicus* Bunge (*A. membranaceus* (Fisch.) Bunge var. *mongholicus* (Bunge) P.K.Hsiao) or *Astragalus membranaceus* (Fisch.) Bunge (Fam. Leguminosae).
It contains not less than 16.0% of dilute ethanol-soluble extractives, not less than 17.0% of water extractives and not less than 0.04% of astragaloside IV.

Description: Cylindrical, few branched, slightly twisted, upper part relatively thick than the lower, 10~90 cm in length, 1~3.5 cm in diameter. Externally grayish-yellow or pale brownish-yellow, with longitudinal wrinkles and transverse lenticels. Texture hard and slightly tenacious, fracture highly fibrous and starchy, bark yellowish-white,

occupying 1/3 of root, wood pale yellow, with radiate striations and fissures, commonly known as "Jyu Hua Sin". Odour slight; taste slightly sweet, slightly bean-like taste on chewing.

Microscopic identification:

1. **Transverse section:**
   Root of *Astragalus mongholicus*: Cork composed of several layers of cells, phelloderm composed of collenchymatous cells, elongated tangentially. Phloem contains fiber bundles, arranged alternately with sieve tube groups; phelloderm occasionally scattered with stone cells and tubular cork tissue; outer part of phloem rays curved and fissured. Cambium in a ring. Xylem vessels singly scattered or 2~3 in groups, containing xylem fiber bundles, xylem rays distinct. Parenchymatous cells contain starch granules.
2. **Powder:** Pale yellow. Phloem fibers slender, 0.6~3.4 μm in length; xylem fibers 0.5~3 μm in length, wall thickened. Vessels mainly reticulate or bordered-pitted, spiral vessels occasionally visible, up to 170 μm in diameter. Stone cells rare, rectangular, subrounded or irregular, wall extremely thickened, a few of stone cells with thin walls. Cork cells polygonal, brown. Starch granules mostly simple, subrounded, 4~15 μm in diameter; occasionally compound granules composed of 2~3 components.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 15 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of astragaloside IV and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-butanol, ethanol, and concentrated ammonia solution (5:1:2) as the developing solvent. Apply 10 μL of the sample solution and reference drug solution and 1 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Total ash: Not more than 7.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 0.3 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).
8. Pesticide residues:
   (1) The total DDT content: Not more than 1.0 ppm (General rule 6305).
   (2) The total BHC content: Not more than 0.9 ppm (General rule 6305).
   (3) The total PCNB content: Not more than 1.0 ppm (General rule 6305).
9. Aflatoxins
   (1) Aflatoxins (sum of B_1, B_2, G_1 and G_2): Not more than 10.0 ppb (General rule 6307).
   (2) Aflatoxin B_1: Not more than 5.0 ppb (General rule 6307).

Assay:

1. Astragaloside IV:
   (1) Mobile phase: A solution of acetonitrile and water (34:66). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of astragaloside IV and dissolve in methanol to produce a solution containing 40 μg and 80 μg per mL.
   (3) Sample solution: Weigh accurately 1.0 g of the powdered sample and place it in a 100-mL round bottom flask, add 50 mL of 4% concentrated ammonia solution in 80% methanol, heat under reflux for 1 hour, cool, filter and transfer to 50-mL volumetric flask, make up to volume with 4% concentrated ammonia solution in 80% methanol, transfer to 100-mL round bottom flask, evaporate to dryness, dissolve the residue in 80% methanol, transfer to 10-mL volumetric flask, make up to volume with 80% methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: It is equipped with an evaporative light-scattering detector (ELSD) and a column packing L1. The drift tube temperature at 60℃. The nebulizer temperature at 70℃. The nebulizer flow rate is about 1.6 L/min (N_2). The number of theoretical plates of the peak of astragaloside IV should not be less than 5,000.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the apparatus, and use a calibration equation of logarithm alteration of two external standards calculate the content.
2. Water extractives: Carry out the method for

determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from moisture and insects.
Usage: Tonifying and replenishing medicinal (Qi-tonifying medicinal).
Property and flavor: Mild warm; sweet.
Meridian tropism: Lung and spleen meridians.
Effects: Tonify qi and upraise yang, defense qi to secure the exterior, expel toxin and promote tissue regeneration, induce diuresis to alleviate edema.
Administration and dosage: 9~30 g.

【Decoction pieces】

ASTRAGALI RADIX

It contains not less than 16.0% of dilute ethanol-soluble extractives, not less than 17.0% of water extractives and not less than 0.04% of astragaloside IV.
Raw medicinal materials are processed to remove impurities, clean selection, soften thoroughly, cut into thin slices, and dry, mostly elliptical or oblong oblique piece. Externally yellowish-white to pale brown, with longitudinal wrinkles; with radiated striations and fissures. Odour slight, taste slightly sweet, bean-like on chewing.

Thin layer chromatographic identification test: The method is the same as that for crude herb.
Impurities and other requirements: Methods and specifications are the same as those for crude herb.
Assay: The method is the same as that for crude herb.
Storage: The method is the same as that for crude herb.
Usage: Tonifying and replenishing medicinal (Qi-tonifying medicinal).
Property and flavor: Mild warm; sweet.
Meridian tropism: Lung and spleen meridians.
Effects: Tonify qi and upraise yang, defense qi to secure the exterior, expel toxin and promote tissue regeneration, induce diuresis to alleviate edema.
Administration and dosage: 9~30 g.

ATRACTYLODIS MACROCEPHALAE RHIZOMA
白朮
Bai Jhu / Bai Zhu
White Atractylodes Rhizome

White atractylodes rhizome is the dried rhizome of *Atractylodes macrocephala* Koidz. (Fam. Compositae).
It contains not less than 18.0% of dilute ethanol-soluble extractives, not less than 22.0% of water extractives and not less than 0.02% of atractylenolide Ⅲ.

Description: Fist-shaped masses, with several warty and short branches and extending axis of rhizomes, swollen as ungulate-shaped at the lower part, 3~13 cm in length, 1.5~7 cm in diameter. Externally yellowish-brown or grayish-brown, with interrupted longitudinal wrinkles and some transverse grooves, with disk-like bud scars at the apex of warty branches, the upper part of rhizome remained with stems or stems scars, the lower part with the spotted roots or its scars. Texture hard, fracture yellowish-white in cortex, color deeper in the middle, cambium ring brown, scattered with yellow dotted oil cavities. The baking-dried material horny and relatively dark colored or cracked in section view. Odour aromatic; taste sweet, slightly pungent and slightly viscous.

Microscopic identification:
1. **Transverse section:**
Rhizome of *Atractylodes macrocephala*: Cork composed of several layers of cork cells, containing 1~2 strips of discontinuous stone cells. Cortex relatively narrow. Phloem narrow and long, relatively old, occasionally with phloem fiber bundles present. Cambium in a ring. Xylem vessel bundles singly stranded or 2~3 branched, arranged radially; vessels singly scattered or several distributed radially; xylem fiber bundles existed in the internal part of the xylem. Pith relatively broad. Cortex, rays and pith all scattered with large lysigenous oil cavities, containing yellow oil droplets. Parenchymatous cells contain inulin and fill with very fine raphides of calcium oxalate.
2. **Powder:** Pale yellowish-brown. Inulin fan-shaped, scattered or existed inside parenchymatous cells. Stone cells subpolygonal, subrectangular, subsquare or suboblong, 37~64 μm in diameter, few stone cells fusiform, up to 117 μm in length, walls vary in thickness, occasionally with distinct striations, pit canals and lumina also present. Raphides of calcium oxalate irregularly scattered in parenchymatous cells, 10~32 μm in length. Fibers fusiform, slightly bended, edge uneven, oblique or relatively truncate at the end, 22~34 μm in diameter, walls extremely thickened, with distinct pit canals, occasionally containing yellowish-brown contents or raphides. Reticulate and bordered-pitted vessels 16~56 μm in diameter. Cork cells and tracheid also exist.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 2.5 g of powdered sample to 30 mL of ethanol, ultrasonicate for 10 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 5 mL of ethanol.
2. Reference drug solution: Take 2.5 g of the reference drug and the method of preparation is the same as which is described above..
3. Reference standard solution: Weigh accurately a quantity of atractylenolide III and dissolve in ethanol to produce a solution containing 0.2 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane and ethyl

acetate (7:3) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 15.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 6.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 400 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 5.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Atractylenolide Ⅲ
   (1) Mobile phase: Acetonitrile as the mobile phase A, and water as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of atractylenolide Ⅲ, and dissolve in methanol to produce a solution containing 5 μg per mL.
   (3) Sample solution: Weigh accurately 1.0 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 25 mL of 75% ethanol, ultrasonicate for 30 minutes, filter to 50-mL volumetric flask with filter paper. Repeat the extraction of the residue one more time. Combine the extracts and make up to volume with 75% ethanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (220 nm) and a a column packing L1. The column temperature is maintained at 30℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of atractylenolide Ⅲ should not be less than 30,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~3	20	80
3~6	20→50	80→50
6~15	50→80	50→20
15~25	80→100	20→0

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Atractylenolide III: (%)= 0.005(r_U/r_S) (C_S) / (W)
   r_U: peak area of atractylenolide III of sample solution
   r_S: peak area of atractylenolide III of reference standard solution
   C_S: concentration of atractylenolide III of reference standard solution (μg/mL)
   W: weight of test sample (g) calculated with dried sample.
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place, and protect from insects.
Usage: Tonifying and replenishing medicinal (Qi-tonifying medicinal).
Property and flavor: Warm; bitter and sweet.
Meridian tropism: Spleen and stomach meridians.
Effects: Tonify qi and fortify the spleen, dry dampness to induce diuresis, relieve sweating, prevent abortion.
Administration and dosage: 6~15 g.

【Decoction pieces】

ATRACTYLODIS MACROCEPHALAE RHIZOMA

It contains not less than 18.0% of dilute ethanol-soluble extractives, not less than 22.0% of water extractives and not less than 0.02% of atractylenolide Ⅲ.
Raw medicinal materials are processed to remove impurities, clean selection, soften thoroughly, cut into thin slices, and dry, mostly irregular thick slices, externally greyish-yellow or greyish-brown. Cut surface yellowish-white to pale brown, scattered with brownish-yellow dotted oil cavities, xylem with radial striations; cut surface horny and with deeper colour and clefts when drying by oven. Odour faint aromatic; taste sweet and slightly pungent, somewhat viscous on chewing.

Thin layer chromatographic identification test: The method is the same as that for crude herb.
Impurities and other requirements: Methods and specifications are the same as those for crude herb.
Assay: The method is the same as that for crude herb.
Storage: The method is the same as that for crude herb.
Usage: Tonifying and replenishing medicinal (Qi-tonifying medicinal).
Property and flavor: Warm; bitter and sweet.

Meridian tropism: Spleen and stomach meridians.
Effects: Tonify qi and fortify the spleen, dry dampness to induce diuresis, relieve sweating, prevent abortion.
Administration and dosage: 6~15 g.

ATRACTYLODIS RHIZOMA
蒼朮
Cang Jhu / Cang Zhu
Atractylodes Rhizome

Atractylodes rhizome is the dried rhizome of *Atractylodes chinensis* (DC.) Koidz. or *Atractylodes lancea* (Thunb.) DC. (Fam. Compositae).
It contains not less than 20.0% of dilute ethanol-soluble extractives and not less than 33.0% of water extractives and not less than 0.3% of atractylodin.

Description:
1. Rhizome of *Atractylodes chinensis*: Lumpy or nodular-cylindrical, 4~9 cm in length, 1~4 cm in diameter. Externally brownish-black, brownish-yellow when peeled. Texture relatively lax, fracture scattered with yellowish-brown oil cavities. Odour relatively weak; taste pungent and bitter.
2. Rhizome of *Atractylodes lancea*: Irregularly moniliform or nodular-cylindrical, slightly curved, occasionally branched, 3~10 cm in length, 1~2 cm in diameter. Externally grayish-brown, with wrinkles and remained fibrous roots, apex with stem scars or remained stem base. Texture compact, fracture yellowish-white or grayish-white, scattered with numerous orange-yellow or brownish-red oil cavities and crystallized out white fine needle crystals after exposing for a long time. Odour characteristic; taste slightly sweet, pungent and bitter.

Microscopic identification:
1. **Transverse section:**
   (1) Rhizome of *Atractylodes chinensis*: Cork composed of several layers of cells, irregular in shape, containing stone cells bands and composing of 2~3 rows of subsquare stone cells. Cortex broad. Phloem narrow. Cambium in a ring. Xylem fiber bundles relatively few, arranged alternately with vessels. Oil cavities relatively few, 125~718 μm in diameter, scattered in parenchymatous cells; oil cavities relatively large in pith.
   (2) Rhizome of *Atractylodes lancea*: Cork composed of 10~40 rows of cork cells, containing subsquare stone cells bands, 130~700 μm in diameter. Cortex relatively broad. Phloem narrow. Cambium in a ring. Xylem with fiber bundles at the inner side, relatively large and numerous, arranged alternately with vessel groups; vessels singly scattered or in bundles, arranged radially. Large oil cells scattered in cortex, rays and pith. Parenchymatous cells contain raphides of calcium oxalate.
2. **Powder:** Brown. Odour fragrant; taste bitter. Cork cells irregular in shape, mostly angular or subsquare, stone cells usually linked with cork cells, subsquare, the margins irregular. Xylem fibers in bundles, slender and fusiform, 80~700 μm in length, 5~40 μm in diameter. Minute raphides of calcium oxalate usually visible, 5~20 μm in length. Reticulate, bordered-pitted and spiral vessels visible, 10~55 μm in diameter.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of ethyl acetate, ultrasonicate for 15 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of atractylodin and dissolve in ethyl acetate to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane and ethyl acetate (15:1) as the developing solvent. Apply 5 μL of each of the sample solution and reference drug solution and 2 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Total ash: Not more than 7.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 1.5% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 5.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
1. Atractylodin:
   (1) Mobile phase: Methanol as the mobile phase A, and water as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of atractylodin and dissolve in water to produce a solution containing 15 μg per mL.
   (3) Sample solution: Weigh accurately 0.2 g of

the powdered sample, add 25 mL of methanol, ultrasonicate for 30 minutes, centrifuge and filter, transfer the filtrate to 50-mL volumetric flask. Repeat the extraction of the residue one more time. Combine the filtrate, make up to volume with methanol, mix well, filter and use the successive filtrate.

(4) Chromatographic system: The liquid chromatography is equipped with an UV detector (340 nm) and a column packing L1. The column temperature is maintained at 30℃. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of atractylodin should not be less than 5,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~20	85	15
20~25	85→100	15→0

(5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Atractylodin (%)=0.005(r_U/r_S) (C_S) / (W)

r_U: peak area of atractylodin of sample solution

r_S: peak area of atractylodin of reference standard solution

C_S: concentration of atractylodin of reference standard solution (μg /mL)

W: weight of test sample (g) calculated with dried sample.

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place, and protect from moisture.
Usage: Dampness-dispelling medicinal (Dampness-resolving with aroma medicinal).
Property and flavor: Warm; pungent and bitter.
Meridian tropism: Spleen and stomach meridians.
Effects: Dry dampness to fortify the spleen, promote sweating, dispel wind dampness.
Administration and dosage: 3~9 g.

【Decoction pieces】

ATRACTYLODIS RHIZOMA

It contains not less than 20.0% of dilute ethanol-soluble extractives and not less than 33.0% of water extractives and not less than 0.2% of atractylodin.
Raw medicinal materials are processed to remove impurities, clean selection, soften thoroughly, cut into thin slices, and dry, mostly irregular subrounded or salt-shaped thick slices. Externally yellowish-brown, wrinkled, sometimes root scars visible. Section yellowish-white or greyish-white, scattered with many orange-yellow or yellow oil glands, and obvious wood fiber bundles. Odour aromatic, taste slightly bitter.

Thin layer chromatographic identification test: The method is the same as that for crude herb.
Impurities and other requirements: Methods and specifications are the same as those for crude herb.
Assay: The method is the same as that for crude herb.
Storage: The method is the same as that for crude herb.
Usage: Dampness-dispelling medicinal (Dampness-resolving with aroma medicinal).
Property and flavor: Warm; pungent and bitter.
Meridian tropism: Spleen and stomach meridians.
Effects: Dry dampness to fortify the spleen, promote sweating, dispel wind dampness.
Administration and dosage: 3~9 g.

AUCKLANDIAE RADIX
木香
Mu Siang / Mu Xiang
Costus Root

Costus root is the dried root of *Aucklandia costus* Falc. (*A. lappa* Decne.) (Fam. Compositae).
It contains not less than 17.0% of dilute ethanol-soluble extractives, not less than 21.0% of water extractives and not less than 0.6% of costunolide.

Description: Cylindrical, occasionally branched, or longitudinal semi-cylindrical lobes, often processed into 5~15 cm small pieces, 0.4~5.5 cm in diameter. Externally yellowish-brown or grayish-brown, with distinct longitudinal furrows, lateral root scars or slender lateral roots, occasionally with visible reticulations. Relatively fine roots with more dense and deep wrinkles and dark resinous spots visible, occasionally with a wide longitudinal furrows, the surface of furrows dark brown, mostly rotted. Texture hard and heavy, fracture relatively even, pale grayish-yellow, thickness of cortex about 1/3 of root radius, nearly cambium gray-brown, pith occasionally with fissures, numerous large brown yellow oil spots (oil cavities) in cortex and wood, the center of old roots decayed into the hollows. Odour characteristic and aromatic; taste sweet and then bitter, slightly numb.

Microscopic identification:

1. **Transverse section:**

Root of *Aucklandia costus*: Cork composed of 2~6 layers of cork cells, rhytidome occasionally remained. Phloem relatively broad, with distinct sieve tube groups; phloem fiber bundles zero, sparsely distributed or arranged in 1~3 interrupted whorls. Cambium in an interrupted ring. Xylem vessels radially elongated, singly scattered or occasionally linked by several, xylem fibers few, distributed among or near vessels, mostly distributed near the root center. Large oil cavities scattered among phloem and xylem rays, the longer one up to

263 μm long, and the shorter one up to 254 μm long, usually containing yellow secretory contents. Parenchymatous cells filled with relative amount of inulin.

2. **Powder:** Brown. Inulin fairly abundant, in irregular masses or fan-shaped, with radial striations. Xylem fibers mostly in bundles, yellow, long-fusiform, oblique or taper at the end, 16~24 μm in diameter, wall 4~5 μm thick, pit apertures transverse-porous, cruciate or V-shaped. Phloem fibers zero or rare, up to 33 μm in diameter, wall up to 9 μm thick. Reticulate vessels frequent, bordered-pitted and scalariform vessels also present, 10~90 μm in diameter, vessel elements generally short, some up to 30 μm in diameter. Pale yellow oil cavities uncommonly present. Cork cells vary in shapes, thin-walled, pale yellowish-brown, anticlinal walls occasionally undulate. Some parenchymatous cells contain small prisms of calcium oxalate.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 3.0 g of powdered sample to 10 mL of ethanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 3.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of costunolide and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane, ethyl acetate, and formic acid (15:5:1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 15.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 4.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 5.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Costunolide:
   (1) Mobile phase: A solution of methanol and water (13:7). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of costunolide, and dissolve in methanol to produce a solution containing 15 μg per mL.
   (3) Sample solution: Weigh accurately 0.3 g of powdered sample and place it in a conical flask with stopper, add accurately 50 mL of chloroform, stopper tightly and weigh. Stand for overnight, ultrasonicate for 30 minutes, cool and weigh again, replenish the loss weight with chloroform, shake, filter, measure accurately 3 mL of the filtrate to an evaporating dish, evaporate to dryness, dissolve the residue in 2 mL of methanol in warm, transfer to 10-mL volumetric flask, and make up to volume, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (225 nm) and a column (4~6 mm ×15~25 cm) packing L1 (5~10 μm). The column temperature is maintained at room temperature. Inject reference standard solution into the liquid chromatography apparatus for 5 times, and record the peak areas. The relative standard deviation of the peak area of costunolide should not be more than 1.5%.
   (5) Procedure: Inject accurately 20 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   Costunolide: (%)=(0.05 / 3) × (r_U/r_S) (C_S) / (W)

   r_U: peak area of costunolide of sample solution

   r_S: peak area of costunolide of reference standard solution

   C_S: concentration of costunolide of reference standard solution (μg/mL)

   W: weight of test sample (g) calculated with dried sample.
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place, and protect from moisture.

Usage: Qi-regulating medicinal.

Property and flavor: Warm; pungent and bitter.

Meridian tropism: Spleen, stomach, large intestine, triple energizers and gallbladder meridians.

Effects: Move qi to relieve pain, warm the middle to harmonize stomach.
Administration and dosage: 1.5~6 g.

AURANTII FRUCTUS IMMATURUS
枳實
Jhih Shih / Zhi Shi
Immature Bitter Orange

Immature bitter orange is the dried young fruit of *Citrus aurantium* L. and its cultivated varieties or *Citrus sinensis* (L.)Osbeck (Fam. Rutaceae).
It contains not less than 12.0% of dilute ethanol-soluble extractives, not less than 20.0% of water extractives and not less than 0.3% of synephrine.

Description: Semispheroidal, a few spheroidal, 0.5~2.5 cm in diameter. Exocarp darkish-green or dark brownish-green, with granular protuberances and wrinkles, remained with distinct stylopodium or fruit stalk scar. Mesocarp slightly protuberant, yellowish-white or yellowish-brown, 0.3~1.2 cm thick, with 1~2 rows of oil cavities on the outer part of pericarp. Pulp vesicles brown. Texture hard. Odour aromatic; taste bitter and slightly sour.

Microscopic identification:
1. **Transverse section:**
   Aurantii Fructus Immaturus: Epidermis of pericarp scattered with villus cells, 100~200 μm in length, epidermis composed of single layer of small cells, 10~15 μm in diameter, inside showing parenchymatous tissue of pericarp, cells arranged densely in irregularly hexagon-shape, cells gradually larger from outside to inside, the outside layer with cells 20~30 μm in diameter, the inside layer with cells up to 150 μm in diameter, pericarp with pit canals, scattered with collenchymatous cells in bundles, normally 3~5 in a group. Cells with oil-shape contents.
2. **Powder:** Pale yellow or brownish-yellow. Mesocarp cells subrounded or irregular in shape, walls thickened unevenly. Epidermal cells of pericarp polygonal, subsquare or rectangular in surface view, stomata actinocytic, 18~26 μm in diameter, with 5~9 subsidiary cells; epidermal cells of pericarp covered with cuticle in sectional view. Prisms of calcium oxalate scattered in pericarp and juice vesicle, oblique-square, irregularly polygonal or double-conical, 2~24 μm in diameter. Hesperidin crystals existed in parenchymatous cells, yellow or colorless, rounded or irregular in shape masses, occasionally with distinct radial striations. Fragments of oil cavities usually found, secretory cells slender and curve. Spiral, reticulate vessels and tracheids fine.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of synephrine and dissolve in methanol to produce a solution containing 0.5 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and the supernatant of *n*-butanol, glacial acetic acid, and water (4:1:5) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of solvent rise to about 5~10 cm from the origin, dry in air. Spray with 1% ninhydrin/EtOH TS, heat at 105℃ until the spots become visible. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 14.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 7.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
1. Synephrine:
   (1) Mobile phase: The solution, mixing with acetonitrile and 0.075% phosphoric acid in 0.1% sodium dodecyl sulfate at the ratio of 32:68, is used as mobile phase. The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of synephrine and dissolve in methanol to produce a solution containing 0.1 mg per mL.
   (3) Sample solution: Weigh accurately 0.5 g of powdered sample and place it in a 50-mL centrifuge tube, add 25 mL of 50% methanol, weigh, ultrasonicate for 30 minutes, centrifuge for 10 minutes. Transfer the supernatant to a 250-mL round bottom flask, repeat the extraction of the residue one more time. Combine the supernatant, and evaporate

to dryness with a rotary evaporator. Dissolve the residue in 50% methanol, transfer to a 25-mL volumetric flask, make up to volume with 50% methanol, mix well, filter and use the filtrate.

(4) Chromatographic system: The liquid chromatography is equipped with an UV detector (224 nm) and a column packing L1. The column temperature is maintained at 25℃. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of synephrine should not be less than 8,000.

(5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Synephrine (%)=2.5(r_U/r_S) (C_S) / (W)

r_U: peak area of synephrine of sample solution

r_S: peak area of synephrine of reference standard solution

C_S: concentration of synephrine of reference standard solution (mg/mL)

W: weight of test sample (g) calculated with dried sample.

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).

3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place, and protect from mold and insects.
Usage: Qi-regulating medicinal.
Property and flavor: Mild cold; bitter, pungent and sour.
Meridian tropism: Spleen and stomach meridians.
Effects: Break qi and resolve accumulation, transforms phlegm and disperses focal distention.
Administration and dosage: 3~10 g.

AZEDARACH FRUCTUS
川楝子
Chuan Lian Zih / Chuan Lian Zi
Sichuan Chinaberry Fruit

Sichuan chinaberry fruit is the dried ripe fruit of *Melia azedarach* L.(*Melia toosendan* Siebold et Zucc.) (Fam. Meliaceae).
It contains not less than 17.0% of dilute ethanol-soluble extractives, not less than 25.0% of water extractives and. among 0.060% ~ 0.20% of toosendanin.

Description: Drupes subspheroidal or elliptic, 2~3.2 cm in diameter. Externally golden to brownish-yellow, slightly lustrous, rarely dented or shrunken, with numerous yellowish-brown or blackish-brown dots. Apex remained with stylopodium, base dented with a fruit stalk scar. Exocarp coriaceous, usually forming a space with sarcocarp. Sarcocarp loose and soft, pale yellow, viscous when moistened. Kernels spheroidal or ovate, texture hard, both ends truncate, with 5~8 longitudinal ribs and 6~8 locules, each loculus containing a blackish-brown oblong seed. Seeds with fine protuberances, oily. Odour characteristic; taste sour and bitter.

Microscopic identification:

1. **Transverse section:**

(1) Pericarp of *Melia azedarach*: Exocarp composed of 1 layer of subsquare cells covered with cuticle. Mesocarp mainly composed of parenchymatous cells, containing starch granules, clusters of calcium oxalate, approximately 16 μm in diameter, and round or oblong secretory cells, scattered with stone cells; fibers radially elongated near mesocarp, tangentially elongated on the inner side. Crystal-containing cells also exist, the walls thickened irregularly, usually several in groups, prisms of calcium oxalate existed in lumen.

(2) Seed of *Melia azedarach*: Epidermis of testa composed of 1 layer of subsquare cells, with fine longitudinal striations, distributed granular protuberances visible on wall surface. Hypodermis composed of 1~2 layers of parenchymatous cells containing reddish-brown contents. Parenchymatous cells composed of 1 layer of subsquare or slightly oblong cells, with radially striations. Pigment layer composed of several layers of parenchymatous cells, containing brown contents. Endocarp mostly scattered with stone cells, occasionally with parenchymatous cells present, subrounded or oblong. Endosperm cells polygonal, filled with oil droplets and starch granules.

2. **Powder:** Yellowish-brown. Pericarp fibers and crystal fibers usually crisscrossed or arranged irregularly. Fibers vary in length, slightly curved and the endings obtusely rounded, 9~36 μm in diameter, walls thickened, pits indistinct, occasionally filled with yellowish-brown granular contents. Crystal-containing walls of crystal fibers vary in thickness, lignified, containing prisms of calcium oxalate, and clusters of calcium oxalate few. Stone cells of pericarp elongated or long-polygonal, with warty protrusions or short obtuse branches, S-shaped bending; some stone cells subrounded or subelliptical, up to 150 μm long, 14~54 μm in diameter, the wall 9~13 μm thick, pits few and short, lumens narrow, forming stellated shape in all short branches; also some stone cells slightly thickened, lumens filled with brown contents. Pit cells of pericarp subpolygonal or strip-shape, the wall slightly thickened and bending, containing round pits or oblique pits, several pits assemble into pits domain. Epidermal cells of testa bright yellow or yellowish-orange, flat in section view, the walls thickened, containing longitudinal pits; polygonal on surface view, with fine and dense granular

striations. Crystal cells of endotesta with walls vary in thickness, lumens filled with pale yellow, yellowish-brown or reddish-brown contents, also containing small prisms of calcium oxalate. Epidermal cells of pericarp, pigment layers of testa, epidermal cells of endotesta and clusters of calcium oxalate also exist.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 30 mL of ethyl acetate, ultrasonicate for 30 minutes and filter, evaporate the filtrate to dryness, and dissolve the residue in 1 mL of ethanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of toosendanin and dissolve in ethanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane and acetone (1:1) as the developing solvent. Apply 5 μL of each of the sample solution and reference drug solution and 2 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with a solution of 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 11.0% dry at 105°C for 5 hours (General rule 6015).
2. Total ash: Not more than 4.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:

1. Toosendanin:
   (1) Mobile phase: A solution of acetonitrile and water (32:68). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of toosendanin, and dissolve in acetonitrile to produce a solution containing 25 μg per mL.
   (3) Sample solution: Weigh accurately 0.5 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 10 mL of 75% methanol, ultrasonicate for 30 minutes. Centrifuge for 10 minutes, transfer the supernatant to 25-mL volumetric flask, repeat the extraction of the residue one more time. Combine the extracts and make up to volume with 75% methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (210 nm) and a column packing L1. The column temperature is maintained at 25℃. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of toosendanin should not be less than 8,000.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   Toosendanin (%)=0.0025 (r_U/r_S) (C_S) / (W)

   r_U: peak area of toosendanin of sample solution

   r_S: peak area of toosendanin of reference standard solution

   C_S: concentration of toosendanin of reference standard solution (μg/mL)

   W: weight of test sample (g) calculated with dried sample.
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place, and protect from insects.
Usage: Qi-regulating medicinal.
Property and flavor: Cold; bitter.
Meridian tropism: Liver, small intestine, and bladder meridians.
Effects: Move qi to relieve pain, soothe liver and clear heat.
Administration and dosage: 4.5~11.5 g.

BAMBUSAE CAULIS IN TAENIAS
竹茹
Jhu Ru / Zhu Ru
Bamboo Shavings

Bamboo shavings is the dried middle shavings of culm of *Phyllostachys nigra* (Lodd.) Munro var. *henonis* (Mitford) Stapf ex Rendle, *Bambusa tuldoides* Munro or *Bambusa beecheyana* Munro var. *pubescens* (P.F.Li) W.C.Lin

(*Sinocalamus beecheyanus* (Munro) McClure var. *pubescens* P.F.Li) (Fam. Gramineae).

Description: Slivers or filamentary, coiled each other in a mass, varying in length, 5~7 mm in width, about 0.5 mm thick. Externally greenish-green or pale yellowish-white, slightly rough, fibrous, with fine longitudinally striations. Texture light and tenacious. Odour slight; taste slightly sweet.

Impurities and other requirements:

1. Loss on drying: Not more than 10.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 4.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.5% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Storage: Refrigerate or store in a cool and dry place, and protect from mold and color changing.
Usage: Phlegm-dispelling medicinal (Heat-phlegm clearing and resolving medicinal).
Property and flavor: Mild cold; sweet.
Meridian tropism: Lung, stomach, heart and gallbladder meridians.
Effects: Clear heat to transform phlegm, eliminate vexation and stop vomiting.
Administration and dosage: 4.5~12 g.

BAMBUSAE CONCRETIO SILICEA
天竺黃
Tian Jhu Huang / Tian Zhu Huang
Tabasheer

Tabasheer is the dried masses of secretion in culm of *Bambusa textilis* McClure or *Schizostachyum chinense* Rendle (Fam. Gramineae).

Description: Irregular masses or granules in nature, larger one 1~1.5 cm in length, smaller one 1~2 mm in length. Externally milky, grayish-white or grayish-blue, surface often accompanied by dust powder. Texture light and fragile, easily broken, fracture lustrous, hygroscopic strongly, silicone-like transparent after absorbing water. Odourless; taste weak, with a cooling sensation, viscous on licking, granular on chewing.

Identification:

1. Check silicon dioxide: Ignite and incinerate a quantity of powdered sample, dissolve the residue in a solution of 1 volume of hydrochloric acid and 1 volume of nitric acid, filter. Take the filtrate, add ammonium molybdate, shake well, add ferrous sulfate, a blue color is produced and indicates the presence of SiO_2.
2. Check alkaline: Add drops of phenolphthalein solution in natural tabasheer extract, a pink color isn't produced; in synthesized tabasheer extract, a purplish-red color is produced.
3. Check reducing substances: Aqueous extract boils with a few drops of potassium permanganate solution, color fading is produced and indicates the presence of reducing substances, such as carbohydrates, etc.
4. Check aluminum salt: Add 1 drop of potassium ferrocyanide to a piece of filter paper, after drying, apply 1 drop of the sample solution in hydrochloric acid, 10 drops of distilled water and 1 drop of 0.1% alizarin red solution in ethanol, expose to ammonia vapor, a red ring is produced and indicates the presence of aluminum salt.
5. Check volume ratio: Take 10.0 g of medium size powdered sample into a measuring cylinder, and the volume not less than 35 mL.
6. Check water absorbing capacity: Take 5.0 g of powdered sample, add 50 mL of water, stand for a moment, filter through a moistened filter paper, the filtrate not more than 44 mL.

Impurities and other requirements:

1. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
2. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
3. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
4. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
5. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Storage: Store in a dry place and preserve in a well-closed container.
Usage: Phlegm-dispelling medicinal (Heat-phlegm clearing and resolving medicinal).
Property and flavor: Cold; sweet.
Meridian tropism: Heart and liver meridians.
Effects: Clear heat to transform phlegm, clear heart to settle fright.
Administration and dosage: 3~10 g.

BENINCASAE SEMEN
冬瓜子
Dong Gua Zih / Dong Gua Zi
Waxgourd Seed

Waxgourd seed is the dried ripe seed of *Benincasa hispida* (Thunb.) Cogn. (Fam. Cucurbitaceae).

It contains not less than 4.0% of dilute ethanol-soluble extractives and not less than 5.0% of water extractives.

Description: Oblate, 1~1.3 cm in length, 6~8 mm in width, 2 mm thick. Externally yellowish-white, fissures occasionally, obtuse at one end, acute at the other end. Acute end with two prominences, hilum present at the relatively small ones; micropyle present obviously at the relatively large ones. Edges smooth (unilateral waxgourd seed) or with a circular edge at the both sides of the edge (bilateral waxgourd seed). Texture loose; cotyledons 2, pale white, oily. Odour slight; taste slightly sweet.

Microscopic identification:

1. **Transverse section:**
   Seed of *Benincasa hispida*: Outermost layer of testa composed of 1 layer of square or subovoid epidermal cells covered with cuticle and numerous non-glandular hairs; the inner side composed of 7~15 layers of parenchymatous cells of testa, the cells present in the outer side relatively large, mostly strip-shaped; the inner side of the cells slightly small, subovoid, subrounded or irregular. The innermost layer of testa composed of 2~4 layers of stone cells, walls extremely thickened, subrounded, subovoid or suboblong, 12~50 μm in diameter, lignified. Contain 2 cotyledons, each composed of about 15 layers of cells, the outer and the inner side both composed of 1 row of dense parenchymatous cells, respectively, subsquare or subrectangular. About 10 layers of cells near testa strip-shaped, arranged palisade-like. Cotyledon cells filled with aleurone grains and oil droplets, unlignified.
2. **Powder:** Yellowish-brown. Odourless, taste slightly sweet. Numerous non-glandular hairs usually existed in the outer side of testa, unicellular, long whip-shaped. Epidermal cells of testa polygonal in surface view. Stone cells existed in the innermost of testa, arranged in a ring on the outer side of cotyledons, with distinct striations, subrounded, subovate or suboblong, 12~50 μm in diameter. Cotyledon cells filled with aleurone grains.

Impurities and other requirements:

1. Loss on drying: Not more than 10.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 6.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from mold and insects.
Usage: Phlegm-dispelling medicinal (Heat-phlegm clearing and resolving medicinal).
Property and flavor: Cool, sweet.
Meridian tropism: Lung, stomach, large intestine, and small intestine meridians.
Effects: Clear heat to transform phlegm, resolve phlegm to expel pus.
Administration and dosage: 9~30 g.

BLETILLAE RHIZOMA
白及
Bai Ji / Bai Ji
Common Bletilla Tuber

Common bletilla tuber is the dried tuber of *Bletilla striata* (Thunb.) Rchb. f. or *Bletilla formosana* (Hayata) Schltr. (Fam. Orchidaceae).
It contains not less than 10.0% of dilute ethanol-soluble extractives, not less than 16.0% of water extractives and not less than 1.9% of militarine.

Description:

1. Tuber of *Bletilla striata*: Irregularly oblate spherical, mostly with 2~3 claw-like braches, 1.5~5 cm in length, 0.5~1.5 cm thick. Externally grayish-white or yellowish-white, processing several concentric rings and brown dotted rootlet scars, with protuberant stem scars at the upper part and a trace jointing to another tuber at the lower part. Texture hard and uneasily broken, fracture whitish and horny. Odour slight; taste bitter and viscous on chewing.
2. Tuber of *Bletilla formosana*: Irregularly conical or long conical, mostly with 3~4 claw-like braches, many scars of broken braches at the end, 2.5~3.5 cm in length, 1~1.5 cm thick. Externally yellowish-brown or brown, shrink, processing several concentric rings and brown dotted rootlet scars, with protuberant stem scars and fibrous leaf base reminded at the upper part and a trace jointing to another tuber at the lower part. Texture hard and uneasily broken, fracture whitish and horny. Odour slight; taste bitter and viscous on chewing.

Microscopic identification:

1. **Transverse section:**
   (1) Tuber of *Bletilla striata*: Outermost layer composed of epidermal cells arranged in order, subrounded, subsquare or long-polygonal,

20~49 μm in diameter, covered with cuticle; inside showing cortex, composed of oblong, long-oblong, long-polygonal or irregular parenchymatous cells, cells vary in size, 45~195 μm in diameter, with intercellular spaces. Stele scattered with some independent vascular bundles, occasionally two vascular bundles connected or abreasted, vascular bundles closed and collateral. Vascular bundles surrounded by fiber groups, forming subrounded shape, 200~320 μm in diameter; fiber groups composed of 2~5 layers of fiber cells, walls about 12 μm thick, extremely lignified, 10~13 μm in diameter. Phloem mostly crescent, cells polygonal or subrounded. Vessels as rectangular or polygonal, walls thickened, extremely lignified, mainly in scalariform and spiral, 10~65 μm in diameter. Ground tissue scattered with subrounded mucilage cells, 100~350 μm in diameter containing raphides of calcium oxalate, about 50 μm in length. Parenchymatous cells contain starch granules, subrounded, with indistinct striations and hilum, simple granules or compound granules composed of 3~4 components, 3~15 μm in diameter.

(2) Tuber of *Bletilla formosana*: Epidermal cells arranged in order, subrounded, subsquare or long-polygonal, covered with cuticle. Velamen cells suboblong with thin wall. cortex composed of oblong, long-oblong, long-polygonal or irregular parenchymatous cells, cells vary in size, 50~155 μm in diameter, with intercellular spaces. Stele scattered with some independent vascular bundles, occasionally two vascular bundles connected or abreasted, vascular bundles closed and collateral. Vascular bundles surrounded by fiber groups, forming subrounded or oblong shape; fiber groups composed of 2~5 layers of fiber cells, walls about 2.5~5 μm thick, lignified, 12.5~25 μm in diameter. Phloem mostly crescent, cells polygonal or subrounded. Vessels as rectangular or polygonal, walls thickened, extremely lignified, 15~65 μm in diameter. Ground tissue scattered with subrounded mucilage cells, 80~420 μm in diameter containing raphides of calcium oxalate. Parenchymatous cells contain starch granules, indistinct because of preprocess.

2. **Powder:**

(1) Tuber of *Bletilla striata*: Yellowish-white. Parenchymatous cells mostly present as irregular fragments. Mucilage cells extremely large, subrounded or oblong, about 380 μm in diameter, containing raphides of calcium oxalate, raphides very fine, 27~88 μm in length. Epidermal cells irregular in surface view, anticlinal walls undulate, slightly thickened, lignified or slightly lignified, with distinct pit canals, periclinal walls with sparsely short cleft-shaped pits; epidermal cells subsquare in sectional view, anticlinal walls moniliform thickened, cuticles relatively thickened. Hypodermal cells subpolygonal, walls slightly bended, occasionally moniliform thickened and lignified. Fibers long-fusiform, walls lignified, containing oblique pits, occasionally crossed, V-shaped; small cells surround fiber bundles containing subrounded silica body, 7~10 μm in diameter, radially connected. Scalariform, bordered-pitted and spiral vessels also exist.

(2) Tuber of *Bletilla formosana*: Yellowish-white. Containing starch gelatinous. Epidermal cells irregular in surface view, anticlinal walls undulate, slightly thickened, lignified or slightly lignified, with distinct pit canals, periclinal walls with sparsely short cleft-shaped pits; epidermal cells subsquare in sectional view, anticlinal walls moniliform thickened, cuticles relatively thickened. Parenchymatous cells mostly present as irregular fragments. Mucilage cells extremely large, subrounded or oblong, about 420 μm in diameter, containing raphides of calcium oxalate, raphides very fine, 20~55 μm in length. Fibers long-fusiform or protrude corner, walls lignified, containing oblique pits, occasionally crossed, V-shaped; small cells surround fiber bundles containing subrounded silica body, 10~12.5 μm in diameter, radially connected. Vessels mainly scalariform, reticular vessels occasionally present.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 1 mL of methanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of militarine and dissolve in methanol to produce a solution containing 1.0 mg per mL
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, *n*-butanol, and water (1:4:5) as the developing solvent. Apply 2 μL of each of the sample solution and reference drug solution and 5 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and

color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 14.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 6.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 400 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 15.0 ppm (General rule 2251, 6301).

Assay:

1. Militarine
   (1) Mobile phase: Acetonitrile as the mobile phase A, and water as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of militarine, and dissolve in 50% methanol to produce a solution containing 20 μg per mL.
   (3) Sample solution: Weigh accurately 0.1 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 30 mL of 50% methanol, ultrasonicate for 30 minutes. Centrifuge for 10 minutes, transfer the supernatant to a 100-mL volumetric flask. Repeat the extraction of the residue two more times. Combine the extracts and make up to volume with 50% methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (223 nm) and a column packing L1. The column temperature is maintained at 23 ± 4℃. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of militarine should not be less than 10,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~5	10	90
5~20	10→25	90→75
20~30	25→40	75→60
30~60	40→55	60→45

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Militarine: (%)= 0.01(r_U/r_S) (C_S) / (W)
   r_U: peak area of militarine of sample solution
   r_S: peak area of militarine of reference standard solution
   C_S: concentration of militarine of reference standard solution (μg/mL)
   W: weight of test sample (g) calculated with dried sample.
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a dry place, and protect from mold and insects.
Usage: Blood-regulating medicinal (Hemostatic medicinal).
Property and flavor: Mild cold; bitter, sweet and astringent.
Meridian tropism: Lung, liver, and stomach meridians.
Effects: Astringent hemostatic, disperse swelling and promote tissue regeneration.
Administration and dosage: 6~15 g.
Precaution and warning: Incompatible with *Aconitum* spp.

BOMBYCIS FAECES
蠶砂
Can Sha / Can Sha
Silkworm Dung

Silkworm dung is the dried dung of larva of *Bombyx mori* Linnaeus (Fam. Bombycidae).

Description: Short cylindrical granules, 3~5 mm in length, 2~3 mm in diameter. Externally blackish-brown, rough and uneven, with 6 longitudinal ridges and 3~4 transverse shallow striations, both ends slightly even, hexagonal. Texture hard and fragile, easily broken into brown fine powder when rubbed or moistened. Odour slightly stinking and grassy.

Microscopic identification:
Powder: Grayish-brown or grayish-green. Cystoliths-containing cells subrounded, this large cells 47~77 μm in diameter. Clusters of calcium oxalate visible, 5~16 μm in diameter. Non-glandular hairs unicellular, 17~40 μm in diameter. Stomata of lower epidermis anomocytic, with 4~6 subsidiary cells. Spiral vessels 6~12 μm in diameter. Prism crystals and laticiferous tubes occasionally found.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, shake for 5 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.

3. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, methanol, and water (10:2:1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:
1. Total ash: Not more than 20.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 11.0% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Storage: Refrigerate or store in a cool and dry place.
Usage: Dampness-dispelling medicinal (Wind-dampness-dispelling medicinal).
Property and flavor: Warm; sweet and pungent.
Meridian tropism: Liver, spleen, and stomach meridians.
Effects: Dispel wind and eliminate dampness, harmonize stomach to eliminate turbid.
Administration and dosage: 9~15 g, wrap-decocted.

BOMBYX BATRYTICATUS
白殭蠶
Bai Jiang Can / Bai Jiang Can
Stiff Silkworm

Stiff silkworm is the dried body of the 4~5th year's larva of *Bombyx mori* Linnaeus (Fam. Bombycidae) died of infection or artificial inoculation of *Beauveria bassiana* (Bals.-Criv.) Vuill., commonly known as "Jiang Chan". It contains not less than 13.0% of dilute ethanol-soluble extractives and not less than 15.0% of water extractives.

Description: Subcylindrical, usually curved and shrunken, 2~5 cm in length, 5 mm in diameter. Externally white, grayish-white or pale green, covered with white powdery (aerial hypha and conidia). Head yellowish-brown, relatively round; 8 pairs of legs, protruding; caudal portion slightly dichotomic; segments protuberant. Texture hard and fragile, fracture green or blackish-brown, even and luster, commonly known as "Jieu Kou Jing Mian", with 4 brown rings of silk glands. Odour slightly stinking; taste slightly bitter.

Microscopic identification:
Powder: Pale yellow or yellowish-brown. Mycelia existed in the body walls or in pale brown translucent crystalline masses. Mycelia almost colorless, slender, 1~5 μm in diameter, rolled and twisted with each other. Broken pieces of trachea walls contain dark brown or colorless spiral filaments, 1~3 extremely fine undulating striations between filaments. Epidermis yellowish-white or grayish-white, the surface with reticulated shrunken striations and small pointed projections. Setae pits rounded or subrounded, the margin of the pits yellowish-brown or brown; setae yellow or yellowish-brown, surface smooth, the inner side irregular. Subcrystalline substances colorless, scattered or embedded in tissue, subsquare or irregular, the surface usually with fissures. Oil droplets, epidermis of mulberry leaf (containing stomata, cystoliths and trichomes), mesophyllous tissue and crystals of calcium oxalate also present.

Impurities and other requirements:
1. Loss on drying: Not more than 13.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 7.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).
9. Aflatoxins
   (1) Aflatoxins (sum of B_1, B_2, G_1, and G_2): Not more than 10.0 ppb (General rule 6307).
   (2) Aflatoxin B_1: Not more than 5.0 ppb (General rule 6307).

Assay:
1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from insects.
Usage: Liver-pacifying and wind-extinguishing medicinal.
Property and flavor: Neutral; salty and pungent.
Meridian tropism: Liver, lung, and stomach meridians.
Effects: Extinguish wind to arrest convulsions, dispel wind to relieve pain, detoxify to dissipate binds.
Administration and dosage: 3~11.5 g.

BORNEOLUM
冰片
Bing Pian / Bing Pian
Borneol

Natural Borneol is the crystal produced from the fresh branches and leaves of *Cinnamomum camphora* (L.) J. Presl (Fam. Lauraceae) by steam distillation, commonly known as "Tian Ran Bing Pian" or the crystals produced by distillation and cooling after sublimation of the resins or broken resins from *Dryobalanops sumatrensis* (J.F.Gmel.) Kosterm. It is commonly known as "Mei Pian". Most of the Borneol sold on the markets are Synthetic Borneol, it is made by hydrogenation of camphor.

Description:

1. Borneol (natural borneol): Transparent or translucent, plate or granular crystals, whitish or pale gray. Odour aromatic; taste pungent, with a cooling sensation. Volatile, smoke may generating when burned.
2. Synthetic borneol: Colorless, transparent, or white, translucent, loose and fragile, plate crystals. Odour aromatic; taste pungent, with a cooling sensation. Volatile, a heavy fume produced when burned with a bright flame.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Dissolve a quantity of powdered sample in methanol to produce a solution containing 5.0 mg per mL.
2. Reference drug solution: Take a quantity of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane and ethyl acetate (3:2) as the developing solvent. Apply 1 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 5% vanillin/H_2SO_4 TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Specific optical rotation (General rule 1007):
Borneol (natural borneol) specific rotation: +34°~+37°.

Impurities and other requirements:

1. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
2. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
3. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
4. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Storage: Store in a cool and dry place.
Usage: Orifice-opening medicinal.
Property and flavor: Mild cold; pungent and bitter.
Meridian tropism: Heart, spleen, and lung meridians.
Effects: Open orifices and lighten spirit, clear heat and relieve pain.
Administration and dosage: 0.15~0.3 g, usually used in pills or powder; used an appropriate amount for external use.
Precaution and warning: Use cautiously during pregnancy.

BOVIS CALCULUS
牛黃
Niou Huang / Niu Huang
Oriental Bezoar

Oriental bezoar is the dried gallstone of *Bos taurus domesticus* Gmelin (Fam. Bovidae). If the bezoar is found during slaughter, the bile is filtered. The drug is collected, removed from surrounding thin membrane, and dried in the shade, commonly known as "Tian Ran Niou Huang". It contains not less than 25.0% of bilirubin.

Description:
According to the different shapes, separate into "Dan Huang" and "Guan Huang":

1. Dan Huang: Mostly ovate, irregularly spheroidal, square round or triangular, 0.6~3.3 cm in diameter. Externally inaurate or brownish-yellow, fine and slightly lustrous, some with a layer of black lustrous thin membrane, commonly known as "Wu Jin Yi", some rough and with cracks. Texture light in weight and fragile, easily broken, fracture yellow, with neat concentric circular striations. Odour aromatic; taste bitter than slightly sweet, with a cooling sensation; not sticky on chewing, the solution can dyed the nails to yellow, commonly known as "Gua Jia".
2. Guan Huang: Tubular, surface uneven or with transverse curved lines, or broken into small pieces, about 3 cm in length, 1~1.5 cm in diameter. Externally reddish-brown or brown, with crack and small protuberance. Fracture less concentric circular striations, some hollow, with dark color.

Microscopic identification:

1. **Powder:** Small yellowish-brown granules or irregular masses, masses contain subsquare crystalloids varying in size.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.

2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of cholic acid and deoxycholic acid and dissolve in ethanol to produce a solution containing 2.0 mg per mL of each.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of xylene, ethyl acetate, and glacial acetic acid (8:1:1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% sulfuric acid and heat at 105℃ until the spots become visible. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
2. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
3. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
4. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
5. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
6. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
1. Bilirubin:
   (1) Mobile phase: A solution of acetonitrile and 1% glacial acetic acid (95：5). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of bilirubin and dissolve in dichloromethane to produce a solution containing 40 μg per mL.
   (3) Sample solution: Weigh accurately 10 mg of the powdered sample, transfer to a conical flask, add 10 mL of 10% oxalic acid solution, mix well, add 100 mL of dichloromethane saturated with water, weigh, mix well, ultrasonicate for 40 minutes, cool, weigh again, replenish the loss of the weight with dichloromethane saturated with water, mix well, centrifugal and use the dichloromethane solution, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (450 nm) and a column packing L1.
   (5) Procedure: Inject accurately 5 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   Bilirubin: (%)= 10(r_U/r_S) (C_S) / (W)

   r_U: peak area of bilirubin of sample solution
   r_S: peak area of bilirubin of reference standard solution
   C_S: concentration of bilirubin of reference standard solution (μg/mL)
   W: weight of test sample (g) calculated

Storage: Refrigerate or store in a cool and dry place, and preserve in a light-resistant, moisture-proof, crush-proof and well-closed container.
Usage: Liver-pacifying and wind-extinguishing medicinal.
Property and flavor: Cool, bitter and sweet.
Meridian tropism: Heart and liver meridians.
Effects: Clear heart and sweep phlegm, open orifices and lighten spirit, clear liver and detoxicate, extinguish wind to arrest convulsions.
Administration and dosage: 0.15~0.3 g, used in pills or powde.

BROUSSONETIAE FRUCTUS
楮實子
Chu Shih Zih/Chu Shi Zi
Paper Mulberry Fruit

Paper mulberry fruit is the dried fruit of *Broussonetia papyrifera* (L.) Vent. (Fam. Moraceae).
It contains not less than 4.0% of dilute ethanol-soluble extractives and not less than 6.0% of water extractives.

Description: Spherical, slightly flat, reddish brown on the epidermal, with reticular grooves or granules, edge on one side. Hard and brittle, fragile. The endosperm is yellowish white and oily. Odor slight, taste light.

Microscopic identification:
1. **Powder:** Reddish-brown. The epidermal cells are subsquare, with thin walls and many have fallen off. 1 column of palisade cells is arranged in a wave shape, and the cell wall is thickened in a thin strip, and the lower one is 1 column of crystal thick cells. The innermost sclerenchyma cells have unclear levels and boundaries, only the texture of thickened walls. The seed coat cells are in 1 row, and the inner wall and the side walls are thickened. Endosperm and cotyledon parenchyma cells are rich in oil droplets and aleurone.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 2.0 g of powdered sample to 50 mL of petroleum ether (30~60℃), ultrasonicate for 30 minutes, filter, discard the filtrate. Repeat the extraction of the residue three more times. Evaporate the residue to dryness, dissolve the residue in 50 mL of methanol, ultrasonicate for 30

minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 1 mL of methanol. .

2. Reference drug solution: Take 2.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of toluene, ethyl acetate, and formic acid (10:8:1.3) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:

1. Loss on drying: Not more than 9.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 9.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Storage: Store in a ventilated and dry place, and protect from insects.
Usage: Tonifying and replenishing medicinal (Blood-tonifying medicinal).
Property and flavor: Cold; sweet.
Meridian tropism: Liver and kidney meridians.
Effects: Tonify kidney and liver, improve vision, promote urination.
Administration and dosage: 6~12 g.

BUDDLEJAE FLOS
密蒙花
Mi Meng Hua / Mi Meng Hua
Pale Butterflybush Flower

Pale butterflybush flower is the dried flower bud and inflorescence of *Buddleja officinalis* Maxim. (Fam. Loganiaceae).
It contains not less than 13.0% of dilute ethanol-soluble extractives, not less than 10.0% of water extractives and not less than 0.5% of buddleoside.

Description: Mainly small branches of inflorescence bearing dense flower buds, irregularly conical, 1.5~3 cm in length. Externally grayish-yellow or brownish-yellow, densely pubescent. Flower buds clavate, with the upper side slightly larger, 0.3~1 cm in length, 0.1~0.2 cm in diameter; calyx campanulate with 4 terminal lobes; corolla tube equal to or slightly longer than calyx, with 4 terminal lobes, lobes ovate, internally purplish-brown, scattered with sparse tomenta; stamens 4, inserted on the middle of corolla tube. Texture soft. Odour slightly aromatic; taste slightly pungent and bitter.

Microscopic identification:

1. **Transverse section:**
   Flower of *Buddleja officinalis*: Sepals, lower epidermis of petals, the upper part of ovary and style densely covered with stellate non-glandular hairs, the basal cells subrounded, the apex usually 2-celled, each cell branched, walls thick, lumens linear. Non-epidermal cells of tuber-like sepals approximately rectangular, epidermal cells of corolla lobe polygonal. Epidermal cells of stigma villiform. Upper epidermis of corolla scattered with a few non-glandular hairs, unicellular, walls with numerous spiny protuberance. Pollen grains spheroidal, externally smooth, with 3 germinal pores.
2. **Powder:** Brown. Stellate hairs mostly broken; intact ones with the body 2-celled, the base juxtaposed, each cell branched, isometric or one long and one short, the apex gradually acute or hook-like. Pollen grains subrounded, the outer wall stratified indistinctly, with 3 germinal pores, externally smooth, granular reticulate striations faintly visible on the surface. Glandular hairs mostly scattered, 2-celled head biseriate arranged in short dumbbell-shaped or butterfly-shaped. Spiral and reticulate vessels visible.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, cool, filter and make up the filtrate to 10 mL.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and dichloromethane as the developing solvent. Apply 10 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with vanillin/H_2SO_4 TS and heat at 105℃ until the spots become visible. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:

1. Loss on drying: Not more than 12.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 8.0% (General rule 6007).

3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Buddleoside:
   (1) Mobile phase: Methanol as the mobile phase A, and a solution of 0.1% phosphoric acid as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of buddleoside, and dissolve in methanol to produce a solution containing 20 μg per mL.
   (3) Sample solution: Weigh accurately 0.1 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 20 mL of methanol, ultrasonicate for 30 minutes. Centrifuge for 10 minutes, transfer the supernatant to a 50-mL volumetric flask. Repeat the extraction of the residue one more time. Combine the supernatant and make up to volume with methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (326 nm) and a column packing L1. The column temperature is maintained at 25°C. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of buddleoside should not be less than 1,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~5	35→45	65→55
5~30	45	55

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   Buddleoside (%)=0.005(r_U/r_S) (C_S) / (W)

   r_U: peak area of buddleoside of sample solution

   r_S: peak area of buddleoside of reference standard solution

   C_S: concentration of buddleoside of reference standard solution (μg/mL)

   W: weight of test sample (g) calculated with dried sample.

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place, and protect from moisture.
Usage: Heat-clearing medicinal (Heat-clearing and fire-purging medicinal).
Property and flavor: Mild cold; sweet.
Meridian tropism: Liver meridians.
Effects: Clear heat and emolliate liver, remove nebula and improve vision.
Administration and dosage: 3~9 g.

BUPLEURI RADIX
柴胡
Chai Hu / Chai Hu
Bupleurum Root

Bupleurum root is the dried root of *Bupleurum chinense* DC. or *Bupleurum scorzonerifolium* Willd. (Fam. Umbelliferae). It is commonly known as "Bei Chai Hu" and "Nan Chai Hu".
It contains not less than 8.0% of dilute ethanol-soluble extractives, not less than 8.0% of water extractives and not less than 0.8% of the total amount of saikosaponin a, saikosaponin c and saikosaponin d.

Description:

1. Root of *Bupleurum chinense* (Bei Chai Hu): Conical or cylindrical, often branched, 6~15 cm in length, 0.3~0.8 cm in diameter, apex remained with 3~15 stem-bases or short fibrous leaf-bases. Externally blackish-brown or pale brown, with longitudinal wrinkles, rootlet scars and lenticels. Texture hard and tenacious, uneasily broken, fracture fibrous slat-shaped, bark pale brown, wood yellowish-white. Odour slightly aromatic; taste slightly bitter.
2. Root of *Bupleurum scorzonerifolium* (Nan Chai Hu): Relatively thin, less branched, 5~14 cm in length, 0.2~0.6 cm in diameter, apex remained with numerous fibrous leaf-bases. Externally reddish-brown or blackish-brown, apex with distinct transverse protuberance. Texture slightly soft, easily broken, fracture slightly even. Odour rancid.

Microscopic identification:

1. **Transverse section:**
   (1) Root of *Bupleurum chinense* (Bei Chai Hu): Cork composed of several layers of cells, inside showing 7~8 layers of phelloderm cells. Cortex scattered with oil cavities and clefts. Phloem scattered with oil cavities, phloem rays broad, sieve tubes indistinct. Cambium in a ring. Xylem vessels scattered sparsely, 1 bundle of xylem fibers arranged in an

interrupted ring in the center; fibers polygonal, with walls thickened and lignified.

(2) Root of *Bupleurum scorzonerifolium* (Nan Chai Hu): Cork composed of about 6~10 layers of cork cells, arranging in crown-shape. Cortex with relatively numerous and large oil cavities. Xylem vessels arranged radially, xylem fibers rare and scattered, mostly existing in the outer side of xylem.

2. **Powder:**

(1) Root of *Bupleurum chinense* (Bei Chai Hu): Grayish-brown. Xylem fibers scattered or in bundles, long-fusiform, 8~17 μm in diameter, wall 2~6 μm thick, lignified, with indistinct striations, primary walls broken into short fibrous, pit canals faintly visible. Oil canals contain yellowish-brown or greenish-yellow strip-shaped secretions, surrounded by mostly shrunken parenchymatous cells. Reticulate and double-helix vessels 7~43 μm in diameter. Cork cells, parenchymatous cells of stem pith and epidermal cells of stem also present.

(2) Root of *Bupleurum scorzonerifolium* (Nan Chai Hu): Yellowish-brown. Xylem fibers long-fusiform, 8~26 μm in diameter, wall 2~10 μm thick, lignified, with dense pits, pit canals faintly visible. Primary walls occasionally broken, with sparsely spiral clefts. Oil canals mostly broken, containing pale yellow strip-shaped secretions. Double-helix vessels easily visible. Fibers of leaf base long strip-shaped, up to about 51 μm in diameter, with densely spiral-shaped overlapping clefts.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 2.0 g of powdered sample to 10 mL of methanol, heat under reflux for 15 minutes, cool, filter and use the filtrate.
2. Reference drug solution: Take 2.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of saikosaponin and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, ethanol, and water (8:2:1) as the developing solvent. Apply 10 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 2% *p*-dimethylaminobenzaldehyde in 40% sulfuric acid (*p*-dimethylaminobenzaldehyde TS) and heat at 60°C until the spots become visible. Examine under visible light and ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Foreign matter: Stems and leaves not more than 10.0% (General rule 6005).
2. Loss on drying: Not more than 13.0% dry at 105°C for 5 hours (General rule 6015).
3. Total ash: Not more than 10.0% (General rule 6007).
4. Acid-insoluble ash: Not more than 3.0% (General rule 6007).
5. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
6. Arsenic (As): Not more than 5.0 ppm (General rule 2211, 6301).
7. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
8. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
9. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Saikosaponin a, saikosaponin c, and saikosaponin d:

(1) Mobile phase: A solution of saikosaponin c in acetonitrile and water (28:72); saikosaponin a, d in acetonitrile and water (35:65). The ratio may be adjusted, if necessary.

(2) Reference standard solution: Weigh accurately a quantity of saikosaponin a, saikosaponin c, and saikosaponin d and dissolve in methanol to produce a solution containing 0.4 mg, 0.5mg and 0.5 mg per mL of each.

(3) Sample solution: Weigh accurately 500 mg of powdered sample and place it in a 50-mL centrifuge tube, add accurately 35 mL of a solution of ammonia solution and methanol (1:20), heat under reflux for 3 hours, cool, make up to 50 mL with methanol, centrifuge. Evaporate 30 mL of the supernatant to dryness, dissolve the residue in methanol to 5 mL, mix well, filter and use the successive filtrate.

(4) Chromatographic system: The liquid chromatography is equipped with an UV detector (203 nm) and a column (4~6 mm × 15~25 cm) packing L1 (5~10 μm). The column temperature is maintained at 40°C. Inject reference standard solution into the liquid chromatography apparatus for 5 times, and record the peak areas. The relative standard deviation of the peak area of saikosaponin a, saikosaponin c and saikosaponin d should not be more than 1.5%.

(5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Saikosaponin a, saikosaponin c, or saikosaponin d (%)=833.33(r_U/r_S) (C_S) / (W)

r_U: peak area of saikosaponin a, saikosaponin c, or saikosaponin d of sample solution

r_S: peak area of saikosaponin a, saikosaponin c, or saikosaponin d of reference standard solution

C_S: concentration of saikosaponin a, saikosaponin c, or saikosaponin d of reference standard solution (mg/mL)

W: weight of test sample (g) calculated with dried sample.

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place, and protect from insects.
Usage: Exterior-releasing medicinal (Pungent-cold exterior-releasing medicinal).
Property and flavor: Mild cold; pungent and bitter.
Meridian tropism: Liver, gallbladder, and lung meridians.
Effects: Harmonize and reduce fever, soothe the liver and release depression, upraise yang qi.
Administration and dosage: 3~10 g.

CANNABIS FRUCTUS
火麻仁
Huo Ma Ren / Huo Ma Ren
Hemp Fruit

Hemp fruit is the dried ripe fruit of *Cannabis sativa* L. (Fam. Moraceae).
It contains not less than 3.0% of dilute ethanol-soluble extractives, not less than 5.0% of water extractives and should not germinate.

Description: Subovate, slightly flattened, 0.4~0.5 cm in length, 0.3~0.4 cm in diameter. Externally grayish-green or grayish-yellow, with reticulations, ribbed on both sides, apex slightly acute, base obtuse with round fruit stalk scar. Pericarp thin, easily broken. Testa green, endosperm milky-white and oily. Odour slight; taste weak then pungent and paralytic.

Microscopic identification:

1. **Transverse section:**
   Fruit of *Cannabis sativa*: Exocarp composed of 1 row of round or elliptical stone cells, about 12 μm in diameter, walls thickened and with distinct striations. Mesocarp composed of 2~4 rows of parenchymatous cells, containing pigments, 1 row of cells adjacent endocarp contain crystals of calcium oxalate, irregular in shape. Endocarp composed of 1 row of stone cells, cell edge contains irregularly undulating protuberance, cells vary in size and shape, subrectangular, triangle or polygonal, lumen extremely small, with distinct striations and pit canals. Walls of epidermal cells of testa thin, cell boundary indistinct, mostly stick on endocarp and not easy to separate. Endosperm grayish-white, surrounded embryo. Cotyledon cells pale yellow, containing fatty oil droplets.
2. **Powder:** Gray. Stone cell of exocarp, cell wall in anticlinal and undulated in surface view, cells vary in size, 60~90 μm in length, 10~50 μm in diameter, thick-walled. Endocarp cells yellowish-brown, palisade in sectional view, 70~220 μm in length, about 30~50 μm wide, cells arranged densely, lumen extremely small, with distinct striations and pit canals. Crystals of calcium oxalate mostly scattered in parenchymatous cells of mesocarp, about 5~15 μm in diameter, mainly prism or cluster crystals, occasionally present sandy crystals.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 50 mL of methanol, ultrasonicate for 1 hour, filter, evaporate the filtrate to dryness, and dissolve the residue in 5 mL of methanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of toluene, ethyl acetate, and formic acid (15:1:0.3) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with vanillin/H_2SO_4 TS and heat at 105℃ until the spots become visible. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:

1. Loss on drying: Not more than 9.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 7.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 4.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place, and protect from hot and insects.
Usage: Purgative medicinal (Laxative medicinal).
Property and flavor: Neutral; sweet.
Meridian tropism: Spleen, stomach, and large intestine meridians.
Effects: Moisten the intestine and relax the bowel.
Administration and dosage: 3~15 g.

CARPESII FRUCTUS
鹤蚤
He Shih/He shi
Common Carpesium Fruit

Common carpesium fruit is the dried ripe fruit of *Carpesium abrotanoides* L. (Fam. Compositae), commonly known as" Bai Heshi".
It contains not less than 10.0% of dilute ethanol-soluble extractives and not less than 16.0% of water extractives and not less than 0.2% of carabrone.

Description: Cylindrical, small, 3~4 mm in length, less than 1 mm in diameter. Externally yellowish-brown or dark brown, with numerous longitudinal ridges. One end contract, forming beak-shape at the top, and the apex expands into a gray-white ring. Base slightly acute, bearing inserted scars. Pericarp thin, fiberous. Testa extremely thin and transparent. Cotyledon 2, whitish, slightly oily. Odour characteristic; taste slightly bitter.

Microscopic identification:
1. **Transverse section:**
   Fruit of *Carpesium abrotanoides*: Epicarp cells 1 row, each containing prisms of calcium oxalate. Several rows of parenchymatous cells of mesocarp, shrunken with indistinct bounds. Fiber bundles located between two ridges, composed of 10 fibers with walls thick and lignified. Endocarp cells 1 row. Testa cells flattened, endosperm remained. Parenchymatous cells of embryo filled with aleurone grains and fatty oil droplets. The outmost layer of cotyledon containing fine crystals of calcium oxalate.
2. **Powder:** Brownish-yellow. Prisms of calcium oxalate large, existing in the exocarp, polychromatic under the polarized microscope. The walls of fibers thick, lignified, existing in the mesocarp, prisms of calcium oxalate occasionally present. Stone cells in groups, walls thick, with pit apertures. Parenchymatous cells of cotyledon contain oil droplets and aleurone grains. Small spiral vessels and fibers occasionally exist together.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 2.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 2.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of carabrone and dissolve in methanol to produce a solution containing 2.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of petroleum ether (40~60 ℃) and acetone (7:3) as the developing solvent. Apply 5 μL of each of the sample solution and reference drug solution and 1 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 6.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 10.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 3.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
1. Carabrone:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and water as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of carabrone and dissolve in ethanol to produce a solution containing 10 μg per mL.
   (3) Sample solution: Weigh accurately 0.2 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 20 mL of 50% ethanol, ultrasonicate for 30 minutes, centrifuge for 10 minutes. Transfer the supernatant to a 50-mL volumetric flask. Repeat the extraction of the residue one more time, combine the supernatant, and make up

to volume with 50% ethanol, mix well, filter and use the filtrate.

(4) Chromatographic system: The liquid chromatography is equipped with an UV detector (212 nm) and a column packing L1. The column temperature is maintained at 35℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of carabrone should not be less than 5,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~20	35→60	65→40
20~25	60→95	40→5

(5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Carabrone (%)=0.005(r_U/r_S) (C_S) / (W)

r_U: peak area of carabrone of sample solution

r_S: peak area of carabrone of reference standard solution

C_S: concentration of carabrone of reference standard solution (μg /mL)

W: weight of test sample (g) calculated with dried sample.

Storage: Store in a cool and dry place.
Usage: Worm-expelling medicinal.
Property and flavor: Neutral; bitter and pungent.
Meridian tropism: Spleen and stomach meridians.
Effects: Expel worms and disperse accumulation.
Administration and dosage: 3~15 g.

CARTHAMI FLOS
紅花
Hong Hua / Hong Hua
Safflower

Safflower is the dried tubular flower of *Carthamus tinctorius* L. (Fam. Compositae).
It contains not less than 30.0% of dilute ethanol-soluble extractives, not less than 30.0% of water extractives and not less than 1.0% of hydroxysafflor yellow A.

Description: Tubular flowers without ovaries, about 1.5 cm in length. Externally red or reddish-orange. Corolla tubes slender, caudate, apex 5-lobed, the lobes narrowly, 5~8 mm in length. Stamens 5, anthers aggregated to a tube, exerted, yellow to brownish-yellow. Stigma 1, cylindrical, yellow, apex slightly 2-cleft. Odour slightly aromatic; taste slightly bitter.

Microscopic identification:
Powder: Orange-red. Secretory cells single layer arranged longitudinal, forming secretory ducts, 15~30 μm in diameter, containing pale yellow to reddish-brown secretions, secretory ducts usually accompanied by spiral vessels. Epidermal cells of corolla subrectangular or long strip-shaped in surface view, anticlinal walls wavy. Epidermal cells of stigma differentiated into conical unicellular hairs, epidermal cells of apex villous. Pollen grains subrounded or olivary, with 3 germinal pores, exine dentate-spinose, 30~70 μm in diameter. Parenchymatous cells contain prisms of calcium oxalate.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of ethanol, ultrasonicate for 30 minutes, cool, then filter and make up the filtrate to 10 mL.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-butanol, glacial acetic acid, and water (7:1:2) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 254 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:
1. Loss on drying: Not more than 15.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 16.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 6.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 10.0 ppm (General rule 2251, 6301).

Assay:
1. Hydroxysafflor yellow A:
   (1) Mobile phase: A solution of acetonitrile, methanol, and 0.7% phosphoric acid (2:26:72). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of hydroxysafflor yellow A and dissolve in 25% methanol to produce a solution containing 0.13 mg per mL.
   (3) Sample solution: Weigh accurately 0.4 g of powdered sample and place it in a conical flask with stopper, add accurately 50 mL of 25% methanol, weigh, ultrasonicate for 40

minutes, cool, weigh again, replenish the loss of the weight with 25% methanol, mix well, filter and use the successive filtrate.

(4) Chromatographic system: The liquid chromatography is equipped with an UV detector (403 nm) and a column packing L1. The number of theoretical plates of the peak of hydroxysafflor yellow A should not be less than 3,000.

(5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Hydroxysafflor yellow A (%)=5(r_U/r_S) (C_S) / (W)

r_U: peak area of hydroxysafflor yellow A of sample solution

r_S: peak area of hydroxysafflor yellow A of reference standard solution

C_S: concentration of hydroxysafflor yellow A of reference standard solution (mg/mL)

W: weight of test sample (g) calculated with dried sample.

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place and preserve in a well-closed container, and protect from moisture and insects.
Usage: Blood-regulating medicinal (Blood-activating and stasis-dispelling medicinal).
Property and flavor: Warm; pungent.
Meridian tropism: Heart and liver meridians.
Effects: Activate blood and dissipate stasis, promoting menstruation to relieve pain.
Administration and dosage: 3~10 g.
Precaution and warning: Use cautiously during pregnancy.

CARYOPHYLLI FLOS
丁香
Ding Sing / Ding Xiang
Clove

Clove is the dried flower bud of *Syzygium aromaticum* (L.) Merr. & L.M.Perry (Fam. Myrtaceae).
It contains not less than 15.0% (v/w) of clove oil.

Description: 10~17.5 mm in length, dark brown or dark red. Hypanthium rectangular prism, slightly compressed. Ovary 2-celled, axile placenta, ovules numerous. Sepals 4, fleshy. Corolla subglobular, petals 4, imbricated, enclosing numerous stamens and one style. Odour strongly aromatic; taste pungent and numb. Sinking or upright in the water, oily after pressing.

Microscopic identification:

1. **Transverse section:** Hypanthium (ovary) of *Syzygium aromaticum*: Epidermis composed of isodiametric sclerenchymatous cells, covered with extremely thick cuticle, with Ranunculaceae type stomata, numerous large oblong oil cavities scattered in the outer layer of parenchymatous tissue, about 200 μm in diameter. Vascular bundles scattered in the inner side of collenchymatous tissue, arranged in a ring. A few sclerenchymatous fibers and spiral vessels scattered among vascular bundles, the innermost layer of parenchymatous tissue chain mesh-shaped, intercellular spaces extremely numerous. Every layer of parenchymatous tissue and pith contains small clusters of calcium oxalate.
2. **Powder:** Dark brown. Fragments of parenchymatous tissue contain large elliptical oil cavities, small spiral vessels and a few fusiform fibers with thick walls, occasionally with crystal tissue. Clusters of calcium oxalate 10~15 μm in diameter, occasionally prism crystals are found. Walls of anther with particular reticular cells. Pollen grains extremely numerous, tetragonal, 15~20 μm in diameter.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of eugenol and dissolve in methanol to produce a solution containing 16 μL per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of petroleum ether (30~60℃) and ethyl acetate (9:1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, remove the plate, dry in air. Spray with 5% vanillin/H_2SO_4 TS and heat at 105℃ until the spots become visible. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and reference standard solution.

Impurities and other requirements:

1. Total ash: Not more than 7.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
3. Foreign matter: Not more than 1.0%, except for pedicels (General rule 6005).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).

5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
Clove oil: Carry out the method for determination of volatile oil (General rule 6013).

Storage: Refrigerate and preserve in a well-closed container.
Usage: Interior-warming medicinal.
Property and flavor: Warm; pungent.
Meridian tropism: Spleen, stomach, lung, and kidney meridians.
Effects: Warm the middle to downbear counterflow, tonify kidney and assist yang.
Administration and dosage: 1~5 g.

CASSIAE SEMEN
決明子
Jyue Ming Zih / Jue Ming Zi
Cassia Seed

Cassia seed is the dried ripe seed of *Senna obtusifolia* (L.) H.S.Irwin & Barneby (*Cassia obtusifolia* L.) or *Senna tora* (L.) Roxb. (*Cassia tora* L.) (Fam. Leguminosae).
It contains not less than 10.0% of dilute ethanol-soluble extractives, not less than 10.0% of water extractives and not less than 0.12% of chrysophanol.

Description:
1. Seed of *Senna obtusifolia*: Rhomboidal-cuboid or shortly cylindrical, one end even and oblique, the other end acuminate, horseshoe-like, 4~7 mm in length, 2~4 mm in width, relatively larger. Externally brown or blackish-brown, with an pale yellow dented line on each side of a rib, hilum pale yellow and dented at the center of one end, fracture grayish-white. Odour slight; viscous on chewing.
2. Seed of *Senna tora*: Flattened cylindrical, 3~5 mm in length, 2~3 mm in width, relatively small. Externally brownish-red or brown, with pale yellow bands on both sides of the rib, hilum white and dented at the center of one end.

Microscopic identification:
1. **Transverse section:**
   (1) Seed of *Senna obtusifolia*: The outermost layer was 1 layer of thick cuticle, inner 1 row of palisade cells present, walls unevenly thickened, 2 light lines existed in 1/2 and lower 1/3 of the cells, respectively, inside showing 1 layer of brace cells, slightly dumbbell-shaped, walls thickened, cell boundary large. Nutritive layer composed of 6~8 rows of parenchymatous cells, containing clusters of calcium oxalate, 3~10 μm in diameter. Endotesta composed of 1 row of rectangular cells, arranged in order, containing prisms of calcium oxalate. Endosperm with walls unevenly thickened, containing clusters of calcium oxalate, oil droplets, aleurone granules, pigments and mucilage contents. Cotyledon cells contain clusters of calcium oxalate, 3~10 μm in diameter.
   (2) Seed of *Senna tora:* The outermost layer was 1 layer of transparent cuticle, inner 1 row of palisade cells present with walls thickened, 1 layer of brace cells present under the palisade cells, slightly dumbbell-shaped, walls thickened, intercellular spaces large. Nutritive layer composed of 5~6 rows of parenchymatous cells, containing numerous clusters of calcium oxalate, 3~8 μm in diameter. Endotesta composed of 1 row of rectangular cells, arranged in order, containing crystals of calcium oxalate. Endosperm cells irregular, containing clusters of calcium oxalate, oil droplets, starch granules and pigments. Clusters of calcium oxalate relatively large, 3~10 μm in diameter.
2. **Powder:**
   (1) Seed of *Senna obtusifolia*: Brown. Cuticle layer 10~20 μm thick, transparent, containing sinuously reticulated patterns on the surface. Palisade cells with walls thickened and slightly shrunken, polygonal in surface view. Brace cells dumbbell-shaped in lateral view, subrounded in surface view, 25~50 μm in diameter, annularly thickened with 2 concentric circles. Parenchymatous cells of nutritive layer contain crystals of calcium oxalate, 3~10 μm in diameter. Endosperm cells with walls unevenly thickened and mucilaginous, containing clusters of calcium oxalate and aleurone granules. Cotyledon cells contain clusters of calcium oxalate, 10~25 μm in diameter.
   (2) Seed of *Senna tora:* Dark brown. Fragments of cuticle relatively rare, polygonal and with reticulated patterns on the surface. Brace cells with walls thickened on the outer part, some parts only with 1 layer of concentric circles in surface view, with curving and fine threads inside. Clusters of calcium oxalate 10~19 μm in diameter, prisms of calcium oxalate also present.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and evaporate the filtrate to dryness, dissolve

the residue in 10 mL of water, add 1 mL of hydrochloric acid, heat under reflux for 30 minutes, cool, extract twice each with 20 mL of ethyl ether, combine the ethyl acetate extracts, evaporate to dryness, dissolve the residue in 1 mL of methanol.

2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of chrysophanol and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane, ethyl acetate, and formic acid (15:5:1) as the developing solvent. Apply 2 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 12.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 5.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).
9. Aflatoxins
   (1) Aflatoxins (sum of B_1, B_2, G_1 and G_2): Not more than 10.0 ppb (General rule 6307).
   (2) Aflatoxin B_1: Not more than 5.0 ppb (General rule 6307).

Assay:

1. Chrysophanol:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and a solution of 0.1% phosphoric acid as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of chrysophanol and dissolve in methanol to produce a solution containing 40 μg per mL.
   (3) Sample solution: Weigh accurately 0.5 g of powdered sample, transfer to a conical flask with stopper, accurately add 50 mL of methanol and weigh, heat under reflux for 3 hours, cool, weigh again, replenish the loss of the weight with methanol, mix well, and filter. Evaporate the filtrate to dryness. Add 30 mL of 10% hydrochloric acid to the filtrate. heat under reflux for 1 hour, cool, extract the filtrate for four times with 30 mL of ethyl acetate. Combine ethyl acetate extracts, and evaporate to dryness. Dissolve the residue, transfer to a 25-mL volumetric flask, make up to volume with methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (254 nm) and a column packing L1. The column temperature is maintained at 35℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of chrysophanol should not be less than 8,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~15	40	60
15~30	40→90	60→10
30~40	90	10

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   Cysophanol (%)=0.0025/r_S) (C_S) / (W)

   r_U: peak area of chrysophanol of sample solution

   r_S: peak area of chrysophanol of reference standard solution

   C_S: concentration of chrysophanol of reference standard solution (μg/mL)

   W: weight of test sample (g) calculated with dried sample.
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place, and protect from moisture.

Usage: Heat-clearing medicinal (Heat-clearing and fire-purging medicinal).

Property and flavor: Mild cold; sweet, bitter and salty.

Meridian tropism: Liver and large intestine meridians.

Effects: Clear liver and tonify kidney, dispel wind to brightens eyes, moisten the intestine and relax the bowel.

Administration and dosage: 9~15 g.

CATECHU
兒茶
Er Cha / Er Cha
Catechu

Catechu is the dried evaporated decoction prepared from the wood of *Acacia catechu* (L. f.) Willd. (Fam. Leguminosae) or from twig with leaf of *Uncaria gambir* (W.Hunter) Roxb. (Fam. Rubiaceae).
It contains not less than 70.0% of dilute ethanol-soluble extractives, not less than 60.0% of water extractives and not less than 21.0% of the total amount of catechin and epicatechin.

Description: Irregular or square masses, externally reddish-brown or black, smooth and slightly lustrous. Texture hard, easily broken, fracture irregular, porous, lustrous, reddish-brown. Odour slight; taste astringent, bitter and then sweet.

Microscopic identification:
Powder: Brown. Raphides bundles and yellow contents present.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 0.5 g of powdered sample to 30 mL of ethyl ether, ultrasonicate for 10 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 5 mL of methanol.
2. Reference drug solution: Take 0.5 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of catechin and epicatechin, dissolving in methanol to produce a solution containing 0.2 mg per mL of each
4. Procedure: Use silica gel plate with sodium carboxymethyl cellulose as the coating substance and a solution of *n*-butanol, acetic acid, and water (3:2:1) as the developing solvent. Apply 5 μL of the sample solution and reference drug solution and 2 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 14.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 5.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 3.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
1. Catechin and epicatechin:
   (1) Mobile phase: A solution of acetonitrile and water (15:85). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of each and dissolve in a solution of methanol and water (1:1) to produce a solution containing 0.15 mg and 0.1 mg per mL of each.
   (3) Sample solution: Weigh accurately 20 mg of powdered sample and place it in a 50-mL amber volumetric flask, add 40 mL of a solution of methanol and water (1:1), ultrasonicate for 20 minutes, make up to volume with 50% methanol, mix well, filter and use the filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (280 nm) and a column packing L1. The column temperature is maintained at room temperature. Inject reference standard solution into the liquid chromatography apparatus for 5 times, and record the peak areas. The relative standard deviation of the peak area of catechin and epicatechin should not be more than 1.5%.
   (5) Procedure: Inject accurately 10~20 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Catechin or epicatechin (%)= 5000(r_U/r_S) (C_S) / (W)
   r_U: peak area of catechin or epicatechin of sample solution
   r_S: peak area of catechin or epicatechin of reference standard solution
   C_S: concentration of catechin or epicatechin of reference standard solution (mg/mL)
   W: weight of test sample (g) calculated with dried sample.
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place, and protect from moisture.
Usage: Astringent medicinal.
Property and flavor: Mild cold; bitter and astringent.
Meridian tropism: Lung and heart meridians.
Effects: Astringes moisture and wound healing, promote tissue regeneration to hemostatic, clear heat to resolve phlegm.
Administration and dosage: 1~4 g.

CELOSIAE CRISTATAE FLOS
雞冠花
Ji Guan Hua/ Ji Guan Hua
Cockscomb Flower

Cockscomb flower is the dried inflorescence of *Celosia cristata* L. (Fam. Amaranthaceae).
It contains not less than 11.0% of dilute ethanol-soluble extractives, not less than 10.0% of water extractive and not less than 0.21% of the total amount of isorhamnetin and kaempferol.

Description: Spikes mostly flatten and fleshy, cockscomb-shaped, 8~25 cm in length, 5~20 cm in width, The upper margin broad, with wrinkles and densely linear scales, narrowed towards the base, with flat stem remained. Externally red, purplish-red or yellowish-white, with numerous florets densely aggregated below the middle part, persistent bracts and perianth of the florets membranous. Fruit utricular, seeds oblate and reniform, black, lustrous. Texture light and flexible. Odour slight; taste weak.

Microscopic identification:
1. **Transverse section:**
   Inflorescence of *Celosia cristata*: Epidermis composed of 1 layer of cells. Cortex narrow, Xylem well developed, composed of vessels, xylem fibres and xylem parenchymatous cells. Vessels singly scattered or in groups. Phloem relatively narrow. Pith broad, collateral vascular bundles scattered in the outer side of the pith. Sandy crystals of calcium oxalate occasionally present in cortex or parenchymatous cells of pith.
2. **Powder:** Light brown. Epidermal cells of peduncle subrectangular or subrectangular, with walls thin. Epidermal cells of testa reddish-brown, polygonal, with reticular striations thickened. Pollen grains spherical, 13~32 μm in diameter, small protrusions and scattered pits present in the outer walls. Vessels mostly scalariform or spiral, 6~28 μm in diameter, Sandy crystals of calcium oxalate present in parenchymatous cells, extremely tiny, bright white or polychromatic under the polarized moicroscope. The fibers of peduncle slender, acuminate at the end, 154~732 μm in length, 5~22 μm in diameter, small branches or septa occasionally visible, walls thin, unlignified or slightly lignified, oblique pits visible.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 0.5 g of powdered sample to 20 mL of ethanol, water, and hydrochloric acid (25:10:4), heat under reflux for 30 minutes, filter, centrifuge for 10 minutes, evaporate 10 mL of the supernatant to dryness, and dissolve the residue in 10 mL of methanol.
2. Reference drug solution: Take 0.5 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of kaempferol and dissolve in methanol to produce a solution containing 0.1 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane, ethyl acetate, formic acid, and glacial acetic acid (10:6:0.5:0.5) as the developing solvent. Apply 5 μL of each of the sample solution and reference drug solution and 2 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with a 1% solution of $AlC1_3$/EtOH TS and heat at 110℃ until the spots become visible. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 14.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 12.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
Isorhamnetin and kaempferol:
1. Mobile phase: Methanol as the mobile phase A, and a solution of 0.2% phosphoric acid as the mobile phase B.
2. Reference standard solution: Weigh accurately a quantity of isorhamnetin and kaempferol and dissolve in methanol to produce a solution containing 10 μg and 20 μg per mL of each.
3. Sample solution: Weigh accurately 0.5 g of powdered sample and place it in a 50-mL round bottom flask with stopper, then add accurately 20 mL of a solution of ethanol, water and hydrochloric

acid (25:15:4), heat under reflux for 30 minutes. Transfer the supernatant to a 50-mL volumetric flask. Repeat the extraction of the residue one more time, combine the supernatant, and make up to volume with ethanol, mix well, filter and use the filtrate.

4. Chromatographic system: The liquid chromatography is equipped with an UV detector (365 nm) and a column packing L1. The column temperature is maintained at 25℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of isorhamnetin and kaempferol should not be less than 8,000 of each.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~5	35	65
5~30	35→100	65→0

5. Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Isorhamnetin or kaempferol (%)=0.005 (r_U/r_S) (C_S) / (W)

r_U: peak area of isorhamnetin or kaempferol of sample solution

r_S: peak area of isorhamnetin or kaempferol of reference standard solution

C_S: concentration of isorhamnetin or kaempferol reference standard solution (μg /mL)

W: weight of test sample (g) calculated with dried sample.

Storage: Store in a ventilated and dry place.
Usage: Astringent medicinal.
Property and flavor: Cool, sweet and astringent.
Meridian tropism: Liver and large intestine meridians.
Effects: Astringes, cool the blood, hemostatic, stanch vaginal discharge, kills worms.
Administration and dosage: 6~12 g.

CELOSIAE SEMEN
青葙子
Cing Siang Zih / Qing Xiang Zi
Feather Cockscomb Seed

Feather cockscomb seed is the dried ripe seed of *Celosia argentea* L. (Fam. Amaranthaceae).

Description: Oblate, relatively thick in the center, 1~1.5 mm in diameter, about 0.5 mm thick. Externally black or reddish-black, smooth, lustrous, with fine and reticulate wrinkles, a slightly dented hilum on the lateral side. Often with yellowish-white cap-shaped shell, apex with filamentous style, 4~5 mm in length. Testa thin and fragile, fracture white. Odour slight; taste weak.

Microscopic identification:
Powder: Blackish-gray. Epidermal cells of testa polygonal, 15~90 μm in diameter, dark reddish-brown, with reticular striations. Endotesta cells polygonal, 20~70 μm in diameter, pale yellow, filled with slender striations.

Impurities and other requirements:
1. Loss on drying: Not more than 13.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 8.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 3.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Storage: Store in a cool and dry place, and protect from moisture.
Usage: Heat-clearing medicinal (Heat-clearing and fire-purging medicinal).
Property and flavor: Mild cold; bitter.
Meridian tropism: Liver meridians.
Administration and dosage: 9~15 g.

CENTELLAE HERBA
積雪草
Ji Syue Cao / Ji Xue Cao
Asiatic Pennywort Herb

Asiatic pennywort herb is the dried herb of *Centella asiatica* (L.) Urb. (Fam. Umbelliferae). Commonly known as “Lei Gong Gen”, “Lao Gong Gen” or “Han Ke Cao”.
It contains not less than 10.0% of dilute ethanol-soluble extractives and not less than 11.0% of water extractives and not less than 1.73% of the total amount of asiaticoside and madecassoside.

Description: Coiled into a mass, root cylindrical, 2~4 cm in length, 1~1.5 mm in diameter; epidermal pale yellow or grayish yellow. Stems are slender and curved, yellow-brown, with fine longitudinal wrinkles, and often have roots on the nodes. The leaves are more shrunken and broken, and the intact ones are nearly circular or kidney-shaped after being flattened, 1~4 cm in diameter; grayish green with rough and blunt teeth at the edges; the petiole is 3~6 cm in length, twisted. Umbel axillary, short. The double-suspension fruit is oblate, with prominent ridges and fine netting, and the stems are very short. Odor slight, taste light.

Microscopic identification:

1. **Transverse section:**
   (1) Stem of *Centella asiatica*: Epidermal cells are subround or subsquare. Below are 2~4 columns of collenchymatous cells. The cortex is 7~9 rows of parenchyma cells, and the walls of the outer array of cells are unevenly thickened. Vertical vascular bundles are 6~8, arranged in a ring; the outer side of the phloem is a micro-lignified fiber group; the formation layer is obvious, which is 2~3 columns of small cells; the xylem catheter is arranged radially. The pith is composed of larger, round, parenchyma cells. The secretory tract is present in the cortex and myeloid line, 23~34μm in diameter , 5~7 surrounding secretory cells.
   (2) Leaf *Centella asiatica*: Upper, and epidermis cells are arranged irregularly. palisade tissue 1~2 columns; spongiocyte 4~6 columns, arranged loosely, both cell boundaries are blurred. collenchymatous cells exist in the rib vascular bundles in the leaf surface and are vertical.
2. **Powder:** Yellowish-brown. Non-glandular hair is multi-celled, has been broken. The pores are infinitive or inequality. The calcium oxalate crystal is a large number of crystals, 3 to 21 μm in diameter, exhibits multicolor under polarized light. The pollen grains are spherical, 11~43 μm in diameter, deeply split, have 3 developmental holes. Calcium oxalate cluster crystals are more common. The catheter is mostly a threaded catheter, 4 to 71 μm in diameter. The secretory tract contains a lot of yellow matter.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 2.0 g of powdered sample to 10 mL of 70% ethanol, ultrasonicate for 30 minutes, centrifuge, filter and use the filtrate.
2. Reference drug solution: Take 2.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of asiaticoside and madecassoside in methanol to produce a solution containing 1.0 mg per mL of each.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, glacial acetic acid, and water (8:3:3) as the developing solvent. Apply 2 μL of each of the sample solution and reference drug solution, 5 μL of the reference standard solution for asiaticoside, and 2 μL of the reference standard solution for madecassoside to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 13.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 13.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 3.5% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. 7Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:

Asiaticoside and madecassoside:

1. Mobile phase: Acetonitrile as the mobile phase A, and water as the mobile phase B.
2. Reference standard solution: Weigh accurately a quantity of asiaticoside and madecassoside and dissolve in 75% ethanol to produce a solution containing 0.15 mg and 0.25 mg per mL of each.
3. Sample solution: Weigh accurately 0.5 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 10 mL of 75% ethanol, ultrasonicate for 30 minutes, centrifuge for 10 minutes. Transfer the supernatant to a 25-mL volumetric flask. Repeat the extraction of the residue one more time, combine the supernatant, and make up to volume with 75% ethanol, mix well, filter and use the filtrate.
4. Chromatographic system: The liquid chromatography is equipped with an UV detector (205 nm) and a column packing L1. The column temperature is maintained at 25℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of asiaticoside and madecassoside should not be less than 10,000 of each.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~10	5→20	95→80
10~40	20→30	80→70

5. Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Asiaticoside or madecassoside (%)=2.5(r_U/r_S) (C_S) / (W)

r_U: peak area of asiaticoside or madecassoside of sample solution

rs: peak area of asiaticoside or madecassoside of reference standard solution
Cs: concentration of asiaticoside or madecassoside of reference standard solution (mg /mL)
W: weight of test sample (g) calculated with dried sample.

Storage: Store in a ventilated and dry place.
Usage: Heat-clearing medicinal (Heat-clearing and dampness-drying medicinal).
Property and flavor: Cold; bitter and pungent.
Meridian tropism: Liver, spleen, and kidney meridians.
Effects: Clear heatand drain dampness, activate blood to hemostatic, disperse swelling and detoxify.
Administration and dosage: 15~30 g.

CENTIPEDAE HERBA
鵝不食草
E Bu Shih Tsao/ E Bu Shi Cao
Small Centipeda Herb

Small centipeda herb is the dried herb of *Centipeda minima* (L.) A.Braun & Asch. (Fam. Compositae).
It contains not less than 12.0% of dilute ethanol-soluble extractives and not less than 14.0% of water extractives and not less than 0.05% of isochlorogenic acid A.

Description: Twisted into masses. Rootlets slender, pale yellow. Stem thin, with numerous branch. Texture fragile, easily broken, fracture yellowish-white. Leaves small, nearly sessile; lamina usually crumpled and broken, spoon-shape as whole, externally grayish-green or brown, with 3~5 planges in margin. Inflorescence yellow or yellowish-brown. Odour aromatic, irritant after longer semlling; taste bitter and slightly pungent.

Microscopic identification:
1. **Transverse section:**
   (1) Root of *Centipeda minima*: Epidermis cells of root subrounded or prolonged tangentially, with thick walls; cortex cells relatively large, subrounded, 5~8 rows, with numerous clefts; endodermis distinct; phloem narrow, with prolonged tangentially cells; xylem broad, with vessels arranged radially, mostly bordered-pitted.
   (2) Stem of *Centipeda minima*: Epidermis cells 1 row in transversely cut section, subrunded or prolonged tangentially; cortex cells 5~8 rows, with relatively large cliefs; fibers 4~15 in bundles outside the phloem; phloem narrow, with cells prolong tangentially; xylem broad, with vessels arranged in radially, mostly spiral, scalariform and reticular; pith distinct.
2. **Powder:** Grayish-green to grayish-brown. Epidermis cells of stem rectangular or subpolygonal, with walls slightly thickened, cuticle striations indistinct. Epidermis cells of leaf subpolygonal, anticlinal walls thin and undulating in surface view; stomata anomocytic, with 4~6 subsidary cells. Glandular hairs sole-shaped in surface view, with cells arranged in pairs, containing yellow contents. Non-glandular hairs with the head 2-celled, one unicellular, slightly short; another bicellular, basal cells slightly short, apical cells hook-shape or curved; fine cuticle striations present at the 2/3 of upper surface.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of isochlorogenic acid A and dissolve in methanol to produce a solution containing 0.2 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of dichloromethane, ethyl acetate, formic acid, and water (5:5:2:0.1) as the developing solvent. Apply 2 μL of each of the sample solution and reference drug solution and 1 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 12.0% dry at 105°C for 5 hours (General rule 6015).
2. Total ash: Not more than 29.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 18.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 10.0 ppm (General rule 2251, 6301).

Assay:
1. Isochlorogenic acid A:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and a solution of 0.1% phosphoric acid as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of isochlorogenic acid A and dissolve in methanol to produce a solution containing 10 μg per mL.
   (3) Sample solution: Weigh accurately 1.0 g of

the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 25 mL of 50% ethanol, vortex oscillation for 30 seconds, ultrasonicate for 30 minutes. Centrifuge for 15 minutes. Transfer the supernatant to a 50-mL volumetric flask. Repeat the extraction of the residue one more time, combine the supernatant, and make up to volume with 50% ethanol, mix well, filter and use the filtrate.

(4) Chromatographic system: The liquid chromatography is equipped with an UV detector (326 nm) and a column packing L1. The column temperature is maintained at room temperature. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The ratio may be adjusted if necessary. The number of theoretical plates of the peak of isochlorogenic acid A should not be less than 6,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~30	10→20	90→80

(5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Isochlorogenic acid A (%)=0.005 (r_U/r_S) (C_S) / (W)

r_U: peak area of isochlorogenic acid A of sample solution

r_S: peak area of isochlorogenic acid A of reference standard solution

C_S: concentration of isochlorogenic acid A of reference standard solution (μg /mL)

W: weight of test sample (g) calculated with dried sample.

Storage: Store in a ventilated and dry place.
Usage: Exterior-releasing medicinal (Pungent-warm exterior-releasing medicinal).
Property and flavor: Warm; pungent.
Meridian tropism: Lung meridians.
Effects: Dispel wind, dissipate cold, drain dampness, remove nebula, relieve the stuffy nose, suppress cough, dispel phlegm, calm panting.
Administration and dosage: 3~12 g; used an appropriate amount for external use.

CHAENOMELIS FRUCTUS
木瓜
Mu Gua / Mu Gua
Floweringquince Fruit

Floweringquince fruit is the dried ripe fruit of *Chaenomeles speciosa* (Sweet) Nakai (Fam. Rosaceae), commonly known as “Zhou Pi Mu Gua”.

It contains not less than 25.0% of dilute ethanol-soluble extractives, not less than 20.0% of water extractives and not less than 0.5% of the total amount of oleanolic acid and ursolic acid.

Description: Oblong, mostly in longitudinally halves, 4~9 cm in length, 2~5 cm in width, sarcocarp about 1 cm thick. Externally brownish-red or purplish-red, with irregular and deep wrinkles; edge of cut surface rolled inwards, sarcocarp pale reddish-brown, central with dented locules. Seed brownish-yellow, mostly fallen off. Texture hard. Odour slight; taste slightly sour and astringent.

Microscopic identification:

1. **Transverse section**:
   Fruit of *Chaenomeles speciosa*: 1 layer of epidermis cells of the receptacle, outer wall is extremely thick, Containing brown matter; cortex thick, stone cell clusters on the outside. Intermittently arranged into a ring; parallel vascular bundles on the inside, Sparse annular arrangement. Stone cells layered exocarp of pericarp, composed of more than 10 layers of dense stone cells; stone cells polygonal or slightly extending, walls thickened, pit canals distinct. Walls of parenchymatous cells of mesocarp slightly thickened, scattered with small vascular bundles. Endocarp composed of several layers of flat sclerenchyma cells, some cells contain brown contents.
2. **Powder:** Dark reddish-brown. Stone cells colorless, pale yellow or orange-yellow, subrounded, subrectangular, strip-shaped, oblong, subtriangle or subsquare, 12~82 μm in diameter, up to 136 μm long, wall 5~20 μm thick, mostly with distinct striations, pit canals fine, some lumen contains brown or reddish-brown contents. Walls of parenchymatous cells of pericarp (original receptacle) slightly thickened, extreme shrunken, cell boundary indistinct, containing yellowish-brown or dark brown contents. Some fibers cross-overlapping in bundles, 11~27 μm in diameter, walls vary in thickness, lignified, usually with longitudinal clefts, lumen contains brown contents. Parenchymatous cells of mesocarp shrunken, pale yellow or brown. Epidermal cells of pericarp (original receptacle) subrectangular in sectional view, the outer wall 14~32 μm thick, cutinized, lumen contains reddish-brown contents. Reticulate and spiral vessels and pigment masses also exist.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 3.0 g of powdered sample to 10 mL of ethanol, ultrasonicate for 1 hour, evaporate the filtrate to dryness, dissolve the residue in 5 mL ethanol.
2. Reference drug solution: Take 3.0 g of the reference drug and the method of preparation is the same as which is described above.

3. Reference standard solution: Weigh accurately a quantity of ursolic acid and dissolve in ethanol to produce a solution containing 0.5 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane, ethyl acetate, acetone, and formic acid (6:0.5:1:0.1) as the developing solvent. Apply 2~3 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with a 10% solution of H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 15.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 5.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
1. Oleanolic acid and ursolic acid:
   (1) Mobile phase: A solution of acetonitrile, methanol, and 0.3% ammonium acetate (67:12:21). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of oleanolic acid and ursolic acid and dissolve in methanol to produce a solution containing 0.1 mg per mL of each.
   (3) Weigh accurately 0.5 g of powdered sample and place it in a conical flask with stopper, then add accurately 25 mL of methanol, weigh, ultrasonicate for 20 minutes, cool, weigh again, replenish the loss of the weight with methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (210 nm) and a column packing L1. The column temperature is maintained at 35℃. The flow rate is about 1 mL/min. The column temperature is maintained at room temperature. Inject reference standard solution into the liquid chromatography apparatus for 5 times, and record the peak areas. The relative standard deviation of the peak area of oleanolic acid and ursolic acid should not be more than 1.5%.
   (5) Inject accurately 20 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Oleanolic acid or ursolic acid: (%)=2.5 (r_U/r_S) (C_S) / (W)
   r_U: peak area of oleanolic acid, or ursolic acid of sample solution
   r_S: peak area of oleanolic acid, or ursolic acid of reference standard solution
   C_S: concentration of oleanolic acid, or ursolic acid of reference standard solution (mg/mL)
   W: weight of test sample (g) calculated with dried sample.
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place or preserve in a dry and well-closed container, and protect from moisture and insects.
Usage: Dampness-dispelling medicinal (Wind-dampness-dispelling medicinal).
Property and flavor: Warm; sour.
Meridian tropism: Liver and spleen meridians.
Effects: Relax sinews and activate collateral, transforms dampness to opens stomach.
Administration and dosage: 6~12 g.

CHEBULAE FRUCTUS
訶子
He Zih / He Zi
Medicine Terminalia Fruit

Medicine terminalia fruit is the dried ripe fruit of *Terminalia chebula* Retz. or *Terminalia chebula* Retz. var. *tomentella* (Kurz) C.B.Clarke (Fam. Combretaceae).
It contains not less than 36.0% of dilute ethanol-soluble extractives and not less than 40.0% of water extractives and not less than 1.2% of gallic acid.

Description: Ovate, 2~4 cm in length, 1.5~2 cm in diameter. Externally grayish-brown or yellowish-brown, slightly lustrous, scattered with 5~6 longitudinal ribs and irregular longitudinal wrinkles, base with a round scar of fruit stalk. Sarcocarp 0.2~0.4 cm thick, yellowish-brown; kernels obtuse round, yellowish-white, texture compact, containing pale yellow seeds. Odour slight; taste sour and astringent, then sweet.

Microscopic identification:

1. **Transverse section:**
   Pericarp of *Terminalia chebula*: Exocarp composed of 5~8 rows of sclerenchymatous cells, cells containing brown contents. Mesocarp composed of parenchymatous cells, sclerenchymatous cell ring and vascular bundles. Parenchymatous cells 2~5 rows, subrounded, containing relatively large oil droplets and clusters of calcium oxalate. Sclerenchymatous cell ring composed of numerous fiber-shaped sclerenchymatous cells arranging criss-cross, mostly elongated tangentially. Vascular bundles irregularly scattered.
2. **Powder:** Grayish-yellow. Vessels mainly pitted, about 60 μm in diameter. Stone cells in groups, about 15~50 μm in diameter, subrounded or rectangular. Fibers in bundles, criss-cross arranged, about 9~30 μm in diameter. Parenchymatous cells contain oil droplets and clusters of calcium oxalate.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 3.0 g of powdered sample to 10 mL of ethanol, ultrasonicate for 20 minutes, filter and use the filtrate.
2. Reference drug solution: Take 3.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of gallic acid and dissolve in ethanol to produce a solution containing 0.5 mg per mL
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of toluene, ethyl acetate, and formic acid (6:3:1) as the developing solvent. Apply 5 μL of each of the sample solution and reference drug solution and 2 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 254 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained with the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 12.0% dry at 105°C for 5 hours (General rule 6015).
2. Total ash: Not more than 4.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Gallic acid
   (1) Mobile phase: Acetonitrile as the mobile phase A, and a solution of 0.1% phosphoric acid as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of gallic acid and dissolve in water to produce a solution containing 25 μg per mL.
   (3) Sample solution: Weigh accurately 0.1g of the powdered sample in a 50-mL centrifuge tube, add 20 mL of 50% ethanol, ultrasonicate for 30 minutes, filter with filter paper. Repeat the extraction of the residue one more time. Combine the filtrate, transfer to 50-mL volumetric flask, make up to volume with 50% ethanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (326 nm) and a column packing L1. The column temperature is maintained at room temperature. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of gallic acid should not be less than 3,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~5	5	95
5~15	5→30	95→70
15~18	30→100	70→0
18~20	100	0

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Gallic acid (%)=0.005 (r_U/r_S) (C_S) / (W)
   r_U: peak area of gallic acid of sample solution
   r_S: peak area of gallic acid of reference standard solution
   C_S: concentration of gallic acid of reference standard solution (μg/mL)
   W: weight of test sample (g) calculated with dried sample.
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from mold and insects.
Usage: Astringent medicinal.

Property and flavor: Neutral; bitter, sour, astringent.
Meridian tropism: Lung and large intestine meridians.
Effects: Costrain the lung, direct qi downward, soothe the throat, astringe the intestines and antidiarrheal.
Administration and dosage: 3~10 g.

CHRYSANTHEMI FLOS
菊花
Jyu Hua / Ju Hua
Chrysanthemum Flower

Chrysanthemum flower is the dried capitulum of *Chrysanthemum morifolium* Ramat. Tzvel. (Fam. Compositae). It is classified into "Bo Jyu", "Chu Jyu", "Gong Jyu" and "Hang Jyu" according to different localities and variations in processing methods.
It contains not less than 22.0% of dilute ethanol-soluble extractives, not less than 22.0% of water extractives, not less than 0.1% (v/v) of volatile oil, not less than 0.2% of chlorogenic acid and not less than 0.08% of luteolin-7-*O*-glucoside.

Description:
1. Bo Jyu: Obconical or cylindrical, 1.5~3 cm in diameter. Involucre dish-shaped; bracts 3~4 layers, ovate or elliptical, yellowish-green or brownish-green, the outer surface covered with white hairs, margin membranous. Receptacle hemispheroidal. Ligulate florets in the outer, several rows, female, whitish or pale yellowish-white, strongly straight and upward, longitudinally folded and wrinkled, scattered with golden glandular spots; tubular florets abundant, hermaphrodite, occurring in the center, concealed by the ligulate florets, yellow, with 5 terminal teeth. Achenes undeveloped, pappus absent. Texture light and soft, lax and fragile when dried. Odour aromatic; taste sweet and slightly bitter.
2. Chu Jyu: Relatively small, irregularly spheroidal or oblate, 1~1.5 cm in diameter; ligulate florets whitish, 1.5 cm in length, about 3 mm in width, irregularly twisted, curved inward, margin wrinkled, sometimes scattered with pale brown glandular spots; tubular florets mostly concealed; base scales indistinct. Texture soft. Odour aromatic.
3. Gong Jyu: Oblate or irregularly spheroidal, 1.5~2.5 cm in diameter; ligulate florets white or whitish, obliquely upward, the upper part folded outward, margin slightly curved inward and wrinkled, glandular spots usually absent; tubular florets few, exposed; base scales extremely less.
4. Hang Jyu: Dish-shaped or oblate, 2.5~4 cm in diameter; ligulate florets whitish or yellow, spread flatly or folded slightly, agglutinated to each other, glandular spots usually absent; tubular florets abundant, exposed; base scales indistinct Texture soft.

Microscopic identification:

Powder: Pale yellow. Pollen grains yellow, subspheroidal, outer walls relatively thickened, with thick protuberance, 3~7 μm in length, with 3 germinal pores. T-shaped hairs mostly broken, apical cells long and large, 375~525 μm in length, 30~40 μm in diameter, basal cells relatively small, 2~5. Glandular hairs without stalk paramecium- like, 4 to 6-celled, arranged in pairs, covered with cuticle. Epidermal cells of corolla with anticlinal walls sinuous, periclinal walls with fine and radial striations; epidermal cells of bracts slender, anticlinal walls sinuous, periclinal walls with thick striations. Cell walls in inner walls of pollen sac reticulate or strip-shaped thickened.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 20 mL of petroleum ether (30~60℃), ultrasonicate for 10 minutes, discard the petroleum ether, evaporate the residue to dryness, add 1 mL dilute hydrochloric acid and 50 mL of ethyl acetate, ultrasonicate for 30 minutes, filter and evaporate the filtrate to dryness, dissolve the residue in 2 mL of methanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of chlorogenic acid and dissolve in methanol to produce a solution containing 0.5 mg per mL.
4. Procedure: Use polyamide as the coating substance and the upper layer of toluene, ethyl acetate, formic acid, glacial acetic acid, and water (1:15:1:1:2) as the developing solvent. Apply 0.5~1 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained with the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Total ash: Not more than 10.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).
   ※Note: "When this TCM herb is sold commercially, the limits of heavy metals, sulfur dioxide and aflatoxins should follow the food standard."

Assay:

1. Chlorogenic acid and luteolin-7-*O*-glucoside:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and a solution of 0.1% phosphoric acid as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of chlorogenic acid and luteolin-7-*O*-glucoside in a brown volumetric flask and dissolve in 70% methanol to produce a solution containing 35 μg and 25 μg per mL of each.
   (3) Sample solution: Weigh accurately 0.25 g of the powdered sample and place it in a conical flask with stopper, accurately add 25 mL of 70% methanol, stopper tightly and weigh, ultrasonicate for 40 minutes, cool, weigh again, replenish the loss of the weight with 70% methanol, mix well, filter and use the filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (348 nm) and a column packing L1. The column temperature is maintained at 25℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~11	10→18	90→82
11~30	18→20	82→80
30~40	20	80

   (5) Procedure: Inject accurately 5 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   Chlorogenic acid or luteolin-7-*O*- glucoside (%) =0.0025(r_U/r_S) (C_S) / (W)

   r_U: peak area of chlorogenic acid or luteolin-7-*O*-glucoside of sample solution

   r_S: peak area of chlorogenic acid or luteolin-7-*O*-glucoside of reference standard solution

   C_S: concentration of chlorogenic acid or luteolin-7-*O*-glucoside of reference standard solution (μg/mL)

   W: weight of test sample (g) calculated with dried sample.
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).
4. Volatile oil: Carry out the method for determination of volatile oil (General rule 6013).

Storage: Refrigerate or store in a cool and dry place.
Usage: Exterior-releasing medicinal (Pungent-cold exterior-releasing medicinal).
Property and flavor: Mild cold; sweet and bitter.
Meridian tropism: Lung and liver meridians.
Effects: Disperse wind to clear heat, detoxicate, pacify the liver and brightens eyes.
Administration and dosage: 5~12 g.

CHUANXIONG RHIZOMA
川芎
Chuan Cyong / Chuan Qiong
Chuanxiong Rhizome

Chuanxiong rhizome is the dried rhizome of *Ligusticum chuanxiong* Hort. (Fam. Umbelliferae).
It contains not less than 25.0% of dilute ethanol-soluble extractives, not less than 29.0% of water extractives and not less than 0.07% of ferulic acid.

Description: Irregular knotty and fist-like, 3~10 cm in length, 2~7 cm in diameter. Externally yellowish-brown, rough and shrunken, with many parallel and protuberant annulations, apex with dent and subrounded stem scar, the lower part and the nodes with numerous tuberculous rootlet scars. Texture compact, uneasily broken, fracture yellowish-white or grayish-yellow, cambium in an undulate ring, scattered with yellowish-brown oil dots. Odour strongly aromatic; taste bitter, pungent and slight numb then sweet.

Microscopic identification:

1. **Transverse section:**
   Rhizome of *Ligusticum chuanxiong*: Cork composed of over 10 layers flat cells. Cortex narrow, scattered with root-trace vascular bundles, cells tangentially elongated, with subrounded oil cavities, up to 200 μm in diameter. Phloem relatively broad, sieve tube groups scattered. Undulate cambium in a ring. Xylem vessels arranged in a U shape, vessels polygonal or subrounded; xylem fiber bundles occasionally found. Pith relatively broad, numerous oil cavities scattered in parenchymatous tissue; parenchymatous cells contain starch granules, some containing clusters of calcium oxalate.
2. **Powder:** Pale yellowish-brown. Starch granules numerous, simple granules subrounded, long-rounded, oval or reniform, up to about 30 μm in length, 5~16 μm in diameter, hilum dotted or strip-shaped, a few V-shaped, striations indistinct; compound granules rare, composed of 2~4 components. Cork cells abundant, dark yellow, polygonal or rectangular, walls extremely thin and slightly undulate. Clusters of calcium oxalate about 20 μm in diameter. Vessels spiral and reticulate, occasionally scalariform and bordered-pitted, 8~10 μm in diameter. Xylem fibers long-fusiform, 112~370 μm in length, 16~27 μm in diameter, pits and pit canals relatively fine, lumen relatively broad. Oil cavities mostly broken, occasionally filled with oil droplets.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of ferulic acid and dissolve in methanol to produce a solution containing 0.2 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of toluene, ethyl acetate, formic acid (6:3:1) as the developing solvent. Apply 5 μL of the sample solution and reference drug solution and 2 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with a 10% solution of H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 15.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 6.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 400 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 5.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Ferulic acid:
   (1) Mobile phase: A solution of methanol and 1% acetic acid (25:75). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of ferulic acid and dissolve in methanol to produce a solution containing 30 μg per mL.
   (3) Sample solution: Weigh accurately 1.0 g of powdered sample, add 10 mL of methanol, ultrasonicate for 30 minutes, filter, transfer to a 25-mL volumetric flask. Repeat the extraction of the residue one more time. Combine the filtrate, make up to volume with methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (320 nm) and a column packing L1. The column temperature is maintained at 35 ℃. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of ferulic acid should not be less than 8000.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Ferulic acid (%) = 0.0025 (*ru*/*rs*)(*Cs*)/(*W*)
   ru: peak area of ferulic acid of sample solution
   rs: peak area of ferulic acid of reference standard solution
   Cs: concentration of ferulic acid of reference standard solution (μg/mL)
   W:weight of test sample (g) calculated with dried sample.
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from insects.
Usage: Blood-regulating medicinal (Blood-activating and stasis-dispelling medicinal).
Property and flavor: Warm; pungent.
Meridian tropism: Liver, gallbladder, and pericardium meridians.
Effects: Activate blood and move qi, dispel wind to relieve pain.
Administration and dosage: 3~10 g.

【Decoction pieces】

CHUANXIONG RHIZOMA

It contains not less than 25.0% of dilute ethanol-soluble extractives, not less than 29.0% of water extractives and not less than 0.07% of ferulic acid.
Raw medicinal materials are processed to remove impurities, clean selection, soften thoroughly, cut into thin slices, and dry, mostly irregular pieces cut longitudinally towards the base of the stem, the edges are not neat and resemble a butterfly. The edge is dark brown, the cut surface is almost yellow, with wrong longitudinal texture, and the color of the pith is lighter. There are small brownish-yellow dots everywhere, and the cambium is irregularly wavy or polygonal, with hard texture and irregular cross-sections. Odor strongly and special; taste bitter, pungent and slight numb.

Thin layer chromatographic identification test: The method is the same as that for crude herb.
Impurities and other requirements: Methods and specifications are the same as those for crude herb.

Assay: The method is the same as that for crude herb.
Storage: The method is the same as that for crude herb.
Usage: Blood-regulating medicinal (Blood-activating and stasis-dispelling medicinal).
Property and flavor: Warm; pungent.
Meridian tropism: Liver, gallbladder, and pericardium meridians.
Effects: Activate blood and move qi, dispel wind to relieve pain.
Administration and dosage: 3~10 g.

CIBOTII RHIZOMA
狗脊
Gou Ji / Gou Ji
East Asian Tree Fern Rhizome

East Asian tree fern rhizome is the dried rhizome of *Cibotium barometz* (L.) J. Sm. (Fam. Dicksoniaceae).
It contains not less than 18.0% of dilute ethanol-soluble extractives, not less than 18.0% of water extractives and not less than 0.02% of protocatechuic acid.

Description: Irregularly long lump-shaped, about 10~18 cm in length, about 3~10 cm in diameter. Externally brown, covered with golden hairs; the upper part exhibiting several reddish-brown petioles and the lower part remained with black fibrous roots. Texture hard, uneasily broken. Odourless; taste slightly astringent.

1. Sheng Gou Ji Pian: Irregular oblong, margin irregular, occasionally remained with golden and soft hairs, about 2~5 mm thick, externally dark brown, fracture yellowish-brown, with yellow protuberant ring at the edge. Texture fragile, easily broken, starchy.
2. Shu Gou Ji Pian: Blackish-brown, similar to Shebggoujipian. Texture hard. Odourless; taste weak.

Microscopic identification:

1. **Transverse section:**
   Rhizome of *Cibotium barometz*: Epidermis composed of 1 row of cells, with remains of golden non-glandular hairs. Sclerenchymatous cells 10~20 rows, cells subrounded or subpolygonal, yellowish-brown, with distinct pits, containing starch granules. Xylem composed of several rows of cells, arranged in a ring, both the inner and outer parts exhibiting phloem and endodermis; both the inner and outer cortex and pith relatively broad, composed of parenchymatous cells, cells filled with starch granules, occasionally containing yellowish-brown contents.
2. **Powder:** Yellowish-brown. Golden non-glandular hairs about 100~700 μm in length, mostly broken. Starch granules abundant, simple granules spheroidal, long-rounded or reniform, varying in size, hilum distinct, large granules with distinct striations; compound granules composed of 2~3 components, but rarely present. Parenchymatous cells contain yellowish-brown and reddish-brown masses. Vessels mainly scalariform, about 20~100 μm in diameter.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 2.0 g of powdered sample to 40 mL of methanol, ultrasonicate for 1 hour, evaporate to dryness, and dissolve the residue in 1 mL of methanol.
2. Reference drug solution: Take 2.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of protocatechuic aldehyde and protocatechuic acid in methanol to produce a solution containing 1.0 mg per mL of each.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of chloroform, ethyl acetate, toluene, and formic acid (5:6:3:1) as the developing solvent. Apply 5~10 μL of the sample solution and reference drug solution and 2 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with a 5% solution of $FeCl_3$/EtOH TS and heat at 105°C for 5 minutes until the spots become visible. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 13.0% dry at 105°C for 5 hours (General rule 6015).
2. Total ash: Not more than 3.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Protocatechuic acid:
   (1) Mobile phase: A solution of acetonitrile and 1% glacial acetic acid (5:95). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of protocatechuic acid and dissolve in a solution of methanol and 1% glacial acetic acid (70:30) to produce a solution containing 50 μg per mL.
   (3) Sample solution: Weigh accurately 1.0 g of powdered sample, transfer to a conical flask

with stopper, add accurately 25 mL of a solution of methanol and 1% glacial acetic acid (70:30), weigh, ultrasonicate for 30 minutes, cool, weigh again, replenish the loss of the weight with a solution of methanol and 1% glacial acetic acid (70:30), mix well, filter and use the successive filtrate.

(4) Chromatographic system: The liquid chromatography is equipped with an UV detector (260 nm) and a column packing L1. The column temperature is maintained at 25℃. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of protocatechuic acid should not be less than 3,000.

(5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Protocatechuic acid (%)=0.0025(r_U/r_S) (C_S) / (W)

r_U: peak area of protocatechuic acid of sample solution

r_S: peak area of protocatechuic acid of reference standard solution

C_S: concentration of protocatechuic acid of reference standard solution (μg/mL)

W: weight of test sample (g) calculated

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from mold and insects.
Usage: Tonifying and replenishing medicinal (Yang-tonifying medicinal).
Property and flavor: Warm; bitter and sweet.
Meridian tropism: Liver and kidney meridians.
Effects: Tonify liver and kidney, strengthen sinew and bone, dispel wind dampness.
Administration and dosage: 6~12 g.

CICADAE PERIOSTRACUM
蟬蛻
Chan Tuei / Chan Tui
Cicada Exuviae

Cicada exuviae is the dried exuviae of nymphs of *Cryptotympana atrata* (Fabricius) (Fam. Cicadidae) during emergence.

Description: Cicada-shape, hollowed and curved, 2~4 cm in length, 1.5~2 cm in width. Externally yellowish-brown, translucent, lustrous. The head with a pair of filiform antenna, usually dropped; compound eye prominent; the anterior end of the frons prominent; mouth and snout developed, labrum short and wide, labium extended into a tube. The dorsal surface of the thorax crisscross split, split margins curved inward; each side of the dorsum bearing two small wings; the prothorax bearing with the first pair of legs, legs swollen and the lower part with spines forming fossorial legs. The abdomen obtuse rounded, 9 segments, bearing three pairs of legs, covered with yellowish-brown minute hairs, 9th segment triangular-shaped and obtuse. Texture light and membranous, easily broken. Odourless; taste weak.

Microscopic identification:
Powder: Yellowish-brown. Fragments of body wall yellowish-brown, subsquare or irregular, densely covered with papillary protuberance, setae scars visible; some fragments only with setae scars on the surface; some only with papillary protuberance on the surface. Setae varying in length, mostly yellowish-brown or reddish-brown, 15~23 μm in length, trichopore obviously visible, slightly double circles shaped. Tracheal walls mostly broken, annular or flaky, colorless, annular striations fine and dense, spiral filaments arranged arc-shaped.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 1 mL of methanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and the lower layer of a solution of dichloromethane, methanol, and water (13:7:2) refrigerate below 6℃ for not less than 10 hours as the developing solvent. Apply 10 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% phosphomolybdic acid/EtOH TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:
1. Loss on drying: Not more than 10.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 33.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 26.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.5 ppm (General rule 6301).

7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 10.0 ppm (General rule 2251, 6301).

Storage: Store in a dry place, and protect from crush.
Usage: Exterior-releasing medicinal (Pungent-cold exterior-releasing medicinal).
Property and flavor: Cold; sweet.
Meridian tropism: Lung and liver meridians.
Effects: Scatters wind and eliminates heat, soothe the throat, outthrust rashes, remove nebula, arrest convulsions.
Administration and dosage: 3~7.5 g.
Precaution and warning: Use cautiously during pregnancy.

CIMICIFUGAE RHIZOMA
升麻
Sheng Ma / Sheng Ma
Largetrifolious Bugbane Rhizome

Largetrifolious bugbane rhizome is the dried rhizome of *Cimicifuga foetida* L., *Cimicifuga heracleifolia* Kom. or *Cimicifuga dahurica* (Turcz.) Maxim. (Fam. Ranunculaceae).
It contains not less than 19.0% of dilute ethanol-soluble extractives, not less than 14.0% of water extractives and not less than 0.1% of isoferulic acid.
Description: Irregular masses, frequently branched, about 10~20 cm in length, 2~4 cm in diameter. Externally blackish-brown, rough, remained with numerous wiry fibrous roots, the upper part remained with several larger subround and hollow stems base, the inner wall of the hole with reticulate furrows, the lower part lumpy, with fibrous root scars. Texture hard and light, uneasily broken, fracture uneven, pale yellow or yellowish-green, cracked, fibrous. Odour slight; taste slightly bitter.

Microscopic identification:
1. **Transverse section:**
   Cimicifugae rhizoma: Metaderm composed of 1~3 rows of cells, subpolygonal in shape, walls vary in thickness, some outer walls thickened by suberization, and occasionally the outer and anticlinal wall of some metaderm cells nipple-shaped thickened, and stretched into the cell cavities. Cortex relatively broad; pericycle scattered with collateral vascular bundles, fiber bundles arranged in an interrupted ring. Phloem radially elongated in neat. Cambium indistinct. Xylem broad, vessels relatively numerous, singly scattered or in groups of 2~7 cells, rays in 2 or more cell row. Pith broad. Parenchymatous cells contain starch granules.
2. **Powder:** Yellowish-brown. Vessels mainly bordered-pitted, also have reticulate, scalariform and spiral, 7~100 μm in diameter. Pericycle fiber bundles fusiform, mostly straight, with the endings acuminate or obtusely rounded, 15~35 μm in diameter, walls slightly thickened and lignified, pits distinct. Simple starch granules spheroid, oblong or reniform, 8~20 μm in diameter, with distinct hilum; compound granules relatively numerous, composed of 2~14 components.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, heat under reflux for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of ferulic acid and isoferulic acid and dissolve in ethanol to produce a solution containing 1.0 mg per mL of each.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of toluene, dichloromethane, and glacial acetic acid (6:1:0.5) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 13.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 12.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 3.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303)
5. Arsenic (As): Not more than 5.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
1. Isoferulic acid
   (1) Mobile phase: A solution of acetonitrile and 0.1% phosphoric acid (15:85). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of isoferulic acid, and dissolve in 10% ethanol to produce a solution containing 0.1 mg per mL.
   (3) Weigh accurately 0.5 g of powdered sample and place it in a round bottom flask, then add accurately 25 mL of 10% ethanol, weigh, heat under reflux for 2.5 hour, cool, weigh again,

replenish the loss of the weight with 10% ethanol, mix well, filter and use the successive filtrate.

(4) Chromatographic system: The liquid chromatography is equipped with an UV detector (316 nm) and a column packing L1. The column temperature is maintained at 23 ± 4℃. The flow rate is about 1 mL/min.

(5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Isoferulic acid : (%)=2.5 (r_U/r_S) (C_S) / (W)

r_U: peak area of isoferulic acid of sample solution

r_S: peak area of isoferulic acid of reference standard solution

C_S: concentration of isoferulic acid of reference standard solution (mg/mL)

W: weight of test sample (g) calculated

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from mold and insects.
Usage: Exterior-releasing medicinal (Pungent-cold exterior-releasing medicinal).
Property and flavor: Mild cold; pungent and sweet.
Meridian tropism: Lung, spleen, stomach, and large intestine meridians.
Effects: Resolve the exterior to vents rash, clear heat and detoxicate, raises yang qi.
Administration and dosage: 3~11.5 g.

CINNAMOMI CORTEX
肉桂
Rou Guei / Rou Gui
Cinnamon Bark

Cinnamon bark is the dried bark of trunk of *Cinnamomum cassia* (L.) J.Presl (Fam. Lauraceae). It is commonly known as “Gui Pi”.
It contains not less than 1.0% (v/w) of volatile oil and not less than 2.0% of *trans*-cinnamaldehyde.

Description: Quilled or semi-quilled, 1~3 mm in width. Outer surface grayish-brown or brown, with some cork, inner surface brown or pale reddish-brown. Fracture even, granularity. Odour strongly aromatic; taste pungent and slight astringent.

Microscopic identification:

1. **Transverse section:**
Bark of trunk of *Cinnamomum cassia*: Cork composed of several layers of cells, the cells of innermost layer with thickened and lignified walls. Parenchymatous cells of cortex contain starch granules, also scattered with stone cells, mucilage cells and oil cells. Stone cell layers arranged in an interrupted ring, containing inner sheath fiber groups with walls thickened and slightly lignified. Phloem broad, mainly composed of parenchymatous cells, scattered with small sieve tubes, phloem fibers scattered in singly or aggregated in groups, numerous mucilage cells and oil cells. Phloem rays arranged radially, 1~3 rows of cells wide, containing starch granules or fine raphides of calcium oxalate. Parenchymatous cells usually contain starch granules or fine raphides of calcium oxalate; raphides mostly distributed in phloem rays cells. In lumen of parenchymatous cells, stone cells and fibers filled with non-crystalline reddish-brown contents, mostly insoluble in general solvents.
2. **Powder:** Yellowish-brown or reddish-brown. Simple granules 5~15 μm in diameter, mostly above 10 μm; compound granules composed of 2~4 components. Stone cells slightly lignified, varying in shape, lumen occasionally containing starch granules. Fibers slightly lignified, walls extremely thickened and slightly undulated, 300~1500 μm in length. Walls of parenchymatous cells reddish-brown. Elongated mucilage cells contain volatile oil or mucilage contents. Phloem rays cells contain fine raphides of calcium oxalate. Cork cell fragments slightly lignified.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of *trans*-cinnamaldehyde and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane and acetone (4:1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 254 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and reference standard solution.

Impurities and other requirements:

1. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
2. Foreign matter: Not more than 2.0% (General rule 6005).

3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 15.0 ppm (General rule 2251, 6301).
8. Pesticide residues:
   (1) The total DDT content: Not more than 0.2 ppm (General rule 6305).
   (2) The total BHC content: Not more than 0.2 ppm (General rule 6305).

Assay:

1. *trans*-Cinnamaldehyde:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and water as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of *trans*-cinnamaldehyde, and dissolve in methanol to produce a solution containing 0.1 mg per mL.
   (3) Sample solution: Weigh accurately 0.2 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 25 mL of 75% ethanol, ultrasonicate for 30 minutes. Centrifuge for 5 minutes, filter the supernatant. Repeat the extraction of the residue one more time. Combine the extracts, filter to 50-mL volumetric flask with filter paper and make up to volume with 75% ethanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (290 nm) and a column packing L1. The column temperature is maintained at 31.5℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of *trans*-cinnamaldehyde should not be less than 8,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~20	32	68
20~30	32→100	68→0
30~40	100	0

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   ***trans*-Cinnamaldehyde: (%)= 5(r_U/r_S) (C_S) / (W)**

   r_U: peak area of *trans*-cinnamaldehyde of sample solution

   r_S: peak area of *trans*-cinnamaldehyde of reference standard solution

   C_S: concentration of *trans*-cinnamaldehyde of reference standard solution (mg/mL)

   W: weight of test sample (g) calculated with dried sample.

2. Volatile oil: Carry out the method for determination of volatile oil (General rule 6013).

Storage: Refrigerate and preserve in a well-closed container.
Usage: Interior-warming medicinal.
Property and flavor: Highly hot; pungent and sweet.
Meridian tropism: Kidney, spleen, heart, and liver meridians.
Effects: Warm and tonify the life gate fire, conduct fire back to its origin, warm the middle and fortify spleen, warm the meridian and dissipate cold to relieve pain.
Administration and dosage: 1~5 g.

CINNAMOMI CORTEX CENTRALIS
桂心
Guei Sin/ Guei Sin
Cinnamon Central Bark

Cinnamon central bark is the dried bark of *Cinnamomum cassia* (L.) J.Presl (Fam. Lauraceae), which remove the outer amd inner skin is Guei Sin.

Description: Externally reddish-brown, fine wrinkles and knob-like ridges, lenticels spotted. Hard and brittle, easy break. special aroma, sweet taste slight sympathy.

Microscopic identification:
Transverse section:
Guei Sin: Cork cells 3~5 columns, outermost cell outer wall thickened. Oil droplets and stone cells scattered in the cortex. Secretory cells and fibers scattered in the phloem. Formation layer obvious. Cell wall of the pith slightly thick, lignified. Fine oxalate calcium needles can be seen.

Impurities and other requirements:
1. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
2. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
3. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
4. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
5. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Storage: Store in a cool and dry place, and preserved in a well-closed container.
Usage: Interior-warming medicinal.
Property and flavor: Highly hot; pungent and sweet.

Effects: Replenish essence to improve vision, disperse stasis and promote tissue regeneration, tonify overfatigue, warm waist and knees, continue sinew and bone.
Administration and dosage: 1.5~10 g.

CINNAMOMI RAMULUS
桂枝
Guei Jhih / Gui Zhi
Cassia Twig

Cassia twig is the dried twig of *Cinnamomum cassia* (L.) J.Presl (Fam. Lauraceae).
It contains not less than 4.0% of dilute ethanol-soluble extractives, not less than 2.0% of water extractives and not less than 1.2% of *trans*-cinnamaldehyde.

Description: Long cylindrical, branched, 30~70 cm in length, 0.3~1 cm in diameter at the thick end. Externally brown or reddish-brown, with fine wrinkles and swellings of leaf scars, branch scars and bud scars, lenticels dotted or dotted-elliptical. Texture hard and fragile, easily broken, fracture of bark reddish-brown, with a pale yellow ring of stone cells, wood yellowish-white to pale yellowish-brown, pith subsquare. Odour characteristically aromatic; taste sweet and slightly pungent, relatively strong at bark. The better character as consistent diameter, reddish-brown, strongly aromatic.

Microscopic identification:
Transverse section:
Twig of *Cinnamomum cassia*: Epidermis composed of 1 row of rectangular or subsquare cells, unicellular non-glandular hairs present in twig. Cork composed of 3~5 rows of cells, cells of the innermost layer with thickened outer wall. Cortex scattered with oil cells and stone cells. Stone cell groups in pericycle arranged in an interrupted ring, accompanied by fiber bundles. Phloem scattered with oil cells, mucilage cells and fibers. Cambium distinct. Xylem rays 1~2 rows of cells wide, containing brown contents and fine raphides of calcium oxalate. Pith with slightly thickened and lignified cell wall. Parenchymatous cells contain starch granules.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, cool and make up to 10 mL.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of *trans*-cinnamaldehyde and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane and acetone (4:1) as the developing solvent. Apply 10 μL of each of the sample solution and reference drug solution and 5 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 254 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 12.0% dry at 105°C for 5 hours (General rule 6015).
2. Total ash: Not more than 3.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 15.0 ppm (General rule 2251, 6301).
9. Pesticide residues:
   (1) The total DDT content: Not more than 0.2 ppm (General rule 6305).
   (2) The total BHC content: Not more than 0.2 ppm (General rule 6305).

Assay:
1. *trans*-Cinnamaldehyde:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and water as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of *trans*-cinnamaldehyde, and dissolve in methanol to produce a solution containing 0.2 mg per mL.
   (3) Sample solution: Weigh accurately 0.5 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 25 mL of 75% ethanol, ultrasonicate for 30 minutes. Centrifuge for 5 minutes. Repeat the extraction of the residue one more time. Combine the extracts, filter to 50-mL volumetric flask with filter paper and make up to volume with 75% ethanol, mix well, filter and use the filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (290 nm) and a column packing L1. The column temperature is maintained at 30°C. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of *trans*-cinnamaldehyde should not be less than 8,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~20	32	68
20~30	32→100	68→0
30~40	100	0

(5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

***trans*-Cinnamaldehyde (%)=5(r_U/r_S) (C_S) / (W)**

r_U: peak area of *trans*-cinnamaldehyde of sample solution

r_S: peak area of *trans*-cinnamaldehyde of reference standard solution

C_S: concentration of *trans*-cinnamaldehyde d of reference standard solution (mg/mL)

W: weight of test sample (g) calculated with dried sample.

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place, and protect from insects.
Usage: Exterior-releasing medicinal (Pungent-warm exterior-releasing medicinal).
Property and flavor: Warm; pungent and sweet.
Meridian tropism: Heart, lung, and bladder meridians.
Effects: Promote sweating to release the flesh, warm frees the channels and vessel, assists yang in transforming qi, direct qi downward.
Administration and dosage: 3~10 g.

CIRSII HERBA
小薊
Siao Ji / Xiao Ji
Common Cephalanoplos Herb

Common cephalanoplos herb is the dried aerial part of *Cirsium arvense* (L.) Scop.(*Cirsium setosum* (Willd.) M.Bieb.) (Fam. Compositae).
It contains not less than 0.70% of linarin.

Description: About 50 cm in length, with rhizomes. Stems cylindrical, easily broken, 2~4 mm in diameter, externally green or purplish-brown, with longitudinal ridges and white pubescence, texture fragile, fracture fibrous and hollow. Leaves alternate, petioled, lamina broken or crumpled, yellowish-green, both surfaces with white arachnoid tomentum, margins entire or undulate, with aureate spines. Captitulum terminal, involucres campanulate, phyllaries yellowish-green, 5~6 layers, linear or lanceolate; corolla fallen off, pappi feathery, often exposed. Odour slight; taste slightly bitter.

Microscopic identification:

1. **Transverse section:**
   (1) Stem of *Cirsium arvense*: Epidermal cells covered with cuticles, occasionally with multicellular non- glandular hairs. Hypodermal collenchyma present at angular regions with slightly lignified walls. Cortex composed of several to more than 10 layers of elongated tangential parenchymatous cells, scattered with secretory cells and stone cells. Vascular bundles in a ring, phloem narrow; pericyclic fiber in bundles, slightly lignified outside the phloem; xylem vessels located in middle and lower parts of xylem, some lignified fiber bundles consist in the inner part of xylem. Pith usually hollow in the center.
   (2) Leaves of *Cirsium arvense*: In surface view, upper epidermal cells subpolygonal, cutin striations distinct; lower epidermal cells irregular in shape, anticlinal walls curved. Stomata anomocytic or anisocytic. Whip-shaped non-glandular hairs mostly broken, composed 3~18 cells in whole, 10~18 μm in diameter at the base, with a slender apical cell, shrunken and twisted. Mesophyll containing irregular masses and crystals of calcium oxalate, mostly needle-clustered, prisms or columnar.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 0.5 g of powdered sample to 5 mL of methanol, ultrasonicate for 30 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 2 mL of methanol.
2. Reference drug solution: Take 0.5 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of linarin and dissolve in methanol to produce a solution containing 0.5 mg per mL.
4. Procedure: Use polyamide as the coating substance and a solution of acetylacetone, butanone, ethanol, and water (1:3:3:13) as the developing solvent. Apply 1 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with $AlCl_3$/EtOH TS. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).

2. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
3. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
4. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
5. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
Linarin:
1. Mobile phase: A solution of methanol and 0.5% acetic acid (55:45). The ratio may be adjusted, if necessary.
2. Reference standard solution: Weigh accurately a quantity of linarin and dissolve in methanol to produce a solution containing 0.1 mg per mL.
3. Sample solution: Weigh accurately 0.1 g of powdered sample, transfer to a conical flask with stopper, accurately add 10 mL of methanol and weigh, ultrasonicate for 15 minutes, cool and weigh again, replenish the loss of solvent with methanol, mix well, filter and use the filtrate.
4. Chromatographic system: The liquid chromatography is equipped with an UV detector (326 nm) and a column packing L1. The column temperature is maintained at 25℃. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of linarin should not be less than 1,500.
5. Procedure: Inject accurately 5 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   Linarin (%)= (r_U/r_S) (C_S) / (W)

   r_U: peak area of linarin of sample solution

   r_S: peak area of linarin of reference standard solution

   C_S: concentration of linarin of reference standard solution (mg/mL)

   W: weight of test sample (g) calculated with dried sample.

Storage: Store in a ventilated and dry place, and protect from mold.
Usage: Blood-regulating medicinal (Hemostatic medicinal).
Property and flavor: Cool, sweet.
Meridian tropism: Heart and liver meridians.
Effects: Cool the blood to hemostatic, detoxicate and disperse abscesses.
Administration and dosage: 3~15 g.

CIRSII JAPONICI HERBA SEU RADIX
大薊
Da Ji / Da Ji
Japanese Thistle Herb or Root

Japanese thistle herb or root is the dried aerial part or root of *Cirsium japonicum* DC. (Fam. Compositae).

It contains not less than 10.0% of dilute ethanol-soluble extractives and not less than 10.0% of water extractives.

Description: 100 cm in length. Stem cylindrical, upper branches, 0.5~2 cm in diameter; externally brown or greenish-brown, with longitudinal ridges and grayish-white filamentous hairs; texture loose, fracture yellowish-white, pith white and mostly hollow. Leaves alternated, crumpled, greenish-brown, oblanceolate or obovate-lanceolate as whole, pinnatipartite, margin with unequal spines, with grayish-white filamentous hairs on both surfaces. Captitulum terminal, subglobose, about 2.5 cm in diameter, involucres yellowish-brown, phyllaries lanceolate, 4~6 layers, slightly purple-black dots; tubular flowers purplish-red, mostly fallen off, pappi feathery and yellowish-white. Odour slight; taste weak. Rhizomes noded, stem base remained on the top, the lower part with numerous slender roots. Roots fusiform, slightly curved, 5~10 cm in length; externally dark brown, with longitudinal wrinkles; texture hard and fragile, easily broken, fracture coarser, bark thin, brown, with fine fissures, wood whitish. Odour specific; taste slightly bitter and astringent.

Microscopic identification:
1. **Transverse section:**
   (1) Stem of *Cirsium japonicum*: Epidermal cells mostly shrunken, occasionally with whip-shaped non-glandular hairs, collenchymatous tissue existed under epidermis of ridges. Cortex composed of 5~9 layers of tangentially elongated parenchymatous cells. Vascular bundles collateral, containing slightly lignified phloem fiber bundles; slightly lignified fiber bundles also existed in the inner side of xylem. The major portion of stem is occupied by pith, the central part often hollow.
   (2) Leaves of *Cirsium japonicum*: Upper epidermal cells subpolygonal on surface view; lower epidermal cells irregular or subrectangular, anticlinal walls undulate. Stomata anisocytic or anomocytic. Whip-shaped non-glandular hairs extremely numerous, mostly broken, 4~18 cells or more in complete, basal cells 15~150 μm in diameter, apical cells extremely slim and twisted, about 7 μm in diameter. Mesophyllous cells contain clusters of calcium oxalate, 13~24 μm in diameter; raphides of calcium oxalate up to 15 μm in length.
   (3) Root of *Cirsium japonicum*: Epidermal cells with lignified walls, usually exfoliated. Cortex relatively broad, close to the outer endodermis scattered with subrounded secretory canals, 70~140 μm in diameter, densely arranged in a ring. Endodermis distinct. Phloem relatively narrow; cambium

arranged in a ring; xylem vessels grouped in several, radially elongated. Rays broad with pith in the center.

2. **Powder:** Brownish-green. Whip-shaped non-glandular hairs extremely long, mostly broken, 4~30 cells in complete; 1~2 or several cells on the apex very slim; shrunken and twisted, 17~182 μm in diameter, the wall 3~14 μm thick, some basal cells with thick walls and slightly curved cuticular striations, containing yellowish-brown contents. Unicellular non-glandular hairs (aigrettes) vary in length, up to 17 μm in diameter. Upper epidermal cells subpolygonal in surface view, anticlinal walls slightly thickened or moniliformed; lower epidermal cells undulate; fine cuticular striations present on both upper and lower epidermises. Stomata anomocytic or anisocytic, with 3~5 subsidiary cells. Crystals of calcium oxalate clustered needle-like or fan-shaped, 3~18 μm in diameter, present in leaf epidermis and mesophyllous cells. Epidermal cells of involucres strip-shaped in surface view, anticlinal walls moniliform thickened, oblique pits visible, scattered with sclerenchyma cells (short and stiff hairs). Sclerenchyma cells yellow, ovoid in surface view, 40~58 μm in length, 28~35 μm in diameter, wall 8~15 μm thick, lignified or slightly lignified, with distinct striations; lumen subrounded or narrow slit-shaped, occasionally containing yellowish-brown contents; subrounded in sectional view, protuberances visible on epidermis. Upper epidermal cells of involucres slim, 8~15 μm in diameter, wall slightly thickened, some contain brownish-yellow contents. Stone cells of endocarp rhombic, subrectangular or irregular, 14~58 μm in diameter, 38~144 μm in length, wall 3~14 μm thick, some with pit canals or small prisms of calcium oxalate. Parenchymatous cells of exocarp, flaky and strip-shaped, with slightly oblique ends, thin-walled, with very fine and dense crossed striations. Epidermal cells of exocarp subpolygonal in surface view, scattered with oblong cells containing fine spiral striations. Fibers of exocarp fusiform, 47~167 μm in length, 10~17 μm in diameter, wall 3~5 μm thick, containing round pits and distinct pit canals. Fibers of involucres 8~25 μm in diameter, wall 3~7 μm thick, containing oblique pit apertures. Fibers of stem slim, 10~26 μm in diameter, the wall up to 3 μm thick, containing small round pits.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 2 mL of methanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Weigh accurately a quantity of linarin and dissolve in methanol to produce a solution containing 20 μg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, formic acid, and water (8:1:1) as the developing solvent. Apply 5 μL of each of the sample solution and reference drug solution and 20 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Soak with a solution of aluminum chloride in ethanol ($AlC1_3$/EtOH TS) and heat at 105℃ until the spots become visible.. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Total ash: Not more than 9.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 3.0% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place.
Usage: Blood-regulating medicinal (Hemostatic medicinal).
Property and flavor: Cool, sweet and bitter.
Meridian tropism: Heart and liver meridians.
Effects: Cool the blood to hemostatic, dissipate stasis and disperse abscesses.
Administration and dosage: 10~15 g for dried one, 30~60 g for fresh one.

CISTANCHIS HERBA
肉蓯蓉
Rou Cong Rong / Rou Cong Rong
Desert-living Cistanche

Desert-living cistanche is the dried fleshy stem with scale leaves of *Cistanche deserticola* Y.C.Ma or *Cistanche tubulosa* (Schenk) Wight (Fam. Orobanchaceae).
It contains not less than 35.0% of dilute ethanol-soluble extractives and not less than 0.3% of the total amount of echinacoside and verbascoside of the dried fleshy stem of *Cistanche deserticola*. It contains not less than 25.0% of dilute ethanol-soluble extractives and not less than 1.5% of the total amount of echinacoside and verbascoside of the dried fleshy stem of *Cistanche tubulosa*.

Description:

1. Stem of *Cistanche deserticola*: Fattened cylindrical, slightly curved, 3~15 cm in length, 3~6 cm in diameter. Externally grayish-brown, with longitudinal furrows and imbricated fleshy triangular scale leaves, the scars of scale leaves often remain. Texture hard and tenacious, uneasily broken, fracture brown, with vascular bundles arranged in serrated rings. Odour slight; taste slightly sweet and slightly bitter.
2. Stem of *Cistanche tubulosa*: Subfusiform, flattened-fusiform and flattened-cylindrical, slightly curved, 5-25 cm long, 2.5-9 cm in diameter. Externally brown to dust-color. Fracture granular, greyish-brown to greyish-brown, dotted with scattered vascular bundles.

Microscopic identification:

1. **Transverse section:**
   Cistanches Herba: Epidermis composed of 1 layer of subpolygonal cells, covered with cuticle. Cortex composed of more than 10 layers of parenchymatous cells, subrectangular or polygonal, arranged densely, lumen contains pale yellow pigments. Vascular bundles arranged in serrate-shaped ring; parenchymatous cells of phloem arranged densely; cambium indistinct; xylem vessels mostly in groups; rays distinct; pith polygonal, occasionally the center smashes forming a cavity. Cortex and pith parenchymatous cells contain starch granules, simple granules subrounded and elliptical.
2. **Powder:** Dark brown. Starch granules numerous, simple granules subrounded or elliptical, about 5~45 μm in diameter, hilum mostly dotted, cleft-shaped or Y-shaped; compound granules relatively less, composed of 2~4 components. Vessels mainly reticulated, a few spiral, about 11~54 μm in diameter. Fibers mostly in bundles, pale yellow, long-subrhombic, about 90~500 μm in length and 9~25 μm in diameter.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 20 mL of methanol, ultrasonicate for 15 minutes, filter, evaporate the filtrate to dryness, dissolve the residue in 2 mL of methanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and the lower layer of dichloromethane, methanol, and water (26:14:5) as the developing solvent. Apply 2 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with *p*-anisaldehyde/H_2SO_4 TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:

1. Total ash: Not more than 8.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Echinacoside and verbascoside:
   (1) Mobile phase: Methanol as the mobile phase A, and a solution of 0.1% formic acid as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of echinacoside and verbascoside and dissolve in 50% methanol to produce a solution containing 0.2 mg per mL of each.
   (3) Sample solution: Weigh accurately 1.0 g of powdered sample and place it in a 100-mL amber volumetric flask. Add accurately 50 mL of 50% methanol, stopper tightly and mix well, weigh, and macerate for 30 minutes, ultrasonicate for 40 minutes, cool and weigh again, replenish the loss of the weight with 50% methanol, mix well, stand, filter the supernatant and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (330 nm) and a column packing L1. Program the chromatographic gradient

system as follows. The number of theoretical plates of the peak of echinacoside should not be less than 3,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~17	26.5	73.5
17~20	26.5→29.5	73.5→70.5
20~27	29.5	70.5

(5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Echinacoside or verbascoside: (%)= 5(r_U/r_S) (C_S) / (W)

r_U: peak area of echinacoside or verbascoside of sample solution

r_S: peak area of echinacoside or verbascoside of reference standard solution

C_S: concentration of echinacoside or verbascoside of reference standard solution (mg/mL)

W: weight of test sample (g) calculated with dried sample.

3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from mold and insects.
Usage: Tonifying and replenishing medicinal (Yang-tonifying medicinal).
Property and flavor: Warm; sweet and salty.
Meridian tropism: Kidney and large intestine meridians.
Effects: Tonify kidney and assist yang, tonify essence and blood, moisten the intestine and relax the bowel.
Administration and dosage: 6~12 g.

CITRI FRUCTUS IMMATURUS
枳殼
Jhih Ke / Zhi Ke
Bitter Orange

Bitter orange is the dried immature fruit of *Citrus aurantium* L. and its cultivated varieties (Fam. Rutaceae). It contains not less than 18.0% of dilute ethanol-soluble extractives, not less than 20.0% of water extractives and not less than 2.5% of naringin.

Description: Semispheroidal, 3~5 cm in diameter. Exocarp brown, slightly rough, with granular protuberance, apex of protuberance with dented oil spots (oil cavity), the scars of style or fruit stalk distinct in the center. Mesocarp yellowish-white, smooth and slightly protuberant, 0.4~1.3 cm thick, with 1~2 rows of oil cavities at the outer part of pericarp. Pulp vesicles 7~12, rarely up to 15, juice vesicles dried and shrunken, brown, containing seeds. Axis compact, 5~9 mm in width, yellowish-white, with an interrupted ring of vascular bundle. Texture hard, uneasily broken. Odour aromatic; taste bitter and slightly sour.

Microscopic identification:

1. **Transverse section:**
   Fruit of *Citrus aurantium*: Cell structures of bitter orange are very similar to immature bitter orange. Bitter orange with relatively thin epidermis, without villus, cells gradually larger from outside to inside, containing oil-like contents sedimentary and collenchymatous cell groups, scattered among parenchymatous cells.
2. **Powder:** Brown. Parenchymatous cells of mesocarp vary in shape, wall mostly thickened unevenly and unlignified, 8~16 μm in diameter. Epidermal cells of pericarp polygonal, square or slender in surface view, up to 20~32 μm in length and up to about 13 μm in diameter; stomata subrounded, with 5~8 subsidiary cells; oblique-square in sectional view, up to about 40 μm in length. Epidermal cells of juice vesicles slender, wall extremely thin, undulately curved, or cells shrinking as lines, inside showing parenchymatous tissue scattered with numerous prisms of calcium oxalate. Fragments of oil cavities, volatile oil droplets, fine vessels and tracheids also present.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 0.2 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 5 mL of methanol.
2. Reference drug solution: Take 2.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of naringin and dissolve in methanol to produce a solution containing 0.5 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-butanol, acetic acid, and water (4:1:1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with a 1% solution of $AlC1_3$/EtOH TS. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 14.0% dry at 105°C for 5 hours (General rule 6015).
2. Total ash: Not more than 7.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).

4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Naringin:
   (1) Mobile phase: A solution of acetonitrile and water (21.5: 80.5), and adjust pH value to 3.0 with phosphoric acid. The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of naringin, and dissolve in methanol to produce a solution containing 60 μg per mL.
   (3) Sample solution: Weigh accurately 200 mg of powdered sample and place it in a centrifuge tube, add 100 mL of methanol, ultrasonicate for 15 minutes, filter and use the filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (283 nm) and a column (4~6 mm × 15~25 cm) packing L1 (5~10 μm). The column temperature is maintained at room temperature. The retention time of naringin is about 10 minute. Inject reference standard solution into the liquid chromatography apparatus for 5 times, and record the peak areas. The relative standard deviation of the peak area of naringin should not be more than 1.5%.
   (5) Procedure: Inject accurately 20 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Naringin (%)=0.01(r_U/r_S) (C_S) / (W)
   r_U: peak area of naringin of sample solution
   r_S: peak area of naringin of reference standard solution
   C_S: concentration of naringin of reference standard solution (μg/mL)
   W: weight of test sample (g) calculated with dried sample.
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place, and protect from insects.
Usage: Qi-regulating medicinal.
Property and flavor: Mild cold; bitter, pungent and sour.
Meridian tropism: Spleen and stomach meridians.
Effects: Move qi and expand center, resolve phlegm and food.
Administration and dosage: 3~10 g.

CITRI MAXIMAE EXOCARPIUM
化橘紅
Hua Jyu Hong / Hua Ju Hong
Pummelo Exocarp

Pummelo exocarp is the dried exocarp of immature or almost ripe *Citrus maxima* 'Tomentosa' (*Citrus grandis* 'Tomentosa')or *Citrus maxima* (Burm.) Merr. (*Citrus grandis* (L.) Osbeck) (Fam. Rutaceae).
It contains not less than 18.0% of dilute ethanol-soluble extractives, not less than 21.0% of water extractives and not less than 1.5% of naringin.

Description:

1. Exocarp of *Citrus maxima* 'Tomentosa': The exocarp cut into pentagonal, hexagonal or heptagonal, opposite-folded, commonly known as "Wu Zhua", "Liu Zhua" or "Qi Zhua", or only fold the edge into plum flower form, as whole, 14~28 cm in diameter, 2~5 mm thick. The single piece oval and acute, commonly known as "Jian Hua Hong", about 10 cm in length, about 3.5 cm in width. Externally pale green, yellowish-green or brownish-yellow, coarse, with dense round pits (oil cavities), tomentellate; inner surface yellowish-white, with veins striations. Texture fragile, fracture with one row sunken oil cavity in the outer border. Odour slightly aromatic; taste bitter and astringent.
2. Exocarp of *Citrus maxima*: Externally yellowish-green or yellowish-brown, no tomentum.

Microscopic identification:

1. **Powder:**
   (1) Exocarp of *Citrus maxima* 'Tomentosa': Grayish-brown. Mesocarp parenchymatous cells irregular in shape, with irregular 2~5 μm thickened walls. Epidermal cells of exocarp subsquare in sectional view, the cuticle 5~9 μm thick; polygonal or subsquare in surface view, 5~14 μm in diameter; stomata with 5~8 subsidiary cells. The scars of non-glandular hairs visible, surrounded by about 10 cells arranged in a ring. Non-glandular hairs unicellular with several sections, complete ones 170~454 μm long, 14~35 μm in diameter, the wall 4~10 μm thick; inner walls shrunken, outer walls with warty protrusions; lumens contain 1~10 extremely thin sections, separated non-glandular hairs into multicellular, some sections relatively thickened. Prisms of calcium oxalate existed in parenchymatous tissue of mesocarp and exocarp, occasionally single cell contains several crystals, polyhedral, biconical,

rhombic or subsquare, up to 31 μm long, 5~18 μm in diameter. Small vessels, tracheid, irregular brown masses and occasionally with oil droplets also exist.

(2) Exocarp of *Citrus maxima*: Grayish-brown or yellowish-green. The walls of mesocarp parenchymatous cells 1.5~10 μm thick. The cuticle of exocarp 7~11 μm thick; 6~26 μm in diameter in surface view, walls relatively thin. Prisms of calcium oxalate 45 μm long, 7~32 μm in diameter. Some fibers and stone cells also present.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of naringin and dissolve in methanol to produce a solution containing 0.4 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and the upper layer of the mixture of ethyl acetate, methanol, and water (10:2:3) at 10℃ as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with a 5% solution of $AlCl_3$/EtOH TS. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 15.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 7.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Naringin:
   (1) Mobile phase: Methanol as the mobile phase A, and a solution of 0.1% phosphoric acid as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of naringin, and dissolve in methanol to produce a solution containing 0.15 mg per mL.
   (3) Sample solution: Weigh accurately 0.5 g of powdered sample, add 30 mL of methanol, ultrasonicate for 30 minutes, centrifuge, filter, use the filtrate. Repeat the extraction of the residue two more times. Combine the filtrate, make up the filtrate to 100 mL with methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (252 nm) and a column packing L1. The column temperature is maintained at 25℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~20	35→45	65→55
20~30	45→95	55→5
30~35	95	5

   (5) Procedure: Inject accurately 20 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Naringin : (%)=10 (r_U/r_S) (C_S) / (W)
   r_U: peak area of naringin of sample solution
   r_S: peak area of naringin of reference standard solution
   C_S: concentration of naringin of reference standard solution (mg/mL)
   W: weight of test sample (g) calculated with dried sample.
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place, and protect from mold and insects.
Usage: Qi-regulating medicinal.
Property and flavor: Warm; pungent and bitter.
Meridian tropism: Lung and spleen meridians.
Effects: Move qi and expand center, dry dampness to resolve phlegm.
Administration and dosage: 3~10 g.

CITRI RETICULATAE PERICARPIUM
橘皮
Jyu Pi/Ju Pi
Tangerine Peel

Tangerine peel is the dried pericarp of *Citrus reticulata* Blanco and its cultivated varieties (Fam. Rutaceae).
It contains not less than 27.0% of dilute ethanol-soluble extractives and not less than 27.0% of water extractives and not less than 4.0% of hesperidin.

Description: Peeled into several flaps, some broken into irregular sheets, 0.5 to 1.5 mm in thick. The outer epidermal orange-yellow to orange-red, and the oil spot is fine; the inner epidermal yellowish white. Tough and easy to bend. Odor slight, taste bitter and spicy.

Microscopic identification:

1. **Transverse section:**
   Pericarp of *Citrus reticulata*: Epidermis is 1 row of small subsquare cells, which are surrounded by the stratum corneum, sometimes with stomata; the lower layers of parenchyma are scattered with 1~2 columns of oil chambers, oval or elliptical, irregularly arranged. Parenchyma cells contain calcium oxalate crystals, which are many cells in the near epidermis; some cells contain fan-shaped crystals, and the aggregates are aggregated into a mass. The wall of the mesocarp parenchyma is thick, and the cells adjacent to the epidermis are rectangular, tangentially elongated; the cells on the inner side are subround, arranged loosely, and the wall is unevenly thickened. The vascular bundles are vertical, distributed in a vertical and horizontal direction.
2. **Powder:** Pale yellowish-brown. Epidermal cells of the pericarp have a polygonal, subsquare or rectangular shape, a slightly thick vertical wall, a circular stomata, 18~26 μm in diameter, and subsidiary cells are not conspicuous. The oil chamber has been broken, and the parenchyma cells on the periphery are slightly thickened. The mesocarp parenchyma cells are irregular in shape, the walls are unevenly thickened, the thickness is about 8 μm, there is no lignification, and some are in the form of beaded thickening. The catheter is small, 6~9 μm in diameter. Calcium oxalate crystals are present in mesocarp parenchyma cells, polyhedral, rhomboid or biconical; colorful under polarized light microscopy. Fan-shaped crystals are mainly found in parenchyma cells, yellow or colorless, usually aggregated into round or amorphous mass; pale yellow or bright orange under polarized light.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of hesperidin and dissolve in methanol to produce a solution containing 0.5 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, methanol, and water (10:2:1) as the developing solvent. Apply 2 μL of each of the sample solution and reference drug solution and 5 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Expose to iodine vapor for 3~5 minutes. Examine under the ultraviolet light at 254 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 16.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 4.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).
9. Aflatoxins
   (1) Aflatoxins (sum of B1, B2, G1 and G2): Not more than 10.0 ppb (General rule 6307).
   (2) Aflatoxin B_1: Not more than 5.0 ppb (General rule 6307).

Assay:

1. Hesperidin:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and water as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of hesperidin and dissolve in methanol to produce a solution containing 80 μg per mL.
   (3) Sample solution: Weigh accurately 0.1 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 15 mL of methanol, ultrasonicate for 30 minutes, centrifuge for 15 minutes. Transfer the supernatant to a 50-mL volumetric flask. Repeat the extraction of the residue two more times. Combine the supernatant and make up to volume with methanol, mix well, filter and use the filtrate.
   (4) Chromatographic system: The liquid

chromatography is equipped with an UV detector (280 nm) and a column packing L1. The column temperature is maintained at 40℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of hesperidin should not be less than 3,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~25	15→30	85→70
25~30	30→95	70→5
30~35	95	5

(5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Hesperidin (%)=0.005(r_U/r_S) (C_S) / (W)

r_U: peak area of hesperidin of sample solution

r_S: peak area of hesperidin of reference standard solution

C_S: concentration of hesperidin of reference standard solution (μg/mL)

W: weight of test sample (g) calculated with dried sample.

Storage: Store in a cool and dry place, and protect from mold and insects.
Usage: Qi-regulating medicinal.
Property and flavor: Warm; bitter and pungent.
Meridian tropism: Lung and spleen meridians.
Effects: Regulates qi, regulate the middle jiao, dry dampness, resolve phlegm.
Administration and dosage: 3~12 g.

CITRI RETICULATAE PERICARPIUM VETUM
陳皮
Chen Pi / Chen Pi
Aged Tangerine Peel

Aged tangerine peel is the dried pericarp of the ripe fruit of *Citrus reticulata* Blanco and its cultivated varieties (Fam. Rutaceae). The drug is subdivided into two classes, commonly known as “Guang Chen Pi” and “Chen Pi”.
It contains not less than 22.0% of dilute ethanol-soluble extractives, not less than 24.0% of water extractives and not less than 2.0% of hesperidin.

Description:
1. Guang Chen Pi: Often peeled in three lobes, 1~2 mm thick, often curved inwards. Externally yellowish-orange or reddish-orange, shrunken, with numerous dented or protuberant oil dots (oil cavity). Internally pale yellowish-white, spongy. Texture light and slightly tenacious. Odour aromatic; taste slightly bitter and pungent.
2. Chen Pi: Often peeled in several lobes or in irregular slices, 2~3 mm thick. Externally orange-red or brown, darkened after storage, with fine oil dots. Internally pale yellowish-white. Texture relatively fragile, easily broken. Odour relatively weak; taste bitter and pungent.

Microscopic identification:
1. **Transverse section:**
   (1) Guang Chen Pi: Epidermis of exocarp composed of 1 layer of small subsquare cells, covered with cuticle, with stomata; inside showing several layers of parenchyma tissue scattered with 1~2 layers of oil cavities, oil cavities round or elliptical, 0.3~1 mm in diameter, 0.5~1.3 mm in length. Mesocarp cells irregular in shape, wall thickened unevenly, with large intercellular spaces; vascular bundles scattered in collateral type. Parenchymatous cells containing prisms of calcium oxalate, mostly distributed near epidermis; some cells contain hesperidin crystals.
   (2) Chen Pi: Prisms of calcium oxalate relatively numerous, rhombic, polyhedral or biconical, up to about 37 μm in length, a few of crystals arranged parallelly, composed of two polyhedron, up to about 43 μm in length.
2. **Powder:** Pale yellowish-brown. Parenchymatous cells of mesocarp varying in shape, wall unevenly thickened, about 8 μm thick, unlignified, occasionally moniliform thickened or containing hesperidin crystals. Epidermal cells of exocarp polygonal, subsquare or rectangular in surface view, wall thin, stomata subrounded, with 6~8 subsidiary cells; inside showing parenchymatous cells containing prisms of calcium oxalate, polyhedral, biconical or subsquare, up to about 32 μm in length, 19 μm in diameter, occasionally containing hesperidin crystals. Oil cavities mostly broken, vessels and tracheids fine.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and make up the filtrate to 10 mL.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of hesperidin and dissolve in methanol to produce a saturated solution.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, methanol, and water (100:17:13) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 3 cm from the origin, dry in air, and then use the upper layer of toluene, ethyl acetate, formic acid, and water (20:10:1:1) as the developing solvent. Once

the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with $AlCl_3$/EtOH TS. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained with the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Total ash: Not more than 7.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).
8. Pesticide residues:
   (1) The total DDT content: Not more than 0.2 ppm (General rule 6305).
   (2) The total BHC content: Not more than 0.2 ppm (General rule 6305).
9. Aflatoxins
   (1) Aflatoxins (sum of B_1, B_2, G_1 and G_2): Not more than 10.0 ppb (General rule 6307).
   (2) Aflatoxin B_1: Not more than 5.0 ppb (General rule 6307).

Assay:

1. Hesperidin:
   (1) Mobile phase: A solution of acetonitrile and 0.2% phosphoric acid (20：80). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of hesperidin, and dissolve in methanol to produce a solution containing 0.15 mg per mL.
   (3) Sample solution: Weigh accurately 0.2 g of the powdered sample, add 20 mL of methanol, ultrasonicate for 30 minutes, cool, filter, make up the filtrate to 25 mL with methanol and mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (280 nm) and a column (4~6 mm × 15~25 cm) packing L1 (5~10 μm). The retention time of hesperidin is about 10 minutes.
   (5) Procedure: Inject accurately 20 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Hesperidin (%)=2.5(r_U/r_S) (C_S) / (W)
   r_U: peak area of hesperidin of sample solution
   r_S: peak area of hesperidin of reference standard solution
   C_S: concentration of hesperidin of reference standard solution (mg/mL)
   W: weight of test sample (g) calculated with dried sample.
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a dry place, and protect from mold and insects.
Usage: Qi-regulating medicinal.
Property and flavor: Warm; bitter and pungent.
Meridian tropism: Lung and spleen meridians.
Effects: Regulates qi, regulate the middle jiao, dry dampness, resolve phlegm.
Administration and dosage: 3~11.5 g.

CITRI RETICULATAE PERICARPIUM VIRIDE
青皮
Cing Pi / Qing Pi
Green Tangerine Peel

Green tangerine peel is the dried pericarp of the young or immature fruit of *Citrus reticulata* Blanco (Fam. Rutaceae) and its cultivated varieties, commonly known as “Ge Qing Pi” and “Si Hua Qing Pi”.
It contains not less than 12.0% of dilute ethanol-soluble extractives, not less than 12.0% of water extractive and not less than 5.0% of hesperidin.

Description:

1. Ge Qing Pi (young fruits): Subspheroidal, 0.5~2 cm in diameter. Exocarp grayish-green or blackish-green, slightly rough, with numerous dented oil cavities, apex remained with stylopodium, base with a rounded scar of fruit stalk. Mesocarp yellowish-white or pale yellowish-brown, 1~2 mm thick, with 1~2 layers of oil cavities at the edges, pulp vesicles 8~10 in the center, pale grayish-brown. Odour delicately aromatic; taste bitter and pungent.
2. Si Hua Qing Pi (immature fruits): Pericarp cut into four lobes, oblong, 4~6 cm in length, 1~2 mm thick. The outer surface grayish-green or blackish-green, with dense and numerous oil cavities; the inner surface whitish or yellowish-white, with yellowish-white or yellowish-brown small veins.

Microscopic identification:

1. **Transverse section:**
   Pericarp of *Citrus reticulata*: Outermost layer composed of 1 layer of epidermis covered with cuticle, cells flat-rectangular or flat-square, with stomata. Mesocarp occupied about 1/2 of the pericarp, composed of parenchymatous cells, oil

cavities and vascular bundles; parenchymatous cells with walls slightly thickened, 3~5 layers of cells near the outer part flat-rectangular, subsquare or subrounded, containing orange-yellow granule-like contents, scattered with prisms of calcium oxalate, cells gradually large from outside to inside, elongated radially, with intercellular spaces; oil cavities scattered irregularly, 1~2 layered, suboval or suboblong, varying in size, composed of numerous flat-rectangular or flat-elliptical secretory cells, containing oil droplets. Vascular bundles scattered, composed of vessels and parenchymatous cells; vessels mainly spiral and annular, 3~6 μm in diameter, arranged tangentially or radially, cells subrounded or long strip-shaped; parenchymatous cells small, subrounded or long strip-shaped. Endocarp occupied about 1/2 of the pericarp, composed of parenchymatous cells, arranged sparsely, containing aerenchyma.

2. **Powder:** Pale grayish-yellow. Parenchymatous cells of mesocarp vary in size, walls irregularly thickened, 2~7 μm thick, extremely thickened at corners, occasionally with some pit canals, cells containing pale yellow hesperidin crystals subrounded or irregular in shape. Epidermal cells of pericarp polygonal or subsquare in surface view, up to about 14 μm in diameter, walls thin; stomata with 7~9 subsidiary cells. Prisms of calcium oxalate existed in parenchymatous cell of pericarp, biconical, rhombic, cylindrical or irregularly polyhedral, 3~15 μm in diameter, up to 22 μm in length. Vessels, tracheids and fragments of oil cavities occasionally present.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of hesperidin and dissolve in methanol to produce a solution containing 0.5 mg per mL.
4. Procedure: Use silica gel plate with 0.5% sodium hydroxide solution as the coating substance and a solution of ethyl acetate, methanol, and water (100:17:13) as the developing solvent. Apply 5 μL of each of the sample solution and reference drug solution and 8 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with $AlC1_3$/EtOH TS. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 14.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 7.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Hesperidin:
   (1) Mobile phase: Methanol as the mobile phase A, and water as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of hesperidin and dissolve in methanol to produce a solution containing 0.1 mg per mL.
   (3) Sample solution: Weigh accurately 0.2 g of powdered sample and place it in a 50-mL volumetric flask, add accurately 30 mL of methanol, ultrasonicate for 30 minutes, cool, make up to volume with methanol, mix well and filter. Take 2 mL of the filtrate to a 5-mL volumetric flask, make up to volume with methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (285 nm) and a column packing L1. The column temperature is maintained at 25℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of nüzhenide should not be less than 3,500.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~5	25	75
5~25	25→75	75→25

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Hesperidin (%)=12.5(r_U/r_S) (C_S) / (W)

r_U: peak area of hesperidin of sample solution

r_S: peak area of hesperidin of reference standard solution

C_S: concentration of hesperidin of reference standard solution (mg/mL)

W: weight of test sample (g) calculated with dried sample.

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place, and protect from insects.
Usage: Qi-regulating medicinal.
Property and flavor: Warm; pungent and bitter.
Meridian tropism: Liver, gallbladder, and stomach meridians.
Effects: Soothe liver and breaks qi, promote digestion and remove food stagnation.
Administration and dosage: 3~10 g.

CITRI EXOCARPIUM RUBRUM
橘紅
Jyu Hong / Ju Hong
Red Tangerine Exocarp

Red tangerine exocarp is the dried exocarp of *Citrus reticulata* Blanco and its cultivated varieties (Fam. Rutaceae).
It contains not less than 14.0% of dilute ethanol-soluble extractives, not less than 18.0% of water extractives and not less than 1.7% of hesperidin.

Description: Long stripes or irregular thin slices, margin shrunken and curved inward. The outer surface yellowish-brown or orange-red, becoming brown and with numerous yellowish-white protruding or dented-dotted oil cavities after storage. The inner surface yellowish-white, with numerous sunken and transparent small spots. Texture fragile, easily broken. Odour aromatic; taste slightly bitter and numb.

Microscopic identification:
Powder: Pale yellowish-brown. Epidermal cells of exocarp polygonal, subsquare or rectangular in surface view, anticlinal walls thickened. Stomata subrounded, 18~26 μm in diameter, subsidiary cells indistinct. The walls of parenchymatous cells of fragments of oil cavities slightly thickened. Prisms of calcium oxalate abundant, 4~31 μm in diameter, occurring singly in parenchymatous cells, rhombic, double-conical to irregularly polygonal; polychromatic under the polarized microscope. Fan-shaped cluster crystals yellow, sometimes visible, usually aggregated into spheroid or amorphous masses; polychromatic under the polarized microscope.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 15 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of hesperidin and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, ethanol, and 4N ammonia (4:2:1) as the developing solvent. Apply 10 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with vanillin/H_2SO_4 MeOH TS and heat at 105°C until the spots become visible. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Total ash: Not more than 5.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
1. Hesperidin:
   (1) Mobile phase: A solution of methanol and water (40:60). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of hesperidin and dissolve in methanol to produce a solution containing 60 μg per mL.
   (3) Sample solution: Weigh accurately 0.2 g of the powdered sample, add accurately 20 mL of methanol, heat under reflux for 1 hour, cool, filter, transfer the solution to 50-mL volumetric flask, and wash the residue and flask with a small quantity of methanol and make up to volume with methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (284 nm) and a column (4~6 mm × 15~25 cm) packing L1 (5~10 μm). The column temperature is maintained at room temperature. Inject reference standard solution into the liquid chromatography apparatus for 5 times, and record the peak areas. The relative standard deviation of the

peak area of hesperidin should not be more than 1.5%.

(5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Hesperidin (%)=0.005(r_U/r_S) (C_S) / (W)

r_U: peak area of hesperidin of sample solution

r_S: peak area of hesperidin of reference standard solution

C_S: concentration of hesperidin of reference standard solution (μg /mL)

W: weight of test sample (g) calculated with dried sample.

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from insects.
Usage: Qi-regulating medicinal.
Property and flavor: Warm; pungent and bitter.
Meridian tropism: Lung and spleen meridians.
Effects: Dissipate cold, dry dampness, promotes qi, resolve phlegm.
Administration and dosage: 3~10 g.

CITRI SARCODACTYLIS FRUCTUS
佛手柑
Fo Shou Gan / Fo Shou Gan
Finger Citron

Finger citron is the dried immature fruit of *Citrus medica* L. var. *sarcodactylis* Swingle (Fam. Rutaceae).
It contains not less than 31.0% of dilute ethanol-soluble extractives, not less than 20.0% of water extractives and not less than 0.03% of hesperidin.

Description: Slices cut in longitudinal section, elliptical, 6~9 cm in length, 3~6 cm in width, 1~2 mm thick. The apex relatively board, with 3~5 finger-shaped lobes, lobes lanceolate, the base relatively narrow, occasionally with a scar of fruit stalk. Exocarp yellowish-green or orange-yellow, with dented oil spots. Mesocarp grayish-white or pale yellowish-white, scattered with yellow dotted or criss-cross vascular bundles. Texture soft. Odour aromatic; taste sour and bitter.

Microscopic identification:
Powder: Pale brownish-yellow. Parenchymatous cells of mesocarp numerous, irregular or subrounded, walls unevenly thickened. Epidermal cells of pericarp irregularly polygonal in surface view, subrounded stomata occasionally present. Prisms of calcium oxalate grouped as polyhedral, rhombic or biconical in the polygonal parenchymatous cells.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of absolute ethanol, ultrasonicate for 20 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 0.5 mL of absolute ethanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane and ethyl acetate (3:1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 254 nm and 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:
1. Loss on drying: Not more than 15.0% dry at 105°C for 5 hours (General rule 6015).
2. Total ash: Not more than 5.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
1. Hesperidin:
   (1) Mobile phase: A solution of methanol, water, and glacial acetic acid (33:63:2). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of hesperidin and dissolve in methanol to produce a solution containing 15 μL per mL.
   (3) Sample solution: Weigh accurately 0.5 g of powdered sample and place it in a conical flask with stopper, accurately add 25 mL of methanol, weigh, heat under reflux for 1 hour, cool, weigh again, replenish the loss of the weight with methanol, mix well and filter, use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (284 nm) and a column packing L1. The number of theoretical plates of the peak of hesperidin should not be less than 5,000.

(5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Hesperidin (%)=0.0025(r_U/r_S) (C_S) / (W)

r_U: peak area of hesperidin of sample solution

r_S: peak area of hesperidin of reference standard solution

C_S: concentration of hesperidin of reference standard solution (μg/mL)

W: weight of test sample (g) calculated with dried sample.

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from mold and insects.
Usage: Qi-regulating medicinal.
Property and flavor: Warm; pungent, bitter and sour.
Meridian tropism: Liver, spleen, stomach, and lung meridians.
Effects: Soothe the liver and regulate qi, harmonize the stomach and relieve pain, dry dampness to resolve phlegm.
Administration and dosage: 3~10 g.

CLEMATIDIS CAULIS
川木通
Chuan Mu Tong / Chuan Mu Tong
Clematis Stem

Clematis Stem is the dried stem of *Clematis montana* Buch.-Ham. ex DC. or *Clematis armandii* Franch. (Fam. Ranunculaceae).
It contains not less than 4.0% of dilute ethanol-soluble extractives, not less than 6.0% of water extractives and should not contain aristolochic acid I & aristolochic acid II.

Description:
1. Stem of *Clematis montana*: Long cylindrical, slightly twisted, 50~100 cm in length, 2~3.5 cm in diameter. Externally yellowish-brown, with longitudinal furrows and ridges, occasionally with longitudinal torn; nodes slightly swollen, with scars of leaves and branch. Texture hard, uneasily broken, fracture uneven, bark yellowish-brown, wood pale yellowish-brown and pale yellow, with radial cracks, vessel pores varying in size, scattered densely, pith whitish or yellowish-brown. Odour slight; taste slightly bitter.
2. Stem of *Clematis armandii*: Slender cylindrical, 30~60 cm in length, 0.8~2 cm in diameter. Externally reddish-brown or grayish-yellow, with longitudinal ridges, mostly torn, easily exfoliated from wood, nodes swollen. Odour slight; taste bitter.

Microscopic identification:
Transverse section:
Stem of *Clematis armandii*: Cork consists of 1 layer of cells. Cortex extremely thin, usually shrunken or separated. Groups of fibers and some groups of stone cells scattered in pericyclic, arranged in an undulating ring. Phloem thin. Cambium in a ring. Xylem relatively narrow, composed of vessels, xylem fibers and xylem parenchymatous cells. Vessels polygonal, bigger ones tangentially arranged irregular, cells of primary xylem extended to pith. Medullary rays lignified, composed of more than 6~10 rows of cells. Cells of pith round and lignified, arranged loose. No existence of crystals of calcium oxalate and starch granules in parenchymatous cells.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 3.0 g of powdered sample to 10 mL of ethanol, ultrasonicate for 30 minutes, filter and make up to 10 mL.
2. Reference drug solution: Take 3.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of petroleum ether (30~60℃), ethyl acetate, and formic acid (6:2:0.1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under visible light and ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:
1. Loss on drying: Not more than 13.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 3.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).
9. Should not contain aristolochic acid I & II:
   (1) Sample solution: Add 3.0 g of powdered sample to 10 mL of ethanol, ultrasonicate for 30 minutes, filter.
   (2) Reference standard solution: Weigh accurately a quantity of aristolochic acid and

dissolve in ethanol to produce a solution containing 0.2 mg per mL.

(3) Procedure: Carry out the method for thin layer chromatography (General rule 1621.3), use silica gel F_{254} as the coating substance and a solution of chloroform, ethyl acetate and ethanol (17:1:3) as the developing solvent. Apply 10 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air, and examine under the ultraviolet light at 254 nm. Spray with vanillin/H_2SO_4 TS, dry in air, and examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution should not corresponding in R_f values and color to the spots in the chromatogram obtained from the reference standard solution.

Assay:

1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place, and protect from moisture.
Usage: Dampness-dispelling medicinal (Dampness-draining diuretic medicinal).
Property and flavor: Cold; bitter.
Meridian tropism: Heart, small intestine, and bladder meridians.
Effects: Induce diuresis and relieve strangury, clear heart to downbear fire, promoting lactation.
Administration and dosage: 3~6 g.

CLEMATIDIS RADIX ET RHIZOMA
威靈仙
Wei Ling Sian / Wei Ling Xian
Clematis Root

Clematis root is the dried root and rhizome of *Clematis chinensis* Osbeck, *Clematis hexapetala* Pall. or *Clematis terniflora* DC. var. *manshurica* (Rupr.) Ohwi (*Clematis manshurica* Rupr.) (Fam. Ranunculaceae).
It contains not less than 17.0% of dilute ethanol-soluble extractives, not less than 14.0% of water extractives and not less than 0.6% of hederagenin.

Description:

1. Root of *Clematis chinensis*: Rhizomes horizontal, irregular cylindrical, 1.5~10 cm in length, 0.3~1.5 cm in diameter, with numerous rootlets at the lower and lateral part. Externally pale brownish-yellow, bark easily exfoliated, fibrous, nodes protuberant, apex remained with lignified stems. Texture relatively tough, fracture fibrous. Roots slender cylindrical, slightly curved, 7~20 cm in length, 0.1~0.3 cm in diameter. Externally brown or blackish-brown, with longitudinally fine wrinkles, occasionally exposing pale yellow wood when bark exfoliated. Texture hard and fragile, easily broken, fracture showing broad bark, often with cleft between bark and wood. Odour slight; taste bitter.
2. Root of *Clematis hexapetala*: Rhizomes short cylindrical, 1~4 cm in length, 0.5~1 cm in diameter. Roots relatively small, 4~20 cm in length, 0.1~0.2 cm in diameter. Externally brown to brownish-black. Fracture showing smaller wood, shorter than 1/2 diameter of the root. Taste salty.
3. Root of *Clematis terniflora* var. *manshurica*: Rhizomes cylindrical, 1~11 cm in length, 0.5~2.5 cm in diameter, with numerous rootlets at the upper part, horsetail-like. Externally brownish- black or brown, with numerous distinct fine wrinkles. Fracture showing white bark, wood subrounded, relatively smaller. Taste pungent.

Microscopic identification:

1. **Transverse section:**
   (1) Root of *Clematis chinensis*: Epidermal cells relatively small, subrectangular or subovate, outer wall thickened, dark brown. Exodermal cells arranged densely; cortex broad, cells with distinct pits, containing starch granules and sandy crystals of calcium oxalate, some cells containing volatile oil; endodermis distinct with Casparian strip visible. Phloem narrow. Xylem appearing diarch, completely lignified, vessels broad, xylem fibers and xylem parenchymatous cells with thick walls. Phloem of rhizomes or old roots with a few of lignified fibers and stone cells. Cambium distinct. Vessels mainly pitted, reticulate and spiral.
   (2) Root of *Clematis hexapetala*: Both young and old roots without phloem fibers. Stele relatively small, cortex broad.
   (3) Root of *Clematis terniflora* var. *manshurica*: Phloem of young roots with no or a few of fibers; old roots with more phloem fibers. Vessels with large pits. Cortex broad, cells oblong, about 14~16 layers, arranged in a ring. Xylem appearing triarch.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Weigh 1.0 g of the powdered sample to 100 mL of ethyl acetate, heat under reflux for 2 hours, heat under reflux for 2 hours, cool, filter and discard the filtrate. Evaporate the residue to dryness, add 25 mL of methanol, ultrasonicate for 30 minutes, filter, and use the filtrate. Repeat the extraction of the residue one more time. Combine the filtrate, Combine the filtrates. Evaporate the solvent to dryness. Dissolve the residue in 30 mL of hydrochloric acid (7.3%, w/v), heat under reflux for

2 hours, cool, extract shaking for three times each with 30 mL of ethyl acetate. Combine the ethyl acetate extracts and evaporate the solvent to dryness. Dissolve the residue in methanol, and make up to 10 mL.

2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of hederagenin and dissolve in methanol to produce a solution containing 0.5 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of dichloromethane and methanol (15:1) as the developing solvent. Apply 2 μL of each of the sample solution and reference drug solution and 1 μL of the reference standard solution to the plate. Once the top of solvent rise to about 5~10 cm from the origin, dry in air. Spray with a solution of 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 14.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 8.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 3.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Hederagenin:
   (1) Mobile phase: A solution of acetonitrile and water (90:10). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of hederagenin, and dissolve in methanol to produce a solution containing 0.75 mg per mL.
   (3) Sample solution: Weigh accurately 1 g of powdered sampl and place it in a 250-mL flask, then add accurately 100 mL of ethyl acetate, heat under reflux for 2 hour, evaporate the filtrate to dryness, transfer the residue to 50-mL centrifuge tube, add 25 mL of methanol, ultrasonicate for 30 minutes, filter with filter paper. Repeat the extraction of the residue one more time. Combine the extracts and transfer to a 50-mL volumetric flask, make up to volume with methanol and transfer the solution to 100-mL flask, evaporate to dryness. The residue dissolve in 30 mL of 7.3% (w/v) hydrochloric acid, heat under reflux for 2 hour, cool to room temperature. Transfer the solution to a separatory funnel, extract shaking 3 times each with 30 mL of ethyl acetate, combine the ethyl acetate extracts and transfer the ethyl acetate extracts to 100-mL flask, evaporate to dryness. The residue dissolve in methanol and transfer to 10-mL volumetric flask, make up to volume with methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (205 nm) and a column packing L1. The column temperature is maintained at 35℃. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of hederagenin should not be less than 4,000.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   Hederagenin (%)=1(r_U/r_S) (C_S) / (W)

   r_U: peak area of hederagenin of sample solution

   r_S: peak area of hederagenin of reference standard solution

   C_S: concentration of hederagenin of reference standard solution (mg/mL)

   W: weight of test sample (g) calculated with dried sample.
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place.
Usage: Dampness-dispelling medicinal (Wind-dampness-dispelling medicinal).
Property and flavor: Warm; pungent and salty.
Meridian tropism: Bladder meridians.
Effects: Dispel wind and eliminate dampness, free the collateral vessels to relieve pain.
Administration and dosage: 6~12 g.

CNIDII FRUCTUS
蛇床子
She Chuang Zih / She Chuang Zi
Common Cnidium Fruit

Common cnidium fruit is the dried ripe fruit of *Cnidium monnieri* (L.) Cusson (Fam. Umbelliferae).

It contains not less than 9.0% of dilute ethanol-soluble extractives, not less than 10.0% of water extractives and not less than 1.0% of osthol.

Description: Cremocarp, ellipsoidal, about 2~4 mm in length, about 1 mm in diameter. Externally grayish-yellow, with 2 outcurved persistent stylopodium at the summit. Dorsal surface of mericarps slightly protuberant, with five longitudinal ridges, commissural surface flattened, with two brown and slightly protuberant longitudinal ribs. Pericarp lax and fragile, easily rubbed off. Seed small, grayish-brown and oily. Odour aromatic; taste pungent, numb on chewing.

Microscopic identification:

1. **Transverse section:**
   Mericarp of *Cnidium monnieri*: Slightly pentagonal, with 5 wing-shaped ridges. Exocarp composed of 1 row of epidermal cells, usually shrunken, covered with cuticle. Mesocarp composed of several rows of parenchymatous cells, containing strip-shaped reticulate cells, mostly distributed inside vascular bundles; there are 6 vittae, including 1 vitta between each 2 ridges and 2 vittae at commissural surface, vitta oblong, up to about 110 μm in length, containing yellowish-brown oil, when the fruit matured, vittae walls becoming dark brown cuticle; vascular bundles located in the center of ridge, xylem vessels subrounded or polygonal, accompanied by a few of fibers, phloem located at two sides of bundles. Endocarp composed of 1~2 rows of flat cells. Testa composed of 1 row of pale brown cells. Endosperm cells contain fatty oil and starch granules, each granules containing fine cluster crystals. Embryo round, locating in the center of endosperm, composed of parenchymatous cells, containing a few of starch granules.
2. **Powder:** Yellowish-brown. Epidermal cells of exocarp subsquare or subpolygonal in surface view, anticlinal walls undulated or wave-curved, with cutinized striations. Reticulate cells subsquare, subrounded or subrectangular, wall slightly thickened, unlignified or slightly lignified, with strip-shaped or reticulate thickenings. Fragments of vittae yellowish-brown or dark reddish-brown, some with septa, cellular trace faintly visible on the surface. Inlaid (endocarp) cells occasionally with walls moniliform thickened. Endosperm cells, fatty oil droplets and clusters of calcium oxalate also visible.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, cool, filter and make up the filtrate to 10 mL.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of osthol and dissolve in ethanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane, toluene, and ethyl acetate (2:3:3) as the developing solvent. Apply 10 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained with the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 12.0% dry at 105°C for 5 hours (General rule 6015).
2. Total ash: Not more than 13.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 5.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Osthol:
   (1) Mobile phase: A solution of acetonitrile and water (65:35). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of osthol and dissolve in ethanol to produce a solution containing 45 μg per mL.
   (3) Sample solution: Weigh accurately 0.1 g of the powdered sample, transfer to a conical flask with stopper, accurately add 25 mL of absolute ethanol, stopper tightly and weigh, stand for 2 hours, ultrasonicate for 30 minutes, cool and weigh again, replenish the loss of the weight with absolute ethanol and mix well. Transfer 5 mL of the supernatant to a 10-mL volumetric flask, make up to volume with absolute ethanol, mix well, filter and use the filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (322 nm) and a column packing L1. The number of theoretical plates of the peak of osthol should not be less than 3,000.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Osthol (%)=0.005(r_U/r_S) (C_S) / (W)
   r_U: peak area of osthol of sample solution

rs: peak area of osthol of reference standard solution
Cs: concentration of osthol of reference standard solution (μg/mL)
W: weight of test sample (g) calculated with dried sample.

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place.
Usage: Tonifying and replenishing medicinal (Yang-tonifying medicinal).
Property and flavor: Warm; pungent and bitter.
Meridian tropism: Kidney meridians.
Effects: Warm kidney and invigorate yang, dissipate cold and dispel wind, dry dampness to kill worms, relieve itching.
Administration and dosage: 3~11.5 g; used an appropriate amount for external use, usually decocted for fuming-washing therapy or ground into powder for application.

CODONOPSIS RADIX
黨參
Dang Shen / Dang Shen
Pilose Asiabell Root

Pilose asiabell root is the dried root of *Codonopsis pilosula* (Franch.) Nannf., *Codonopsis pilosula* (Franch.) Nannf. var. *modesta* (Nannf.) L.T.Shen or *Codonopsis tangshen* Oliv. (Fam. Campanulaceae).
It contains not less than 26.0% of dilute ethanol-soluble extractives, not less than 43.0% of water extractives and not less than 0.02% of lobetyolin.

Description:

1. Root of *Codonopsis pilosula*: Long cylindrical, fusiform-cylindrical or long conical, 10~45 cm in length, 0.4~2.5 cm in diameter. Externally grayish-yellow to grayish-brown, with numerous warty protuberant stem scars and buds on the root stock gathering into spheroidal, commonly known as “Shih Zih Pan Tou”, and densely transverse annulations occurring below the root stock, gradually sparse downwards. Texture soft or hard, fracture relatively even, with clefts or striated radially, bark pale yellowish-white to pale brown, wood pale yellow. Odour slightly aromatic; taste sweet.
2. Root of *Codonopsis pilosula* var. *modesta*: Relatively short, 10~35 cm in length, less branched. Externally yellowish-white to grayish-yellow, dense transverse annulations occurring below the root stock, frequently up to over half length of the root. Fracture more clefts, uneven, bark white to pale brown, wood pale yellow.
3. Root of *Codonopsis tangshen*: Less branched, 15~40 cm in length. Externally grayish-brown, cork often exfoliated partially, the upper part annulations relatively lax. Fracture bark thick, with less clefts. Taste slightly sweet and sour.

Microscopic identification:

1. **Transverse section:**
   (1) Root of *Codonopsis pilosula*: Cork composed of several to dozens rows of cells, stone cells present in the outer layer of cork, singly scattered or in groups. Cortex narrow. Phloem broad, pale yellow groups of laticiferous tubes arranged alternately with sieve tubes, usually with clefts. Cambium ring distinct. Vessels singly scattered or several in groups, arranged radially in xylem. Parenchymatous cells contain inulin and few starch granules.
   (2) Root of *Codonopsis pilosula* var. *modesta*: Stone cells present in a complete ring in the outer layer of cork, composed of 2~5 rows of cells. Groups of laticiferous tubes arranged radially in the inner part of phloem, phloem rays curved in the outer part, occasionally arranged tangentially in an interrupted ring. The other characters are similar to root of *Codonopsis pilosula*.
   (3) Root of *Codonopsis tangshen*: Stone cells present in the outer layer of cork, singly scattered or several in groups, arranging in an interrupted ring. Groups of laticiferous tubes arranged irregularly. The other characters are similar to root of *Codonopsis pilosula*.
2. **Powder:**
   (1) Root of *Codonopsis pilosula*: Yellowish-white. Inulin masses slightly fan-shaped or subrounded, with radial striations on the surface. Stone cells relatively numerous, singly scattered or in groups, polygonal, rectangular or irregular, 24~25 μm in diameter, up to 120 μm in length. Vessels mainly bordered-pitted, reticulate and scalariform, 21~80 μm in diameter. Laticiferous tubes 12~15 μm in diameter, filled with oil droplets and fine granules. Cork cells rectangular or polygonal, lignified, with longitudinal striations.
   (2) Root of *Codonopsis pilosula* var. *modesta*: Pale yellow. Stone cells extremely numerous, 19~60 μm in diameter, 35~256 μm in length, pits sparse, pit canals distinct. Xylem parenchymatous cells fusiform, secondary walls reticular or scalariform thickened. Starch granules simple, spheroidal or ovate.
   (3) Root of *Codonopsis tangshen*: Off-white. Stone cells relatively few, 25~36 μm in diameter, 60~76 μm in length, occasionally the middle walls thickened, lumen dumbbell-shaped, pit canals distinct, trumpet-shaped or funnel-shaped. Parenchymatous cells

fusiform, reticular or moniliform. Starch granules relatively numerous, simple granules spheroidal or subrounded, 6~20 μm in diameter, hilum dotted or indistinct; compound granules composed of 2~7 components.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 5 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of lobetyolin and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, methanol, and water (8:2:1) as the developing solvent. Apply 2 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Total ash: Not more than 6.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 3.0% (General rule 6007).
3. Sulfur dioxide: Not more than 400 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Lobetyolin:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and a solution of 0.2% glacial acetic acid as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of lobetyolin, and dissolve in methanol to produce a solution containing 60 μg per mL.
   (3) Sample solution: Weigh accurately 2.5 g of the powdered sample and place it in a 125-mL conical flask, then add accurately 50 mL of methanol, ultrasonicate for 30 minutes, filter with filter paper. Repeat the extraction of the residue one more time. Combine the filtrate, evaporate the filtrate to a small amount and transfer to 10-mL volumetric flask, make up to volume with methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (280 nm) and a column packing L1. The column temperature is maintained at room temperature. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of lobetyolin should not be less than 8,000. The ratio may be adjusted if necessary.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~20	15→30	85→70
20~22	30→95	70→5

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Lobetyolin (%)=0.001 (r_U/r_S) (C_S) / (W)

r_U: peak area of lobetyolin of sample solution

r_S: peak area of lobetyolin of reference standard solution

C_S: concentration of lobetyolin of reference standard solution (μg /mL)

W: weight of test sample (g) calculated with dried sample.

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place, and protect from insects.

Usage: Tonifying and replenishing medicinal (Qi-tonifying medicinal).

Property and flavor: Neutral; sweet.

Meridian tropism: Spleen and lung meridians.

Effects: Tonify middle and replenish qi, engender fluid to nourish blood.

Administration and dosage: 9~30 g.

【Decoction pieces】

CODONOPSIS RADIX

It contains not less than 26.0% of dilute ethanol-soluble extractives, not less than 43.0% of water extractives and not less than 0.02% of lobetyolin.

Raw medicinal materials are processed to remove impurities, clean selection, soften thoroughly, cut into thin

slices, and dry, mostly irregular longitudinal section or oblique slices, externally greyish-yellow, yellowish-brown to greyish-brown, sometimes with plentiful warty prominent stem scars and buds on the root stock. Cut surface pale brownish-yellow to yellowish-brown in bark part and pale yellow to yellow in wood part, with clefs or radial striations. Odour characteristic and aromatic, taste sweet.

Thin layer chromatographic identification test: The method is the same as that for crude herb.
Impurities and other requirements: Methods and specifications are the same as those for crude herb.
Assay: The method is the same as that for crude herb.
Storage: The method is the same as that for crude herb.
Usage: Tonifying and replenishing medicinal (Qi-tonifying medicinal).
Property and flavor: Neutral; sweet.
Meridian tropism: Spleen and lung meridians.
Effects: Tonify middle and replenish qi, engender fluid to nourish blood.
Administration and dosage: 9~30 g.
Precaution and warning: Incompatible with Veratri Nigri Radix et Rhizoma.

COICIS SEMEN
薏苡仁
Yi Yi Ren / Yi Yi Ren
Coix Seed

Coix seed is the dried ripe kernel of *Coix lacryma-jobi* L. var. *ma-yuen* (Rom.Caill.) Stapf (Fam. Gramineae).

Description: Oblong, 4~8 mm in length, 3~6 mm in width. Externally milky white, smooth, occasionally with remained reddish-brown testa. Dorsal surface rounded and protruding; ventral surface with a longitudinal furrow, about 2 mm in width. One end obtusely rounded, the other end relatively broad and slightly dented with a brownish-black semi-annular scar and pale brown dotted hilum. Texture compact, fracture white and starchy. Odour slight; taste slightly sweet.

Microscopic identification:
Powder: Yellowish-white. Starch granules mostly aggregated into masses, simple granules rounded-polygonal, subspheroidal or ovate, 2~20 μm in diameter, hilum Y-shaped, V-shape or slit-shaped, striations indistinct; compound granules composed of 2~3 components. Endosperm cells subpolygonal, walls extremely thin and slightly curved, lumen filled with starch granules. Epidermal cells of pericarp slender, wall thin, anticlinal walls sinuous. Mesocarp cells irregularly long strip-shaped, slightly curved, wall extremely thin, with irregular intercellular spaces spongy tissue-like.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of *β*-sitosterol and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane amd ethyl acetate (5:3) as the developing solvent. Apply 5 μL of each of the sample solution and reference drug solution and 1 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 50% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 15.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 4.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).
9. Aflatoxins
   (1) Aflatoxins (sum of B_1, B_2, G_1 and G_2): Not more than 10.0 ppb (General rule 6307).
   (2) Aflatoxin B_1: Not more than 5.0 ppb (General rule 6307).

Storage: Refrigerate or store in a cool and dry place, and protect from insects.
Usage: Dampness-dispelling medicinal (Dampness-draining diuretic medicinal).
Property and flavor: Cool, sweet and bland.
Meridian tropism: Spleen, stomach, and lung meridians.
Effects: Fortify spleen and drain dampness, clear heat to expel pus, eliminates impediment and antidiarrheal.
Administration and dosage: 9~30 g.
Precaution and warning: Use cautiously during pregnancy.

COPTIDIS RHIZOMA
黃連
Huang Lian / Huang Lian
Coptis Rhizome

Coptis rhizome is the dried rhizome of *Coptis chinensis* Franch., *Coptis deltoidea* C.Y.Cheng & P.K.Hsiao or *Coptis teeta* Wall. (Fam. Ranunculaceae), commonly known as 'Wei-lian', 'Ya-lian' or 'Yun-lian' resepectively. It contains not less than 4.2% of berberine, calculated with berberine chloride.

Description: Mostly curved, 1~5 mm in diameter, up to 4 cm in length, bearing with numerous fine rootlet or not. Apex often remained with leaf petiole. Externally yellowish-gray, with numerous protuberance. Fracture uneven. Odourless; taste extremely bitter, saliva dyed yellow on chewing.

Microscopic identification:

1. **Transverse section:**
   Coptidis rhizoma: The outer layer was cork cells with thin walls, parenchyma outside cortex containing stone cell groups, with yellow fiber bundles near cambium. Xylem composed of yellow vessels, tracheids and xylem fibers. In the center showing huge pith, mostly hollowed. Parenchymatous cells occasionally contain stone cells.
2. **Powder:** Yellowish-brown. The fragments showing cork cells, stone cells and fibers. Vessels bordered-pitted and spiral. Parenchymatous cells yellow, without starch granules and crystals of calcium oxalate.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 0.5 g of powdered sample to 15 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 0.5 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of berberine chloride and dissolve in methanol to produce a solution containing 1.0 mg per mL of each.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-butanol, glacial acetic acid, and water (4:1:2) as the developing solvent. Apply 5 μL of the sample solution and reference drug solution and 1 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Total ash: Not more than 5.0% (General rule 6007).
2. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
3. Arsenic (As): Not more than 5.0 ppm (General rule 2211, 6301).
4. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
5. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
6. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

Berberine chloride:

1. Mobile phase: Add 3.4 g potassium dihydrogen phosphate and 1.7 g sodium lauryl sulfate in a 1,000 mL solution of acetonitrile and water (1:1). The ratio may be adjusted, if necessary.
2. Reference standard solution: Weigh accurately a quantity of berberine chloride and dissolve in methanol to produce a solution containing 0.1 mg per mL.
3. Sample solution: Weigh accurately 0.2 g of the powdered sample, accurately add 30 mL of the solution of methanol and dilute hydrochloric acid (100:1), heat under reflux for 30 minutes, cool, filter. Repeat the extraction of the residue one more time, combine the filtrate, transfer the filtrate to a 100-mL volumetric flask, make up to volume with methanol, mix well, filter and use the successive filtrate.
4. Chromatographic system: The liquid chromatography is equipped with an UV detector (345 nm) and a column packing L1. The column temperature is maintained at 35℃. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of berberine chloride should not be less than 5,000.
5. Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   Berberine chloride (%)=10(r_U/r_S) (C_S) / (W)

   r_U: peak area of berberine chloride of sample solution

   r_S: peak area of berberine chloride of reference standard solution

   C_S: concentration of berberine chloride of reference standard solution (mg/mL)

   W: weight of test sample (g) calculated with dried sample.

Storage: Store in a ventilated and dry place, and protect from mold and insects.

Usage: Heat-clearing medicinal (Heat-clearing and dampness-drying medicinal).

Property and flavor: Cold; bitter.

Meridian tropism: Heart, spleen, stomach, liver, gallbladder, and large intestine meridians.

Effects: Clear heat and dry dampness, purge fire and detoxicate.
Administration and dosage: 1.5~11.5 g; used an appropriate amount for external use.

【Decoction pieces】

COPTIDIS RHIZOMA

It contains not less than 4.2% of berberine, calculated with berberine chloride.
Raw medicinal materials are processed to remove impurities, clean selection, soften thoroughly, cut into thin slices, and dry, mostly irregular thin slices. Externally yellowish-brown, cut surface fresh yellow or reddish-yellow, with striations. Odour slight, taste extremely bitter.

Thin layer chromatographic identification test: The method is the same as that for crude herb.
Impurities and other requirements: Methods and specifications are the same as those for crude herb.
Assay: The method is the same as that for crude herb.
Storage: The method is the same as that for crude herb.
Usage: Heat-clearing medicinal (Heat-clearing and dampness-drying medicinal).
Property and flavor: Cold; bitter.
Meridian tropism: Heart, spleen, stomach, liver, gallbladder, and large intestine meridians.
Effects: Clear heat and dry dampness, purge fire and detoxicate.
Administration and dosage: 1.5~11.5 g; used an appropriate amount for external use.

CORDYCEPS
冬蟲夏草
Dong Chong Sia Cao / Dong Chong Xia Cao
Cordyceps

Cordyceps is a composite consisting of the stroma of the fungus, *Ophiocordyceps sinensis* (Berk.) G.H.Sung, J.M.Sung, Hywel-Jones & Spatafora (Fam. Clavicipitaceae), parasitized on the larva and the dead caterpillar of some species of insects (Fam. Hepialidae).
It contains not less than 0.01% of adenosine.

Description: A dead caterpillar jointed with a stroma growing in the head of the larva. The caterpillar resembling a silkworm, 3~5 cm in length, 3~8 mm in diameter; externally dark yellow to yellowish-brown, with 20~30 annulations, 8 pairs of feet in the abdomen, 4 pairs of the feet in the middle relatively conspicuous. Stroma one or 2~3, slender and cylindrical, slightly tortuous, slightly swollen above, 4~7 cm in length, rare up to 11 cm in length, about 3 mm in diameter; externally grayish-brown or dark brown, with fine longitudinal wrinkles. Caterpillar texture fragile, fracture whitish; stroma texture relatively tenacious, fracture whitish, fibrous. Odour slightly fleshly; taste slightly bitter.

Microscopic identification:
Transverse section:
Head of stroma of *Ophiocordyceps sinensis*: Perithecia born near surface, base fell into asci, oblong to ovoid, 273~550 μm in length, 140~245 μm in diameter, perithecia contains numerous ascus. Asci slender, 240~485 μm in length, 12~16 μm in diameter, wall thickened on the apex, containing a narrow linear-shaped hole in the center; Asci composed of 2~4 ascospores, spores linear-shaped, 160~470 μm in length, 5~6.5 μm in diameter, with numerous transverse septa.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Take a quantity of coarse powdered sample, defat with ethyl ether, extract with ethanol and concentrate to small amount.
2. Reference drug solution: Take a quantity of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-butanol, acetic acid, and water (4:1:6) as the developing solvent. Apply appropriate amount of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with a 0.5% solution of potassium periodate TS and 0.5% benzidine/EtOH TS. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:
1. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
2. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
3. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
4. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
1. Adenosine:
   (1) Mobile phase: A solution of phosphate (pH 6.5) [add 68.5 mL of 0.01 M sodium dihydrogen phosphate solution to 31.5 mL of 0.01 M disodium hydrogen phosphate solution, and mix well (pH 6.5)] and methanol (17:3).
   (2) Reference standard solution: Weigh accurately a quantity of adenosine and dissolve in 90% methanol to produce a solution containing 20 μg per mL.
   (3) Sample solution: Weigh accurately 0.5 g of powdered sample and place it in conical flask with stopper, accurately add 10 mL of 90% methanol, stopper tightly, mix well and weigh, heat under reflux for 30 minutes, cool, and

weigh again, replenish the loss weight with 90% methanol, mix well, filter, and use the successive filtrate.

(4) Chromatographic system: The liquid chromatography is equipped with an UV detector (260 nm) and a column (4~6 mm × 15~25 cm) packing L1 (5~10 μm). The column temperature is maintained at room temperature. Inject reference standard solution into the liquid chromatography apparatus for 5 times, and record the peak areas. The relative standard deviation of the peak area of adenosine should not be more than 2.0%. The number of theoretical plates of the peak of adenosine should not be less than 2,000.

(5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Adenosine: (%)= 0.001(r_U/r_S) (C_S) / (W)

r_U: peak area of adenosine of sample solution

r_S: peak area of adenosine of reference standard solution

C_S: concentration of adenosine of reference standard solution (μg/mL)

W: weight of test sample (g) calculated with dried sample.

Storage: Refrigerate or store in a cool and dry place, and protect from moisture, mold and insects.
Usage: Tonifying and replenishing medicinal (Yang-tonifying medicinal).
Property and flavor: Warm; sweet.
Meridian tropism: Lung and kidney meridians.
Effects: Tonify lung and replenish kidney, hemostatic to resolve phlegm.
Administration and dosage: 3~10 g.

CORNI SARCOCARPIUM
山茱萸
Shan Jhu Yu / Shan Zhu Yu
Cornus Sarcocarp

Cornus sarcocarp is the dried ripe sarcocarp of *Cornus officinalis* Siebold & Zucc. (Fam. Cornaceae).
It contains not less than 35.0% of dilute ethanol-soluble extractives, not less than 50.0% of water extractives and not less than 0.6% of loganin.

Description: Irregularly flaky or bladdery, 1-1.5 cm long and 0.5-1 cm wide. Externally purplish-black, shrunken, lustrous. The fleshy and soft purple-red color is preferred. Showing a rounded scar of persistent calyx at the apex and a scar of fruit stalk at the base. Texture soft; taste sour, astringent and slightly bitter.

Microscopic identification:

1. **Transverse section:**
Sarcocarp of *Cornus officinalis*: Exocarp composed of 1 layer of slightly flat cells, covered by relatively thick cuticle. Mesocarp broad, composed of numerous rows of parenchymatous cells varying in size, some cells contain dark brown pigment masses. 8 Vascular bundles, arranged in an interrupted ring on the inner side, with existence of stone cells and fiber bundles near stalk.
2. **Powder:** Reddish-brown. Epidermal cells of exocarp polygonal or subrectangular at surface, 16~30 μm in diameter, anticlinal walls slightly moniliform thickened, outer periclinal walls granularly cutinized and thickened, lumen containing pale orange-yellow contents. Mesocarp cells orange-brown, mostly shrunken. Stone cells subsquare, existed in mesocarp near stalk, ovoid or rectangular in shape, usually with distinct pits and large lumen (exist in mesocarp near the stalk). Clusters of calcium oxalate rare, 12~32 μm in diameter.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of ethanol, shake for 5 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of loganin and dissolve in ethanol to produce a solution containing 0.5 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, formic acid, and water (6:1:1) as the developing solvent. Apply 10 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS, and heat at 105℃ until the spots become visible. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Foreign matter: Not more than 2.0%, including pedicels (General rule 6005).
2. Total ash: Not more than 6.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule

2251, 6301).

9. Pesticide residues:
   (1) The total DDT content: Not more than 0.2 ppm (General rule 6305).
   (2) The total BHC content: Not more than 0.2 ppm (General rule 6305).
10. Aflatoxins
   (1) Aflatoxins (sum of B_1, B_2, G_1 and G_2): Not more than 10.0 ppb (General rule 6307).
   (2) Aflatoxin B_1: Not more than 5.0 ppb (General rule 6307).

Assay:

1. Loganin:
   (1) Mobile phase: A solution of acetonitrile and 0.05 M sodium dihydrogen phosphate solution (1:6). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of loganin and dissolve in 50% methanol to produce a solution containing 0.1 mg per mL.
   (3) Sample solution: Weigh accurately 0.5 g of powdered sample and place it in a conical flask with stopper, accurately add 30 mL of 50% methanol, ultrasonicate for 15 minutes, centrifuge, takes the supernatant. Repeat the extraction of the residue one more time. Combine the supernatant, make up to 100 mL with 50% methano, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (240 nm) and a column (6.0 mm × 15 cm) packing L1(5~10 μm). The column temperature is maintained at 40℃. Inject reference standard solution into the liquid chromatography apparatus for 5 times, and record the peak areas. The relative standard deviation of the peak area of loganin should not be more than 1.5%.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   Loganin (%)=10 (r_U/r_S) (C_S) / (W)

   r_U: peak area of loganin of sample solution

   r_S: peak area of loganin of reference standard solution

   C_S: concentration of loganin of reference standard solution (mg/mL)

   W: weight of test sample (g) calculated with dried sample.
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from insects.

Usage: Tonifying and replenishing medicinal (Yin-tonifying medicinal).

Property and flavor: Mild warm; sour and astringent.

Meridian tropism: Liver and kidney meridians.

Effects: Supplements liver and kidney, astringent and secure, astringe essence, antihidrotics.

Administration and dosage: 5~12 g.

CORYDALIS RHIZOMA
延胡索
Yan Hu Suo / Yan Hu Su
Corydalis Tuber

Corydalis tuber is the dried tuber of *Corydalis yanhusuo* W.T.Wang (Fam. Papaveraceae).

It contains not less than 11.0% of dilute ethanol-soluble extractives, not less than 9.0% of water extractives and not less than 0.07% of dehydrocorydaline.

Description: Irregularly oblate, 0.3~2 cm in diameter. Externally grayish-yellow or yellowish-brown, irregularly reticulate wrinkles. Apex with slight dented stem scar, base dented as hilum-like or conical protuberances. Texture hard, fracture yellow, horny, waxy-sheeny. Odour slight; taste bitter.

Microscopic identification:

1. **Transverse section:**
   (1) 1/3 upper portion of the tuber of *Corydalis yanhusuo*: Cork composed of over 10 layers of flat cells, pale yellow, scattered with 2~3 layers of sclerenchymatous cells at outer side, walls lignified and slightly thickened, with dense pits. Phloem broad, sieve tubes and laticiferous tubes intermittently arranged in several ring; treated with Sudan III, the contents of laticiferous tube showing red color. Xylem vessels fine, arranged in a ring. Pith in the center.
   (2) Central part of the tuber of *Corydalis yanhusuo*: Xylem usually 4~7 in a bundle and arranged in a ring.
   (3) Small spheroidal-shaped tubers adhered to the rhizome of *Corydalis yanhusuo*: Xylem usually 2~4 in a bundle, arranged sparsely in a ring. Parenchymatous cells filled with starch gelatinous masses. Stone cells subpolygonal, long-rounded or long-polygonal, grouped in few or scattered in cortex of stem scars.
2. **Powder:** Greenish-yellow. Parenchymatous cells filled with starch gelatinous masses. Sclerenchymatous cells of cortex long strip-shaped, walls lignified and slightly thickened, with dense pits. Stone cells (in the cortex of stem scars) subpolygonal, long-rounded or long-polygonal, 88~160 μm in length. Vessels mostly spiral, reticulate rare.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of 70% ethanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of tetrahydropalmatine and dissolve in 70% ethanol to produce a solution containing 0.1 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane, ethyl acetate, and methanol (8:2:1) as the developing solvent. Apply 5 μL of each of the sample solution and reference drug solution and 1 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 13.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 3.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 5.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).
9. Aflatoxins
   (1) Aflatoxins (sum of B_1, B_2, G_1 and G_2): Not more than 10.0 ppb (General rule 6307).
   (2) Aflatoxin B_1: Not more than 5.0 ppb (General rule 6307).

Assay:

1. Dehydrocorydaline nitrate:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and a solution of 0.1% phosphoric acid (adjust pH value to 6.0 with triethylamine) as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of dehydrocorydaline nitrate, and dissolve in 75% methanol to produce a solution containing 50 μg per mL. (Dehydrocorydaline =weight of dehydocorydaline nitrate × 0.855)
   (3) Sample solution: Weigh accurately 1.0 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 10 mL of 75% methanol, ultrasonicate for 30 minutes. Centrifuge for 10 minutes, filter the supernatant. Repeat the extraction of the residue one more time. Combine the filtrate, transfer to 20-mL volumetric flask and make up to volume with 75% methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (266 nm) and a column packing L1. The column temperature is maintained at 35℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of dehydrocorydaline nitrate should not be less than 8,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~22	20→28	80→72
22~30	28→60	72→40

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   Dehydrocorydaline nitrate (%) = 0.00171 (r_U/r_S) (C_S) / (W)

   r_U: peak area of dehydrocorydaline nitrate of sample solution

   r_S: peak area of dehydrocorydaline nitrate of reference standard solution

   C_S: concentration of dehydrocorydaline nitrate of reference standard solution (μg/mL)

   W: weight of test sample (g) calculated with dried sample.
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from insects.

Usage: Blood-regulating medicinal (Blood-activating and stasis-dispelling medicinal).

Property and flavor: Warm; pungent and bitter.

Meridian tropism: Liver and spleen meridians.

Effects: Activate blood, move qi, relieve pain, regulate menstruation.

Administration and dosage: 3~12 g.

【Decoction pieces】

CORYDALIS RHIZOMA

It contains not less than 11.0% of dilute ethanol-soluble extractives, not less than 9.0% of water extractives and not less than 0.07% of dehydrocorydaline.
Raw medicinal materials are processed to remove impurities, clean selection, dry and cut into thin slices, or break to pieces before use, mostly little rounded thick slices or irregular crushed particles, cut surface yellow or yellowish-brown, section yellow and waxy-sheeny, texture hard and fragile, cut surface horny. Odour slight, taste bitter.

Thin layer chromatographic identification test: The method is the same as that for crude herb.
Impurities and other requirements: Methods and specifications are the same as those for crude herb.
Assay: The method is the same as that for crude herb.
Storage: The method is the same as that for crude herb.
Usage: Blood-regulating medicinal (Blood-activating and stasis-dispelling medicinal).
Property and flavor: Warm; pungent and bitter.
Meridian tropism: Liver and spleen meridians.
Effects: Activate blood, move qi, relieve pain, regulate menstruation.
Administration and dosage: 3~12 g.

CRASSOSTREAE CONCHA
牡蠣
Mu Li / Mu Li
Oyster Shell

Oyster shell is the dried shell of *Crassostrea gigas* (Thunberg) or *Crassostrea rivularis* (Gould) (Fam. Ostreidae).

Description:
1. Shell of *Crassostrea gigas*: Long and thick, long strip or long oval, 10~50 cm in length, 4~15 cm in width, dorsal and ventral edges almost parallel. The right shell relatively small, scales strong and thick, arranged in layers or striated. The outer surface smooth or with several depressions, pale purple, grayish-white or yellowish-brown; the inner surface porcelain white, without denticles at both sides of the umbo. The left shell deeply depressed, scales bigger and rougher than those of the right shell, attachment surface of the umbo small. Texture hard, fracture stratiform, white. Odourless; taste slightly salty.
2. Shell of *Crassostrea rivularis*: Subrounded, oval or triangular. The outer surface of the right shell slightly uneven, gray, purple, brown, yellow, etc.; concentric scales in a ring, thin and fragile when immature and overlapped one another after several years of growth. The inner surface white, occasionally the edge pale purple. The left shell relatively larger and thicker. Fracture stratiform distinct, rough and curved.

Microscopic identification:
1. **Transverse section:** Shell of *Crassostrea rivularis*: The leaf blades curved irregularly, 5~10 μm in width, arrange densely.
2. **Powder:** Shell of *Crassostrea rivularis*: Snow white-colored, with purplish-gray fluorescence, opaque, edges obtusely round, occasionally adhering to brownish-red or purplish-black particles.

Identification:
1. Examine the powder under the ultraviolet light, *Crassostrea rivularis* gives a result of purplish-gray fluorescence.
2. Take 1.0 g of powdered sample, add 10 mL of dilute hydrochloric acid, heat, sample dissolve, bubbles containing carbon dioxide is produced, solution is slightly turbid and pale red, with remains of transparent and flaky semi-floating substance.

Impurities and other requirements:
1. Loss on drying: Not more than 2.0% dry at 105℃ for 5 hours (General rule 6015).
2. Acid-insoluble ash: Not more than 9.5% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Storage: Store in a ventilated and dry place.
Usage: Liver-pacifying and wind-extinguishing medicinal.
Property and flavor: Mild cold; salty and astringent.
Meridian tropism: Liver, gallbladder, and kidney meridians.
Effects: Calm spirit by heavy settle, pacify liver to subdue yang and astringent yin, soften hardness and disperse bind.
Administration and dosage: 9~30 g decocted earlier, 1~3 g for powdering.

CRATAEGI FRUCTUS
山楂
Shan Jha / Shan Zha
Hawthorn Fruit

Hawthorn fruit is the dried ripe fruit of *Crataegus pinnatifida* Bunge or *Crataegus pinnatifida* Bunge var. *major* N.E.Br. (Fam. Rosaceae).
It contains not less than 35.0% of dilute ethanol-soluble extractives, not less than 30.0% of water extractives and

not less than 5.0% of organic acids, calculated with citric acid.

Description:

1. Fruit of *Crataegus pinnatifida*: Spheroidal, 1~1.5 cm in diameter, externally brownish-red, with small spots, apex with persistent calyx, base with slender stalk. Texture hard. Sliced pieces rounded, 1~2.5 cm in diameter, 2~4 mm thick, externally red, wrinkled, with small grayish-white spots; sarcocarp dark yellow to pale brown. In cross section, seeds 5, pale yellow, mostly fallen off and loculus hollow, some remained with a short and slender fruit stalk or calyx. Odour slightly aromatic; taste slightly sour.
2. Fruit of *Crataegus pinnatifida* var. *major:* Subspheroidal, 1~2.5 cm in diameter, externally dark red or purplish-red, wrinkled, lustrous, with small grayish-white spots. Apex dented, with persistent calyx at the edge, base with slender fruit stalk or its scar. Seeds 5, arched, pale reddish brown. Odour slightly aromatic; taste slightly sour and sweet.

Microscopic identification:

1. **Powder:**
   (1) Fruit of *Crataegus pinnatifida*: Reddish-brown. Stone cells subrounded, ovate, elongated-rectangular, subpolygonal or subtriangle in shape, 25~92 μm in diameter, up to 176 μm long, the wall up to 20 μm thick, containing brown or orange-red contents. Clusters of calcium oxalate 17~54 μm in diameter; prisms of calcium oxalate 13~47 μm in diameter. Fibers 13~27 μm in diameter, with relatively thin or extremely thick walls. Epidermal cells of exocarp contain yellowish-brown or reddish-brown contents. Parenchymatous cells of pulp and starch granules also exist.
   (2) Fruit of *Crataegus pinnatifida* var. *major:* Dark brown. Stone cells subrounded, elongated-rounded, rounded-polygonal, elongated-rectangular, subtriangle or irregular in shape, up to 185 μm long, 18~173 μm in diameter, the wall up to 53 μm thick, striations distinct, lumen small, occasionally with orange-yellow contents. Clusters of calcium oxalate 27~41 μm in diameter, angles blunt; prisms of calcium oxalate 13~52 μm in diameter. Parenchymatous cells of pulp shrunken (original receptacle), cell boundary indistinct, containing brown contents, starch granules and prims of calcium oxalate usually embedded. Fibers occasionally cross-overlapping in bundles, 11~36 μm in diameter, the walls extremely thick with longitudinal fissures. Epidermal cells of exocarp contain brown or orange-red contents, the cuticle up to 18 μm thick in sectional view.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 4 mL of ethyl acetate, ultrasonicate for 15 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of ursolic acid and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of toluene, ethyl acetate, and formic acid (20:4:0.5) as the developing solvent. Apply 4 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under visible light and ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained with the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Total ash: Not more than 3.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 0.5% (General rule 6007).
3. Sulfur dioxide: Not more than 400 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).
8. Aflatoxins
   (1) Aflatoxins (sum of B_1, B_2, G_1 and G_2): Not more than 10.0 ppb (General rule 6307).
   (2) Aflatoxin B_1: Not more than 5.0 ppb (General rule 6307).

※Note: "When this TCM herb is sold commercially, the limits of heavy metals, sulfur dioxide and aflatoxins should follow the food standard."

Assay:

1. Organic acids (Calculated with citric acid.):
   (1) Sample solution: Weigh accurately 1.0 g of fine powdered sample, accurately add 100 mL of water, soak for 4 hours with occasional shaking at room temperature, filter and use the filtrate.
   (2) Procedure: Weigh accurately 25 mL of filtrate, add 50 mL of water and 2 drops of phenolphthalein, titrate with sodium hydroxide (0.1 M) and calculate the content. Each mL of sodium hydroxide (0.1 M) is

equivalent to 6.404 mg of citric acid. It contains not less than 5.0% of organic acid, calculated with citric acid of the dried one.

Citric acid（%）＝2.5616 (*V*) / (*W*)

V: The volume of organic acid (mL)

W: Weight of test sample (g) calculated with dried sample.

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place, and protect from insects.
Usage: Disgestant medicinal.
Property and flavor: Mild warm; sour and sweet.
Meridian tropism: spleen, stomach, and liver meridians.
Effects: Promote digestion to resolve accumulation, activate blood and eliminate stasis.
Administration and dosage: 3~15 g.
Precaution and warning: Used with caution in peptic ulcer.

CROCI STIGMA
番紅花
Fan Hong Hua / Fan Hong Hua
Saffron Stigma

Saffron stigma is the dried stigma of *Crocus sativus* L. (Fam. Iridaceae).
It contains not less than 50.0% of dilute ethanol-soluble extractives, not less than 43.0% of water extractives and not less than 10.0% of the total amount of crocin I and crocin II.

Description: Linear, dark red, about 2~3 cm in length, the upper part broader funnel-shaped, the margin of apex irregularly dentate and with protuberant tomenta. Texture light, easily broken, spread with yellow pigment when floating on water. Odour characteristic; taste slightly bitter.

Microscopic identification:
Powder: Orange-red. Epidermal cells long strip-shaped in surface view, wall thin, some cells with outer walls papillary or tomentose-shaped protuberance, fine striations faintly visible on the surface, subsquare or subrounded in sectional view, some parts with papillary protuberance. Epidermal cells of apex of stigma tomentose-shaped, mostly broken, 90~140 μm in length, 25~55 μm in diameter, walls 20 μm thick. Vessels mainly spiral or annular, about 12 μm in diameter. Pollen grains spheroidal, pale yellow, 70~200 μm in diameter, with spiny glyph on the surface. Crystals of calcium oxalate cluster-shaped, fusiform or subsquare, 2~10 μm in diameter, mostly exist in parenchymatous cells.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of ethanol, ultrasonicate for 30 minutes, filter and make up the filtrate to 10 mL.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-butanol, glacial acetic acid, and water (7:1:2) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 254 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:
1. Loss on drying: Not more than 14.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 9.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 4.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
1. Crocin I and crocin II:
   (1) Mobile phase: A solution of methanol and water (45:55). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of crocin I and crocin II and dissolve in dilute ethanol to produce a solution containing 30 μg and 12 μg per mL of each.
   (3) Sample solution: Weigh accurately 10.0 mg of the powdered sample and place it in a 50-mL brown volumetric flask, add a quantity of dilute ethanol, ultrasonicate for 20 minutes, stand at room temperature, make up to volume with dilute ethanol, mix well and filter, use the filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (440 nm) and a column packing L1. The column temperature is maintained at room temperature. Inject reference standard solution into the liquid chromatography

apparatus for 5 times, and record the peak areas. The relative standard deviation of the peak area of crocin I and crocin II should not be more than 1.5%.

(5) Procedure: Inject accurately the same amount of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Crocin I or crocin II (%)=5(r_U/r_S) (C_S) / (W)

r_U: peak area of crocin I or crocin II of sample solution

r_S: peak area of crocin I or crocin II of reference standard solution

C_S: concentration of crocin I or crocin II of reference standard solution (μg/mL)

W: weight of test sample (g) calculated with dried sample.

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place and preserve in a well-closed container, and protect from moisture and insects.
Usage: Blood-regulating medicinal (Blood-activating and stasis-dispelling medicinal).
Property and flavor: Neutral; sweet.
Meridian tropism: Heart and liver meridians.
Effects: Activate blood and eliminate stasis, promoting menstruation.
Administration and dosage: 1~3 g.
Precaution and warning: Use cautiously during pregnancy.

CROTONIS SEMEN
巴豆
Ba Dou / Ba Dou
Croton Seed

Croton seed is the dried ripe seed of *Croton tiglium* L. (Fam. Euphorbiaceae).
It contains among 40.0~60.0% of croton oil and not less than 0.8% of crotonoside.

Description: Ovoid or oval, usually 3-ribbed, 1.8-2.2cm in length, 1.5-2cm in diameter. Externally greyish yellow or brownish yellow, rough, with 6 longitudinal lines, the recess is often prone to cracking, apex truncate, base with a fruit stalk scar, 3 loculi in the shell each containing 1 seed. Oval, slightly flat, 1.2~1.5 cm in length, 0.7~1.0 cm in diameter; externally brown or grayish-brown, easily exfoliated to expose the black inner; with a pointed hilum and a caruncle scar at the one end, a slightly dented chalaza at other end, and a protuberant raphe between two ends; testa thin and fragile, perisperm white and membranous, endosperm yellowish-white, oily; cotyledons 2, thinner. Odourless, taste pungent.

Microscopic identification:

1. **Transverse section:**
Seed of *Croton tiglium*: Testa composed of brown or dark brown sclerenchyma palisade cells, 162~432 μm in length, column-shaped, 5~30 μm wide; some cells contain dark brown contents, with obtusely rounded cell end; inner part composed of parenchyma palisade cells, tangentially elongated, subrectangular or suboblong, 55~100 μm in length, 5~40 μm in diameter, containing subtriangle intercellular spaces. Cells of endosperm subrounded, 15~40 μm in diameter, containing starch granules, fatty oil droplets and clusters of calcium oxalate. Cells of cotyledon subrounded to suboblong, with starch granules, fatty oil droplets and clusters of calcium oxalate, 5~40 μm in diameter.
2. **Powder:** Dark brown. Sclerenchyma palisade cells of testa (outer epidermis of endotesta) composed of 1 row of cells, brown or dark brown, column-shaped in sectional view, slightly curved, with endings smooth or obtusely rounded, 162~432 μm in length, the walls extremely thickened, pit canals very fine and dense, lumen linear, some cells contain dark brown contents; polygonal in surface view. Parenchyma palisade cells of testa (inner epidermis of testa) consists of 1 layer of cells, subrectangular in sectional view, 63~90 μm in length, the walls slightly thickened, radial wall undulate; subrounded in surface view, with subtriangle intercellular spaces, large and distinct. Epidermal cells of testa (outer epidermis of testa) pale yellow, polygonal in surface view, with irregular striations, lumen containing brown contents or granules; oblong in sectional view, covered with cuticle. Endosperm and cotyledon cells filled with aleurone granules, crystalloid or spheroid, also containing fatty oil droplets; occasionally containing clusters of calcium oxalate, 7~31 μm in diameter and shedding perisperm tissue.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 0.2 g of powdered sample to 10 mL of water, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 0.2 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of crotonoside and dissolve in water to produce a solution containing 0.5 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, methanol, and water (3:1:1) as the developing solvent. Apply 8 μL of each of the sample solution and reference drug solution and 2 μL of the reference standard solution to the plate. Once the top of the solvent rise

to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 254 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
2. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
3. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
4. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
5. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Crotonoside:
   (1) Mobile phase: A solution of acetonitrile, methanol, and water (1:4:95). The ratio varies as required
   (2) Reference standard solution: Weigh accurately a quantity of crotonoside, and dissolve in water to produce a solution containing 60 μg per mL.
   (3) Sample solution: Weigh accurately 0.3 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 25mL of 25% methanol, ultrasonicate for 30 minutes, filter with filter paper. Repeat the extraction of the residue two more times, combine the extracts, evaporate, transfer to a 50-mL volumetric flask and make up to volume with 25% methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (292 nm) and a column packing L1. The column temperature is maintained at 35℃. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of crotonoside should not be less than 5,000.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Crotonoside : (%)=0.005 (r_U/r_S) (C_S) / (W)
   r_U: peak area of crotonoside of sample solution
   r_S: peak area of crotonoside of reference standard solution
   C_S: concentration of crotonoside of reference standard solution (μg/mL)
   W: weight of test sample (g) calculated with dried sample.
2. Fatty oil:
   Weigh accurately 5.0 g of the coarse powdered sample, grind, transfer to a Soxhlet extractor, heat under reflux with ethyl ether until the fatty oil fully extracted; evaporate ethyl ether, dry the residue for 1 hour at 100℃, cool, weigh accurately, calculate the content of fatty oil.

Storage: Store in a cool and dry place.
Usage: Purgative medicinal (Offensive purgative and water-expelling medicinal).
Property and flavor: Hot; pungent; highly toxic.
Meridian tropism: Stomacht and large intestine meridians.
Effects: Expel water by purgation, warm intestine and remove accumulation with purgation.
Administration and dosage: 0.1~0.5 g, used after made into Crotonis Semen Pulveratum; used an appropriate amount for external use.
Precaution and warning: Unprocessed one highly toxic, store with caution. Forbit to use during pregnancy. Incompatible with Pharbitidis Semen.

CULLENIAE FRUCTUS
補骨脂
Bu Gu Jhih / Bu Gu Zhi
Malaytea Scurfpea Fruit

Malaytea scurfpea fruit is the dried ripe fruit of *Cullen corylifolium* (L.) Medik. (*Psoralea corylifolia* L.) (Fam. Leguminosae).
It contains not less than 10.0% of dilute ethanol-soluble extractives, not less than 9.0% of water extractives and not less than 0.7% of the total amount of psoralen and isopsoralen.

Description: Flattened-ellipsoidal or subreniform, 3~5 mm in length, about 3 mm in width. Externally dark brown or black, with finely reticulate wrinkles, center slightly dented, one side slightly flattened, with a strip-shape hilum. Pericarp thin, seed 1, cotyledons 2, fleshy. Texture hard. Odour aromatic; taste bitter.

Microscopic identification:

1. **Transverse section:**
   Fruit of Cullen corylifolium: Pericarp is wavy, brown, and the cells are shrinking, the boundary of cells is indistinct. Epidermis at sunken spaces have many oblate intramural gland and a few small glandular hairs. Intramural gland grows inwards from pericarp epidermis, which is large in size and composed of more than ten to tens of cells, 135~200 μm in diameter. The cells are longitudinally extended and radially arranged. The top of glandular hair adheres to mesocarp and the superficial view looks sub-rounded. The center with sub-rounded cells groups (base of gland) are composed of many polygon epidermis cells, 36 ~72 μm in diameter. The small glandular hairs are few, sub-rounded heads with 4~5 cells, 30~50 μm in length, 10~32 μm in diameter,

without stalk. Non-glandular hairs are 150~480 μm in length, 15~22 μm in diameter, and the cells on the top are very long. Mesocarp parenchymatous tissue has small collateral vascular bundles; parenchymatous cells contain little columnar crystals of calcium oxalate. Epidermis of testa is composed of 1 layer palisade cells, 34~66 μm in length, 7~14 μm in diameter, and the top part of lateral wall is thicker, and the lower part is thinner, containing reddish-brown contents. There are 1 layer of dumbbell-shaped supporting cells inside, 26~51 μm in length, and the top part is wider, the annular thickening of lateral wall is visible. There are 7~10 layers of parenchymatous cells within the supporting cells. There are 2 cotyledons, each cotyledons is composed of 10 multi-layered cells with 1 layer of tightly arranged parenchymatous cells inside and outside, several layers of cotyledons cells close to testa are ovoid and larger, several layers of cells inside are arranged in a palisade. The cotyledons cells are full of aleurone grains and oil droplets. Without lignification.

2. **Powder:** Grayish-yellow; odour slightly fragrant, taste bitter. Epidermal cells of testa 7~14 μm in width, cell wall V-shaped thickened. Support cells dumbbell-shaped, cell wall thickened at the middle part, 26~51 μm in length. Cotyledon cells and fragments of non-glandular hairs are visible.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of psoralen and isopsoralen, respectively, and dissolve them in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane, ethyl acetate, and formic acid (6:2:0.1) as the developing solvent. Apply 2 μL of each of the sample solution and reference drug solution and 1 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 254 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 9.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 9.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 3.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:

1. Psoralen and isopsoralen:
   (1) Mobile phase: A solution of methanol and water (55:45). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of psoralen and isopsoralen and dissolve in methanol to produce a solution containing 20 μg per mL of each.
   (3) Sample solution: Weigh accurately 0.5 g of the powdered sample and place it in a 50-mL centrifuge tube, add 20 mL of 50% methanol, ultrasonicate for 30 minutes, centrifuge for 15 minutes, use the supernatant. Repeat the extraction of the residue two more times. Combine the filtrate, transfer to a 100-mL volumetric flask, make up to volume with 50% methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (246 nm) and a column packing L1. The column temperature is maintained at room temperature. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of psoralen should not be less than 5,000.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   Psoralen or isopsoralen (%)=0.01(r_U/r_S) (C_S) / (W)

   r_U: peak area of psoralen or isopsoralen of sample solution
   r_S: peak area of psoralen or isopsoralen of reference standard solution
   C_S: concentration of psoralen or isopsoralen of reference standard solution (μg /mL)
   W: weight of test sample (g) calculated with dried sample.
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place, and protect from moisture and insects.
Usage: Tonifying and replenishing medicinal (Yang-assisting medicinal).
Property and flavor: Warm; pungent and bitter.
Meridian tropism: kidney and spleen meridians.
Effects: Warm tonify kidney yang, qi absorption, secure essence and reduce urination, warm spleen and antidiarrheal.
Administration and dosage: 5~12 g.

CURCULIGINIS RHIZOMA
仙茅
Sian Mao / Xian Mao
Common Curculigo Rhizome

Common curculigo rhizome is the dried rhizome of *Curculigo orchioides* Gaertn. (Fam. Amaryllidaceae).
It contains not less than 18.0% of dilute ethanol-soluble extractives, not less than 18.0% of water extractives and not less than 0.1% of curculigoside.
Description: Cylindrical, slightly curved, 3~10 cm in length, 3~8 mm in diameter. Externally blackish-brown or brown, with longitudinal wrinkles, transverse ring patterns, and dented fibrous root scars. Texture hard, easily broken, fracture yellowish-brown, a dark ring pattern in the center, vascular bundle punctate on inner side. Odour pungent and aromatic; taste slightly bitter and pungent.

Microscopic identification:
1. **Transverse section:**
   Rhizome of *Curculigo orchioides*: Cork composed of 5~7 layers of subsquare cells. Cortex broad, composed of parenchymatous cells and mucilage cells, some outer cells at outside containing prisms of calcium oxalate. Parenchymatous cells contain numerous starch granules and distinct intercellular spaces, cells subrounded or polygonal. Mucilage cells subrounded, 100~300 μm in diameter, containing mucilage contents and raphides of calcium oxalate. Vascular bundles scattered, amphivasal or collateral. Vessels mainly spiral, annular or reticulate, 8~30 μm in diameter.
2. **Powder:** Yellowish-brown. Cork cells brown, polygonal or subsquare. Parenchymatous cells filled with abundant starch granules, intercellular spaces distinct. Mucilage cells contain mucilage cells and raphides of calcium oxalate, 60~200 μm in length. Starch granules individual or compound, simple granules subrounded, 5~20 μm in diameter. Vessels mainly spiral, annular or reticulate, pale yellow, 8~30 μm in diameter.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 2.0 g of powdered sample to 20 mL of ethanol, heat and reflux for 30 minutes, filter and evaporate the filtrate to dryness, dissolve the residue in 1 mL of ethyl acetate.
2. Reference drug solution: Use 2.0 g of the reference drug as the same method described above.
3. Reference standard solution: Weigh accurately a quantity of curculigoside and dissolve in ethyl acetate to produce a solution containing 0.5 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, methanol, and formic acid (10:1:0.1) as the developing solvent. Apply 2 μL of each of the above solutions to the plate. Once the top of solvent rise to about 5~10 cm from the origin, dry in air. Spray with vanillin/H_2SO_4 TS and heat at 105℃ until the spots become visible. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 13.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 11.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
1. Curculigoside:
   (1) Mobile phase: A solution of acetonitrile and 0.1% phosphoric acid (21:79). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of curculigoside and dissolve in methanol to produce a solution containing 70 μg per mL.
   (3) Sample solution: Weigh accurately 1.0 g of powdered sample add accurately 50 mL of methanol, accurately weigh, heat under d reflux for 2 hours, cool, weigh again, replenish the loss weight with methanol, mix well, and filter. Take accurately 20 mL successive filtrate, evaporate to dryness, dissolve the residue in a quantity of methanol, transfer to a 10-mL volumetric flask, make up to volume with methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV

detector (285 nm) and a column packing L1. The number of theoretical plates of the peak of curculigoside should not be less than 3,000.

(5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Curculigoside: (%)= 0.0025(r_U/r_S) (C_S) / (W)

r_U: peak area of curculigoside of sample solution

r_S: peak area of curculigoside of reference standard solution

C_S: concentration of curculigoside of reference standard solution (μg/mL)

W: weight of test sample (g) calculated with dried sample.

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place, and protect from moisture.
Usage: Tonifying and replenishing medicinal (Yang-tonifying medicinal).
Property and flavor: Hot; pungent.
Meridian tropism: Kidney and liver meridians.
Administration and dosage: 3~11.5 g.

CURCUMAE LONGAE RHIZOMA
薑黃
Jiang Huang / Jiang Huang
Turmeric Rhizome

Turmeric rhizome is the dried rhizome of *Curcuma longa* L. (Fam. Zingiberaceae).
It contains not less than 7.0% of dilute ethanol-soluble extractives, not less than 5.0% of water extractives, not less than 1.0% of curcumin and not less than 5.0% (v/w) of volatile oil.
Description: Irregularly oval, cylindrical or fusiform, curved and branched in Y-shape, 2~5 cm in length, 1~3 cm in diameter. Externally dark yellowish-brown, rough, with longitudinal wrinkles and distinct annulations of leaves scars, and exhibiting rounded scars of branched rhizomes and fibrous root scars. Texture compact, uneasily broken, fracture brownish-yellow, horny with wax luster, endodermis ring distinct, scattered with dotted vascular bundles. Odour aromatic; taste bitter and pungent.

Microscopic identification:

1. **Transverse section:**
   Rhizome of *Curcuma longa*: Cork composed of 2~5 layers of cork cells or with broken scars, cells subrectangular or subpolygonal. Parenchymatous cells of cortex suboblong or irregular, occasionally with intercellular spaces, cells usually contain yellow secretions, vascular bundles scattered; starch granules visible, subrounded, subrectangular or subpolygonal, prisms of calcium oxalate also visible, 5~10 μm in diameter, subrectangular or subsquare. Endodermal cells irregular, subrectangular or shrunken. Stele scattered with collateral vascular bundles, vessels 5~8, reticulate, spiral and scalariform, 15~90 μm in diameter, cells larger near the center, subrounded or suboblong.
2. **Powder:** Yellow to light yellow. Parenchymatous cells suboblong, containing starch granules, a few of parenchymatous cells filled with yellow to greenish-yellow secretions. Vessels reticulate, spiral and scalariform vessels also visible. Cork cells pale yellow to yellowish-brown. Prisms of calcium oxalate present in parenchymatous cells. Unicellular non-glandular hairs visible.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 15 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of curcumin and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of dichloromethane, methanol, and glacial acetic acid (9:1:0.1) as the developing solvent. Apply 10 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Total ash: Not more than 7.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 4.0% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
5. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
6. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Curcumin:
   (1) Mobile phase: A solution of acetonitrile and 0.4% glacial acetic acid (48:52). The ratio may be adjusted, if necessary.

(2) Reference standard solution: Weigh accurately a quantity of curcumin and dissolve in methanol to produce a solution containing 0.01 mg per mL.

(3) Sample solution: Weigh accurately 0.2 g of the powdered sample and place it in a conical flask with a stopper, accurately add 10 mL of methanol, weigh, heat under reflux for 30 minutes, cool, weigh again, replenish the loss of the weight with methanol, mix well, centrifuge, take 1 mL of the supernatant to 20-mL volumetric flask, and make up to volume with methanol, mix well, filter and use the filtrate.

(4) Chromatographic system: The liquid chromatography is equipped with an UV detector (430 nm) and a column packing L1. The column temperature is maintained at 25℃. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of curcumin should not be less than 4,000.

(5) Procedure: Inject accurately 20 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Curcumin (%)=0.02(r_U/r_S) (C_S) / (W)

r_U: peak area of curcumin of sample solution

r_S: peak area of curcumin of reference standard solution

C_S: concentration of curcumin of reference standard solution (μg /mL)

W: weight of test sample (g) calculated with dried sample.

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).
4. Volatile oil: Carry out the method for determination of volatile oil (General rule 6013).

Storage: Refrigerate or store in a cool and dry place.
Usage: Blood-regulating medicinal (Blood-activating and stasis-dispelling medicinal).
Property and flavor: Warm; pungent and bitter.
Meridian tropism: Spleen and liver meridians.
Effects: Break blood and move qi, promoting menstruation to relieve pain.
Administration and dosage: 3~10 g; used an appropriate amount for external use.

CURCUMAE RADIX
鬱金
Yu Jin / Yu Jin
Curcuma Root

Curcuma root is the dried root tuber of *Curcuma wenyujin* Y.H.Chen & C.Ling, *Curcuma kwangsiensis* S.G.Lee & C.F.Liang, *Curcuma longa* L. or *Curcuma phaeocaulis* Valeton (Fam. Zingiberaceae). According to the different localities and types, the former two are commonly known as “Wun Yu Jin” and “Guei Yu Jin”. The others are commonly known as “Huang Sih Yu Jin” and “Lyu Sih Yu Jin”, according to the different appearance.
It contains not less than 4.0% of dilute ethanol-soluble extractives and not less than 4.0% of water extractives.

Description:

1. Wun Yu Jin: Oblong or ovate, slightly flattened, the two ends tapering, 3~7 cm in length, 1~2.5 cm in diameter. Externally grayish-brown, with irregular longitudinal wrinkles or reticulated fine wrinkles. Texture compact, fracture grayish-brown or brownish-black, with wax-like luster, endodermis with distinct rings. Odour slightly aromatic; taste slightly bitter.
2. Guei Yu Jin: Long conical, oblong, fusiform or oval, 2~7 cm in length, l~1.8 cm in diameter. Externally pale brown or brownish-yellow, with fine longitudinal wrinkles. Texture hard, fracture granules or horny, pale grayish-brown, endodermis with distinct rings. Odour slight; taste slightly pungent and bitter.
3. Huang Sih Yu Jin: Fusiform, less elliptical-conical, some hypertrophy at one end, 2.5~5.5 cm in length, 0.9~1.8 cm in diameter. Externally grayish-brown or grayish-yellow, with fine wrinkles. Texture hard, fracture slightly translucent, horny, outer brownish-yellow or brownish-red, inner orange-yellow or inaurate. Odour aromatic; taste pungent.
4. Lyu Sih Yu Jin: Oblong, slightly flattened, 2~4.5 cm in length, 1~l.5 cm in diameter. Externally gray or grayish-black, with wrinkles, slightly rough. Fracture semi-horny. Taste pungent.

Microscopic identification:

1. **Transverse section:**
   (1) Root tuber of Wun Yu Jin: Epidermis occasionally remained, the outer walls slightly thickened. Velamen narrow, composed of 4~9 rows of cells with slightly sinuous and thin walls, arranged regularly. Cortex occupied about 1/2 of root. Oil cells rarely visible. Endodermis distinct. In stele, phloem bundles and xylem bundles each 35~52, arranged alternately; each phloem bundle with 2~4 vessels, xylem fibers slightly lignified; vessels polygonal, with thin wall. Gelatinized starch granules in parenchymatous cells visible.
   (2) Root tuber of Guei Yu Jin: Velamen composed of 3~6 rows of cells, cell walls occasionally thickened, the inner side of velamen showing 1~2 rows of sclerenchymatous cells arranged in a ring, with distinct striation. In stele, phloem bundles and xylem bundles each 37~58, arranged alternately; each phloem bundle with 2~3 subrounded vessels.

(3) Root tuber of Huang Sih Yu Jin: Epidermis occasionally remained. Velamen composed of 3~6 rows of cells, walls of the innermost layer of velamen thickened. Endodermis distinct. In stele, phloem bundles and xylem bundles each 17~34, arranged alternately; each phloem bundle with 1 or 2~3 polygonal or subrounded vessels. Gelatinized starch granules in parenchymatous cells visible. Oil cells abundant, scattered throughout parenchyma.

(4) Root tuber of Lyu Sih Yu Jin: Velamen composed of 3~6 rows of cells with thin walls. In stele, phloem bundles (shriveled) and xylem bundles each 42~62, arranged alternately; each phloem bundle with 1 or 2~3 flattened vessels.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 15 mL of methanol, shake for 5 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, ethanol, and 4 N ammonia (4:2:1) as the developing solvent. Apply 10 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with vanillin/H_2SO_4 MeOH TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:

1. Total ash: Not more than 13.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 4.0% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 5.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.5 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from insects.
Usage: Blood-regulating medicinal (Blood-activating and stasis-dispelling medicinal).
Property and flavor: Cold; pungent and bitter.
Meridian tropism: Liver, heart, and lung meridians.
Effects: Activate blood to relieve pain, move qi and release depression, clear heart cool the blood, drain bile and reduces jaundice.
Administration and dosage: 3~11.5 g.

CURCUMAE RHIZOMA
莪朮
E Jhu / E Zhu
Zedoaria Rhizome

Zedoaria rhizome is the dried rhizome of *Curcuma phaeocaulis* Valeton, *Curcuma kwangsiensis* S.G.Lee & C.F.Liang or *Curcuma wenyujin* Y.H.Chen & C.Ling (Fam. Zingiberaceae). The drug derived from *Curcuma wenyujin* is commonly known as "Wen E Zhu".
It contains not less than 2.0% of dilute ethanol-soluble extractives, not less than 3.0% of water extractives, not less than 1.0% (v/w) of volatile oil and not less than 0.05% of germacrone.

Description:

1. Rhizome of *Curcuma phaeocaulis*: Ovoid, elongated ovate, conical or elongate fusiform, apex frequently obtuse and acute, base obtuse and rounded, 2~8 cm in length, 1.5~4 cm in diameter. Externally grayish-yellow to grayish-brown, the upper part conspicuously protuberant-annulated and with rounded and slightly dented rootlet scars or remaining rootlets, some exhibiting a row of concave bud scars and subrounded lateral rhizome scars on each of two sides, and some showing knife cut traces. Texture heavy and compact, fracture grayish-brown to bluish-brown, waxy, usually attached with grayish-brown powder, bark and stele easily detachable, endodermal ring deep brown. Odour slightly aromatic; taste slightly bitter and pungent.
2. Rhizome of *Curcuma kwangsiensis*: Slightly raised-annulated, fracture yellowish-brown to brown, usually attached with pale yellow powder, endodermal ring yellowish-white.
3. Rhizome of *Curcuma wenyujin* (Wen E Zhu): Fracture yellowish-brown to brown, usually attached with pale yellow to yellowish-brown powder. Odor aromatic or slightly aromatic.

Microscopic identification:

1. **Transverse section:**
   Rhizome of *Curcuma phaeocaulis*: Cork composed of several rows of cork cells, occasionally removed. Cortex scattered with leaf-trace vascular bundles; endodermis distinct. Stele relatively broad, vascular

bundles collateral and scattered, those along the pericycle relatively small and tightly arranged. Parenchymatous cells filled with gelatinous starch masses; parenchyma scattered with cells containing golden oil contents.

2. **Powder:**
Rhizome of *Curcuma phaeocaulis*: Pale yellow. Non-glandular hairs mostly in fragments, complete ones rare. Starch granules mostly gelatinous, ungelatinous ones mostly simple, ovate or short rod-shaped, 23~41 μm in length, 19~24 μm in width, with distinct striations, hilum eccentric, located at the narrow end. Vessels mostly spiral and scalariform, a few of vessels accompanied by rod-shaped fiber groups, walls pits distinct, vessels and fibers all lignified.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 0.5 g of powdered sample to 10 mL of petroleum ether (40~60℃), ultrasonicate for 20 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 1 mL of ethyl acetate.
2. Reference drug solution: Take 0.5 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of germacrone and dissolve in ethyl acetate to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane and ethyl acetate (4:1) as the developing solvent. Apply 10 μL of each of the sample solution and reference drug solution and 5 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with *p*-anisaldehyde/H_2SO_4 TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Total ash: Not more than 7.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 3.0% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 5.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Germacrone:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and water as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of germacrone, and dissolve in methanol to produce a solution containing 5 μg per mL.
   (3) Sample solution: Weigh accurately 0.4 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 16 mL of 75% methanol, ultrasonicate for 30 minutes, filter to 50-mL volumetric flask with filter paper. Repeat the extraction of the residue two more times. Combine the filtrate and make up to volume with 75% methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (214 nm) and a column packing L1. The column temperature is maintained at 30.5℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of germacrone should not be less than 20,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~3	45	55
3~30	45→65	55→35
30~38	65	35
38~45	65→90	35→10
45~55	90→100	10→0

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

$$\text{Germacrone (\%)} = 0.005 (r_U / r_S) (C_S) / (W)$$

   r_U: peak area of germacrone of sample solution
   r_S: peak area of germacrone of reference standard solution
   C_S: concentration of germacrone of reference standard solution (μg/mL)
   W: weight of test sample (g) calculated with dried sample.

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).
4. Volatile oil: Carry out the method for determination of volatile oil (General rule 6013).

Storage: Refrigerate or store in a cool and dry place, and protect from insects.
Usage: Blood-regulating medicinal (Blood-activating and stasis-dispelling medicinal).
Property and flavor: Warm; pungent and bitter.
Meridian tropism: Liver and spleen meridians.
Effects: Break blood and move qi, resolve accumulation and relieve pain.
Administration and dosage: 6~9 g.

CUSCUTAE SEMEN
菟絲子
Tu Sih Zih / Tu Si Zi
Chinese Dodder Seed

Chinese dodder seed is the dried ripe seed of *Cuscuta australis* R.Br. or *Cuscuta chinensis* Lam. (Fam. Convolvulaceae).
It contains not less than 3.0% of dilute ethanol-soluble extractives, not less than 4.0% of water extractives and not less than 0.1% of hyperoside.

Description: Subspheroidal or ovate, 1~1.5 mm in diameter. Externally grayish-brown or yellowish-brown, rough. Hilum subround on the apex. Testa scattered with fine and dense dots and white and filamentous stripes distributed uneven. Texture hard and uneasily broken. Odourless, taste slightly bitter and astringent.

Microscopic identification:
1. **Transverse section:**
   Cuscutae semen: Epidermis composed of 1 layer of cells, subsquare to subrectangular, lateral wall thickened. Palisade tissue composed of 2 rows elongated cells; outer palisade cells shorter than the inner ones; light line located at the upper half of the inner palisade cells. A narrow parenchyma, composed of mostly shrunken cells, existed underneath the inner layer of palisade cells. Endosperm cells polygonal to subrounded, with thickened cell wall. Cotyledons twisted, several fragments of cotyledon can be seen. Cells of cotyledon subsquare to subrounded, containing aleurone grains.
2. **Powder:** Yellowish-brown or dark brown. Epidermal cells of testa subsquare or subrectangular in sectional view, lateral walls thickened; rounded-polygonal in surface view, walls distinctly thickened at corner. Palisade cells of testa flaky, 2 layers in sectional view, with a light line; cells polygonal in surface view, shrunken. Endosperm cells polygonal or subrounded, lumen containing aleurone grains. Cotyledon cells contain aleurone grains and fatty oil droplets.

Identification:
Take a quantity of powdered sample, macerate in boiling water, a mucilage is produced on the surface; boil until the testa is broken, reveal a yellowish-white, slender and rotary embryo, commonly known as "Tu Sih".

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of hyperoside and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, butanone, formic acid, and water (5:3:1:1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 254 nm and 365 nm, and then spray with 10% $AlCl_3$/EtOH TS, examine under the ultraviolet light at 365 nm again. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained with the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 10.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 10.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 4.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 10.0 ppm (General rule 2251, 6301).

Assay:
1. Hyperoside:
   (1) Mobile phase: A solution of acetonitrile and 0.1% phosphoric acid (17:83). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of hyperoside and dissolve in methanol to produce a solution containing 20 μg per mL.
   (3) Sample solution: Weigh accurately 1.0 g of the powdered sample and place it in a 50-mL round bottom flask, accurately add 40 mL of 80% methanol, ultrasonicate for 1 hour, cool, filter, make up to volume with 80% methanol, mix well, filter, use the filtrate.
   (4) Chromatographic system: The liquid

chromatography is equipped with an UV detector (360 nm) and a column packing L1. The column temperature is maintained at 25°C. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of hyperoside should not be less than 5,000.

(5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Hyperoside (%)=0.005(r_U/r_S) (C_S) / (W)

r_U: peak area of hyperoside of sample solution

r_S: peak area of hyperoside of reference standard solution

C_S: concentration of hyperoside of reference standard solution (μg/mL)

W: weight of test sample (g) calculated with dried sample

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from moisture.
Usage: Tonifying and replenishing medicinal (Yang-assisting medicinal).
Property and flavor: Neutral; pungent and sweet.
Meridian tropism: Liver, kidney, and spleen meridians.
Effects: Supplements liver and kidney, replenish essence and invigorate yang, supplements yang and promotes ying, secure essence and reduce urination, improve vision and secures fetus and antidiarrheal.
Administration and dosage: 6~12 g.

CYATHULAE RADIX
川牛膝
Chuan Niou Si / Chuan Niu Xi
Cyathula Root

Cyathula root is the dried root of *Cyathula officinalis* K.C.Kuan (Fam. Amaranthaceae), commonly known as "Du Niou Shi".
It contains not less than 45.0% of dilute ethanol-soluble extractives, not less than 50.0% of water extractives and not less than 0.03% of cyasterone.

Description: Cylindrical, vary in thickness, slightly twisted, occasionally branched, 30~60 cm in length, 0.5~3 cm in diameter. Externally brownish-yellow or grayish-brown, with longitudinal wrinkles, scars of lateral roots and numerous transverse protuberant lenticels, apex swollen, occasionally remained with rhizomes and stem bases. Texture tenacious, uneasily broken, fracture yellowish-white or brownish-yellow, scattered with numerous pale yellow dots (vascular bundles) arranged in several concentric circles. Odour slight; taste slightly bitter.

Microscopic identification:

1. **Transverse section:**
   Root of *Cyathula officinalis*: Cork composed of 15~20 layers of cells. Phelloderm and cortex narrow. Vascular cylinder large, abnormal vascular bundles interruptedly arranged in 3~8 whorls; vascular bundles collateral; intrafascicular cambium visible; xylem composed of vessels and xylem fibers, extremely lignified. Secondary vascular system usually separated into 2~9 strands at the central, occasionally with sparsely scattered vessels in the center of root. Parenchymatous cells containing sandy crystals and prisms of calcium oxalate.
2. **Powder:** Grayish-brown. Sandy crystals of calcium oxalate filled in parenchymatous cells, triangular, rhombic, arrow-pointed, polygonal or irregular, occasionally aggregated in the corner of cell. Crystal-containing cells relatively large in size, subrectangular or subrounded, surrounded by radically arranged cells. Xylem fibers strip-shaped or irregular long-fusiform, with branching end, 13~49 μm in diameter, walls slightly thickened and unlignified, bordered pits few, pit apertures elongated oblique, occasionally crossed in cruciate shape or V-shaped with single pits present. Pit canals distinct with different spacing, relatively dense walls moniliform. Bordered-pitted vessels 18~110 μm in diameter, walls unlignified, some vessel elements fusiform at the end, perforations in lateral walls; pits round or oblong, transversely elongated to 18 μm long, alternated and arranged densely. Few prisms of calcium oxalate, up to 22 μm in diameter; raphides of calcium oxalate up to 76 μm in diameter and cork cells also present.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 2.0 g of powdered sample to 20 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 2.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of cyasterone and dissolve in methanol to produce a solution containing 0.5 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane, ethyl acetate, methanol, and glacial acetic acid (3:4:1.5:0.2) as the developing solvent. Apply 10 μL of the sample solution and 1 μL of each of the reference drug solution and reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105°Cuntil the spots become visible. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained

from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 12.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 7.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 10.0 ppm (General rule 2251, 6301).

Assay:
1. Cyasterone:
   (1) Mobile phase: Methanol as the mobile phase A, and water as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of cyasterone and dissolve in methanol to produce a solution containing 20 μg per mL.
   (3) Sample solution: Weigh accurately 1.0 g of the powdered sample, add accurately 12.5 mL of 75% methanol, ultrasonicate for 30 minutes, centrifugal filtration, use the filtrate, and transfer to 25-mL volumetric flask, repeat the extraction of the residue one more time. Combine the filtrate and make up to volume with 75% methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (246 nm) and a column packing L1. The column temperature is maintained at 30℃. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of cyasterone should not be less than 8,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~10	20→30	80→70
10~60	30→33	70→67

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Cyasterone (%)=0.0025 (r_U/r_S) (C_S) / (W)

rU: peak area of cyasterone of sample solution
rs: peak area of cyasterone of reference standard solution
Cs: concentration of cyasterone of reference standard solution (μg/mL)
W: weight of test sample (g) calculated with dried sample

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from insects.
Usage: Blood-regulating medicinal (Blood-activating and stasis-dispelling medicinal).
Property and flavor: Neutral; bitter and sour.
Meridian tropism: Liver and kidney meridians.
Effects: Activate blood and eliminate stasis, promoting menstruation, relieve pain.
Administration and dosage: 3~10 g.

【Decoction pieces】

CYATHULAE RADIX

It contains not less than 45.0% of dilute ethanol-soluble extractives, not less than 50.0% of water extractives and not less than 0.03% of cyasterone.
Raw medicinal materials are processed to remove impurities, clean selection, soften thoroughly, cut into thin slices, and dry, mostly subrounded thin slices, surface grayish-yellow or pale yellowish-brown, cut surface even, center yellowish-white, scattered many dots of vascular bundles around, surface with fine longitudinal wrinkle. Odour slight, taste sweet.

Thin layer chromatographic identification test: The method is the same as that for crude herb.
Impurities and other requirements: Methods and specifications are the same as those for crude herb.
Assay: The method is the same as that for crude herb.
Storage: The method is the same as that for crude herb.
Usage: Blood-regulating medicinal (Blood-activating and stasis-dispelling medicinal).
Property and flavor: Neutral; bitter and sour.
Meridian tropism: Liver and kidney meridians.
Effects: Activate blood and eliminate stasis, promoting menstruation, relieve pain.
Administration and dosage: 3~10 g.

CYNANCHI ATRATI RADIX ET RHIZOMA
白薇
Bai Wei / Bai Wei
Blackend Swallowwort Root and Rhizome

Blackend swallowwort root and rhizome is the dried root and rhizome of *Cynanchum atratum* Bunge or *Cynanchum versicolor* Bunge (Fam. Asclepiadaceae).
It contains not less than 12.0% of dilute ethanol-soluble extractives and not less than 12.0% of water extractives.

Description: Rhizomes thick and short, knotty, slightly extending laterally, 0.5~1.2 cm in the diameter, the upper part with rounded stem scars or remained with stem bases, over 5 mm in the diameter, numerous slender roots fascicled bilaterally and the lower part, caudate-shaped. Roots slender about 10~25 cm in length, 1~2 mm in diameter. Externally brownish-yellow, smooth, with tiny longitudinally wrinkles. Texture hard and fragile, easily broken, fracture even, pale yellowish-white, wood yellow. Odour slight; taste slightly bitter.

Microscopic identification:

1. **Transverse section:**
   (1) Root of *Cynanchum atratum* or *Cynanchum versicolor*: Epidermal cells subpolygonal, outer walls slightly thickened. Cortex composed of about 20 layers of subrounded parenchymatous cells, containing small starch granules and clusters of calcium oxalate; endodermal cells prolate, with distinct Casparian dots. Pericycle composed of 1~2 layers of tangentially elongated parenchymatous cells; phloem narrow; cambium in a ring; the walls of xylem vessels, tracheid, xylem fibers and xylem parenchymatous cells all lignified, vessels 8~56 μm in diameter.
   (2) Rhizome of *Cynanchum atratum* or *Cynanchum versicolor*: Epidermis elongated radially. Cortex contains stone cells at the nodes. Phloem relatively narrow; cambium in a ring; xylem vessels usually singly scattered or 2~4 arranged tangentially, the walls of xylem fibers and xylem parenchymatous cells all lignified; internal phloem sieve tube groups arranged in a ring. Pith eccentric, scattered with few stone cells. Parenchymatous cells contain starch granules, some containing clusters of calcium oxalate.
2. **Powder:** Pale grayish-white. Clusters of calcium oxalate 7~42 μm in diameter, occasionally one cell contain 2 crystals, some crystal-containing cells radially connected. Epidermal cells of rhizome subpolygonal or long-polygonal in surface view, up to 94 μm in length, 16~40 μm in diameter, wall slightly thickened; secretory cells present in epidermal tissue, subpolygonal, up to 45 μm in length, 14~33 μm in diameter, containing yellow secretions. Epidermal cells subsquare or slightly flatten in sectional view, occasionally tangentially split into 2, yellow secretory cells present as external cells. Hypodermal cells of root subrectangular, walls undulate; subrounded secretory cells scattered in hypodermal tissue, containing yellow secretions. Bordered-pitted, reticulate and spiral vessels present, 10~50 μm in diameter. Xylem fibers mostly in bundles, 10~25 μm in diameter, walls 2.5~11 μm thick, with oblique pits or small round pits. Endodermal cells rectangular in surface view, anticlinal walls undulate and slightly lignified. Individual starch granules subrounded, hilum dotted, cleft-shaped or Y-shaped, compound granules composed of 2~6 components; walls of fibers extremely thickened, lumen fine or indistinct, occasionally the primary walls separated from the secondary walls.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and the upper layer of petroleum ether (30~60℃), ethyl acetate, and formic acid (4:1:0.1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:

1. Loss on drying: Not more than 11.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 14.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 4.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place.
Usage: Heat-clearing medicinal (Deficiency heat-clearing medicinal).
Property and flavor: Mild cold; bitter and salty.
Meridian tropism: Stomach, liver and kidney meridians.
Effects: Clear heat and detoxicate, disperse abscesses and nodules, wound heal and promote tissue regeneration.

Administration and dosage: 3~10 g.

CYNANCHI STAUNTONII RHIZOMA ET RADIX
白前
Bai Cian / Bai Qian
Willowleaf Swallowwort Rhizome

Willowleaf swallowwort rhizome is the dried rhizome and root of *Cynanchum stauntonii* (Decne.) Schltr. ex H.Lév. or *Cynanchum glaucescens* (Decne.) Hand.-Mazz. (Fam. Asclepiadaceae).

It contains not less than 9.0% of dilute ethanol-soluble extractives and not less than 9.0% of water extractives.

Description:

1. Rhizome of *Cynanchum stauntonii*: Slenderly cylindrical, branched, 4~15 cm in length, 1.5~4 mm in diameter. Externally yellowish-white, yellowish-brown or blackish-brown, with longitudinal wrinkles, obviously nodose, internodes 1.5~4.5 cm in length, with numerous whisker rootlets, apex remained with grayish-green stems. Texture fragile, fracture white, pith membranous, hollow, commonly known as "A Guan Bai Chian". Root slender and winded up into masses, up to 11 cm in length, 0.3~1 mm in diameter, much-branched. Externally reddish- brown, with wrinkles. Texture light and shrunken, fragile, fracture white. Odour slight; taste sweetish.
2. Rhizome of *Cynanchum glaucescens*: Relatively shorter and smaller, or slightly lump-shaped. Externally grayish-green or grayish-yellow, internodes 1~2 cm in length. Texture relatively hard. Roots slightly curved, about 1 mm in diameter, less branched.

Microscopic identification:

1. **Transverse section:**
   (1) Root of *Cynanchum stauntonii*: Epidermis composed of 1 layer of brown walled subpolygonal cells, the outer walls slightly thickened. Cortex composed of about more than 10 layers of subrounded parenchymatous cells, containing starch granules and clusters of calcium oxalate, 10~40 μm in diameter; endodermal cells flat and small, with distinct Casparian dots. Stele small and oblong, pericycle composed of 1 row of subrounded parenchymatous cells; phloem located at the both sides of xylem; xylem diarch arranged in stripes, containing more than 10 bordered-pitted and spiral vessels, vessels 6~24 μm in diameter; xylem parenchymatous cells unlignified.
   (2) Rhizome of *Cynanchum stauntonii*: Epidermis composed of 1 layer of radially elongated cells; hypodermis arranged in order. Cortex contains laticiferous tubes. Thick rhizome contains pericyclic fiber bundles arranged in a ring. Phloem narrow, arranged in an interrupted ring. Cambium in a ring. Xylem vessels singly scattered or 2 arranged radially; xylem fibers and xylem parenchymatous cells lignified. Internal phloem consists of numerous sieve tube groups, arranged in a ring around pith. Pith mostly hollowed. Parenchymatous cells contain starch granules, occasionally containing clusters of calcium oxalate.
   (3) Rhizome of *Cynanchum glaucescens*: Cortex without laticiferous tubes.
2. **Powder:** Pale yellowish-white. Epidermal cells composed of 1 layer of prolate cells in longitudinal view, covered with yellowish-brown cuticles. Vessels mainly reticulated, bordered-pitted, 200~330 μm in length, 16~34 μm in diameter. Walls of xylem fibers thin, both ends truncate or acute long, with distinct pits. Starch granules numerous, singly scattered or composed of 2 to several components, subrounded, suboblong, subconchoidal, semicircular or fan-shaped, about 4~8 μm in size. Clusters of calcium oxalate scattered, mostly existed in small parenchymatous cells, singly scattered or linked by 2, angles dish-shaped or crushing small pieces, 8~40 μm in size, hilum slightly distinct, yellowish-brown.

Identification:

Take 1.0 g of powdered sample, add 10 mL of 70% ethanol, heat under reflux for 1 hour, filter and use the filtrate. Evaporate 1 mL of filtrate to dryness, dissolve the residue in 1 mL of acetic anhydride, add 1 drop of concentrated sulfuric acid, a reddish-violet color is produced and turn to dark green after stand for a moment for rhizome of *Cynanchum stauntonii*; a brownish-red color is produced permanently for rhizome of *Cynanchum glaucescens*. Color would not change over time.

Impurities and other requirements:

1. Loss on drying: Not more than 13.0% dry at 105°C for 5 hours (General rule 6015).
2. Total ash: Not more than 9.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 5.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).

2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a dry place, and protect from insects.
Usage: Phlegm-dispelling medicinal (Cold-phlegm warming and resolving medicinal).
Property and flavor: Warm; pungent and bitter.
Meridian tropism: Lung meridians.
Effects: Dispel phlegm, direct qi downward to suppress cough.
Administration and dosage: 3~10 g.

CYNOMORII HERBA
鎖陽
Suo Yang / Suo Yang
Songaria Cynomorium Herb

Songaria cynomorium herb is the dried fleshy stem of *Cynomorium coccineum* L. subsp. *songaricum* (Rupr.) J.Léonard (*Cynomorium songaricum* Rupr.) (Fam. Cynomoriaceae).
It contains not less than 19.0% of dilute ethanol-soluble extractives and not less than 20.0% of water extractives.

Description: Flattened cylindrical or one end slightly slender, 8~21 cm in length, 2~5 cm in diameter. Externally reddish-brown or dark brown, shrunken forming distinct longitudinal furrows or irregular dents, occasionally remained with triangular and blackish-brown scales and partial inflorescence. Texture hard, uneasily broken, fracture slightly granular, brown and soft, occasionally with white triangular or irregular vascular bundles. Odour slightly aromatic; taste slightly bitter and astringent.

Microscopic identification:
1. **Transverse section:**
   Stem of *Cynomorium coccineum* subsp. *songaricum*: Cork mostly fallen off, residual of cells occasionally found. Cortex narrow, cells containing brown contents, with strip-shaped striations on the surface. Stele broad, scattered with abundant vascular bundles, several arranged fan-shaped or semirounded, small in the outermost layer, and relatively large inward. Vessels lignified. Parenchymatous cells contain numerous starch granules.
2. **Powder:** Pale brown. Starch granules round, mostly simple, 4~30 μm in diameter, hilum distinct, slightly stellate, V-shaped or slit-shaped; compound granules occasionally found, composed of 2~3 components. Vessels mainly reticulate or spiral. Parenchymatous cells contain brown contents.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 20 mL of ethyl acetate, ultrasonicate for 30 minutes, cool, filter, and evaporate the filtrate to 1 mL.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of ursolic acid and dissolve in methanol to produce a solution containing 0.5 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of toluene, ethyl acetate, and formic acid (20:4:0.5) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray a 10% solution of H_2SO_4/EtOH TS and heat at 105°C until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 12.0% dry at 105°C for 5 hours (General rule 6015).
2. Total ash: Not more than 12.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place.
Usage: Tonifying and replenishing medicinal (Yang-tonifying medicinal).
Property and flavor: Warm; sweet.
Meridian tropism: Liver, kidney, and large intestine meridians.
Effects: Tonify kidney and assist yang, tonify essence and blood, moisten the intestine and relax the bowel.
Administration and dosage: 5~11.5 g.

CYPERI RHIZOMA
香附
Siang Fu / Xiang Fu
Cyperus Rhizome

Cyperus rhizome is the dried rhizome of *Cyperus rotundus* L. (Fam. Cyperaceae).
It contains not less than 3.0% of dilute ethanol-soluble extractives and not less than 4.0% of water extractives.

Description: Frequently fusiform, some slightly curved, 2~3.5 cm in length, 0.5~1 cm in diameter. Externally brown or blackish-brown, with longitudinally wrinkles and some protuberant annular nodes. Mau shiang fu (directly dried in the sun): nodes with brown fibrous roots and scars of roots. Guang shiang fu (burnt off the fibrous roots and dried in the sun): relatively smooth, with indistinct annular nodes. Texture hard, fracture of steamed rhizomes appearing yellowish-brown or reddish-brown, horny; fracture of the unsteamed ones white and starchy, endodermis ring obvious, stele darkened in color, with scattered dotted vascular bundles. Odour aromatic; taste slightly bitter.

Microscopic identification:

1. **Transverse section:**
   Rhizome of *Cyperus rotundus*: Epidermis brownish-yellow, accompanied by hypodermal fiber bundles, inside showing 2~3 layers of hypodermal cells with thick walls. Cortex scattered with leaf-trace vascular bundles in closed collateral type, secretory cells subrounded, containing yellow secretions, with 5~8 parenchymatous cells arranged radially in a circle. Endodermis distinct. Stele composed of numerous amphivasal vascular bundles and secretory cells. Parenchymatous cells contain starch granules.
2. **Powder:** Pale brown. Ungelatinous starch granules subrounded, subtriangular, subsquare or gear-shaped, 3~27 μm in diameter. Secretory cells subrounded, 35~72 μm in diameter, containing yellowish-brown or reddish-brown secretions, with 7~8 parenchymatous cells radially arranged in a circle. Hypodermal fibers and leaf base fibers in bundles, reddish-brown or yellowish-brown, 5~22 μm in diameter, wall extremely thickened; fiber bundles occasionally surrounded by small cells containing silica masses. Hypodermal cells subpolygonal or subsquare, wall slightly thickened and lignified, with distinct pit canals. Stone cells subsquare, polygonal or slightly elongated, 17~48 μm in diameter, wall 5~8 μm thick. Scalariform, spiral and reticulate vessels also present.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, heat under reflux for 30 minutes, cool, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane and ethyl acetate (4:1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with *p*-anisaldehyde/H_2SO_4 TS and heat at 105℃ until the spots become visible, examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:

1. Loss on drying: Not more than 15.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 4.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).
9. Aflatoxins
   (1) Aflatoxins (sum of B_1, B_2, G_1 and G_2): Not more than 10.0 ppb (General rule 6307).
   (2) Aflatoxin B_1: Not more than 5.0 ppb (General rule 6307).

Assay:

1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place, and protect from insects.
Usage: Qi-regulating medicinal.
Property and flavor: Neutral; pungent, mild bitter and mild sweet.
Meridian tropism: Liver, spleen, and triple energizers meridians.
Effects: Regulate qi and release depression.
Administration and dosage: 6~11.5 g.

DENDROBII CAULIS
石斛
Shih Hu / Shi Hu
Dendrobium Stem

Dendrobium stem is the fresh or dried stem of *Dendrobium nobile* Lindl., *Dendrobium loddigesii* Rolfe., *Dendrobium chrysanthum* Wall. ex Lindl., *Dendrobium fimbriatum* Hook., *Dendrobium officinale* Kimura & Migo, *Dendrobium chrysotoxum* Lindl. or *Dendrobium tosaense* Makino (Fam. Orchidaceae).
It contains not less than 5.0% of dilute ethanol-soluble extractives and not less than 6.0% of water extractives of dried stem.

Description:

1. Stem of *Dendrobium nobile*: Flattened-cylindrical of middle and upper parts, branchlets zigzag, 18~60 cm in length, middle part 0.4~1 cm in diameter, internodes 1.5~6 cm in length. Externally golden or greenish-yellow, lustrous, deeply furrowed longitudinally, with longitudinal wrinkles, nodes swelled, brown. Texture hard and fragile, fracture relatively lax. Odour slight; taste bitter.
2. Stem of *Dendrobium loddigesii*: Long cylindrical, often curved, winded up into masses or bundles, 11~40 cm in length, 1~3 mm in diameter, internodes 0.4~2.3 cm in length. Externally golden, lustrous, with fine longitudinally wrinkles. Texture tenacious and hard, fracture relatively even. Odour slight; taste slightly bitter, viscous on chewing.
3. Stem of *Dendrobium chrysanthum*: Slender and conical, irregular curved of the middle and upper parts, 23~120 cm in length, 2~5 mm in diameter, internodes 2~3.5 cm in length. Externally golden or brownish-yellow, with longitudinally wrinkles. Texture light and compact, fracture slightly fibrous. Odour slight; taste slightly bitter, viscous on chewing.
4. Stem of *Dendrobium fimbriatum*: Some branched of the upper part, 30~150 cm in length, 2~8 mm in diameter, internodes 2~5.0 cm in length. Externally brownish-yellow, with 8~9 deeply longitudinally furrows. Texture lax, fracture fibrous. Odour slight; taste slightly bitter. Sliced pieces often cut into 1.5~3 cm in length, fracture grayish-white.
5. Stem of *Dendrobium officinale*: Spiral or spring-like after processed, usually 2~4 spiral patterns, as whole, 3.5~8 cm in length, 1.5~3 mm in diameter, internodes 1~3.5 cm in length. Externally yellowish-green or yellow, with fine longitudinal wrinkles, with short fibrous root at one edge. Texture compact and fragile, fracture even. Viscous on chewing, no fiber residue; taste sweet.
6. Stem of *Dendrobium tosaense*: Cylindrical, 14~38 cm in length, internodes in base 2~4 cm in length, 2.2~4.6 mm in diameter; internodes 1.4~3.2 cm in length, 1.2~3.6 mm in diameter. Externally yellow to golden, lustrous, gradually slender to base. Internodes cylindrical, furrowed longitudinally, with longitudinal wrinkles distinct. Pedicels, bud scars, leaf scars And remaining membranous leaf sheath present in the upper internodes. Texture compact, tenacious and hard, fracture yellowish-white, short-fiber like vascular bundles present. Odour slight, viscous on chewing, taste slightly.

Microscopic identification:

1. **Transverse section:**
   (1) Stem of *Dendrobium nobile*: About 7 mm in diameter, composed of 1 layer of thin and flat cells, with thick and orange-yellow cuticles. Cortex narrow. Vascular bundles of stele numerous, scattered, slightly arranged in 7~8 whorls. Fiber groups outside of closed collateral vascular bundles composed of 1~6 rows of fibers, 22~42 μm in diameter, walls 1.5~7 μm thick, fine and small parenchymatous cells embed near the margin, occasionally containing subrounded silica bodies, 5~9 μm in diameter; phloem broad; xylem vessels 1~4 relatively large, about 51 μm in diameter; no fibers or 1~2 rows present at the inner. Mucilage cells and raphides of calcium oxalate, 50~130 μm in length, also present.
   (2) Stem of *Dendrobium loddigesii*: About 3 mm in diameter, vascular bundles slightly arranged in 3~4 whorls. Fiber groups outside of vascular bundles composed of 2~5 rows of fibers, up to 27 μm in diameter, walls 1.6~3 μm thick; xylem vessels 1~2 relatively large, 30~40 μm in diameter. Raphides-containing cells mostly accompanied by vascular bundles, the raphides 50~74 μm in length.
   (3) Stem of *Dendrobium chrysanthum*: About 5 mm in diameter, vascular bundles slightly arranged in 5~6 whorls. Fiber groups outside of vascular bundles composed of 1~6 rows of fibers, up to 29 μm in diameter, walls 1.5~5 μm thick; silica bodies relatively numerous, 3~10 μm in diameter; xylem vessels 1~3 relatively large, up to 48 μm in diameter. Raphides-containing cells mostly accompanied by vascular bundles, the raphides 33~83 μm in length.
   (4) Stem of *Dendrobium fimbriatum*: About 8 mm in diameter, epidermis flat-rounded, the outer and lateral walls thickened and lignified, with distinct striations. Cortex composed of 3~4 layers of cells. Vascular bundles slightly arranged in 6~7 whorls. Fiber groups outside of vascular bundles composed of 2~8 layers of fibers, up to 29 μm in diameter, walls 3~8 μm thick; silica bodies relatively numerous, 6~16 μm in diameter; xylem vessels 1~4 relatively large, up to 54 μm in diameter.
   (5) Stem of *Dendrobium officinale*: About 4.5 mm in diameter, epidermis composed of 4~5 rows of cells. Fiber groups outside of vascular

bundles composed of 1~5 layers of fibers, up to 21 μm in diameter, walls 3~6 μm thick; xylem vessels similar in size, up to 24 μm in diameter. Raphides-containing cells mostly existed near epidermis, the raphides 60~100 μm in length.

(6) Stem of *Dendrobium tosaense*: Leaf sheath 120~370 μm thick. Outside composed of epidermis with cells subsquare and subpolygonal, 46~96 μm in longitudinal, 16~38 μm in transverse, small spheroidal-shaped silica bodies present in surface, 2~8 μm in diameter. Raphides occasionally present in parenchymatous cells, 10~70 μm in length, 1~2 μm in diameter. Stomata 80~280 μm in length, 14~24 μm in diameter. 8~10 subrounded protuberant vascular bundles 40~190 μm in longitudinal, 20~24 μm in transverse. Tracheid in xylem mainly spiral and scalariform, vessles mainly reticular, 12~40 μm in diameter. Pseudo stem in the center with outer orange-yellow to golden cuticles, 4~12 μm in thick, connecting with oblong, polygonal and rectangular epidermis cells, 11~29 μm in longitudinal, 7~27 μm in transverse. Cortex slightly lignified, composed of parenchymatous cells. Raphides bundles present in testa, 82~115 μm in length, 1~2 μm in diameter, scattered with different size of fiber boundles, gradually become larger from outside to inside, subrounded or oblong, 64~124 μm in longitudinal, 66~242 μm in transverse. Fiber subpolygonal or long polygonal, 6~26 μm in diameter. Tiny parenchymatous cells at the outside containing numerous small spheroidal-shaped silica bodies, 2~6 μm in diameter. Tracheid in xylem mainly reticular, bordered pits and spiral, vessles mainly reticular, 6~28 μm in diameter.

Thin layer chromatographic identification test (General rule 1621.3):

1. Stem of *Dendrobium nobile*:
   (1) Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
   (2) Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
   (3) Reference standard solution: Weigh accurately a quantity of dendrobine and dissolve in methanol to produce a solution containing 1.0 mg per mL.
   (4) Procedure: Use silica gel F_{254} as the coating substance and a solution of petroleum ether (30~60℃) and acetone (7:3) as the developing solvent. Apply 20 μL of each of the sample solution and reference drug solution and 5 μL of reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with modified Dragendorff's reagent. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.
2. Stem of *Dendrobium chrysanthum*:
   (1) Sample solution: Add 1.0 g of powdered sample to 50 mL of methanol, stand for 20 minutes, ultrasonicate for 45 minutes, evaporate to dryness, dissolve the residue in 5 mL of methanol.
   (2) Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
   (3) Reference standard solution: Weigh accurately a quantity of erianin and dissolve in methanol to produce a solution containing 0.2 mg per mL.
   (4) Procedure: Use silica gel F_{254} as the coating substance and a solution of petroleum ether (30~60℃) and ethyl acetate (3:2) as the developing solvent. Apply 5~10 μL of each of the sample solution and reference drug solution and 5 μL of reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with a 10% solution of H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.
3. Stem of *Dendrobium fimbriatum*:
   (1) Sample solution: Add 0.5 g of powdered sample to 25 mL of methanol, ultrasonicate for 45 minutes, filter, evaporate to dryness, and dissolve the residue in 25 mL of methanol.
   (2) Reference drug solution: Use 0.5 g of the reference drug as the same method described above.
   (3) Reference standard solution: Weigh accurately a quantity of gigantol and dissolve in methanol to produce a solution containing 0.2 mg per mL.
   (4) Procedure: Use silica gel F_{254} as the coating substance and a solution of petroleum ether (30~60℃) and ethyl acetate (3:2) as the developing solvent. Apply 5~10 μL of each of the sample solution and reference drug solution and 5 μL of reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with a 10% solution of H_2SO_4/EtOH TS and heat at 105℃ until the

spots become visible. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 14.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 7.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: The dried product should be stored in a ventilated and dry place, and protected from moisture; the flesh product should be stored in a cool and damp place, and protected from freezing.
Usage: Tonifying and replenishing medicinal (Yin-tonifying medicinal).
Property and flavor: Mild cold, sweet.
Meridian tropism: Stomach and kidney meridians.
Effects: Supplement stomach and engender fluid, nourish yin and clear heat.
Administration and dosage: 6~15 g.

DESMODII STYRACIFOLII HERBA
廣金錢草
Guang Jin Cian Cao / Guang Jin Qian Cao
Snowbell-leaf Tickclover Herb

Snowbell-leaf tickclover herb is the dried aerial part of *Desmodium styracifolium* (Osbeck) Merr. (Fam. Leguminosae).
It contains not less than 3.0% of dilute ethanol-soluble extractives, not less than 5.0% of water extractives and not less than 0.13% of schaftoside.

Description: Stems cylindrical, up to 1 m in length, densely covered with yellow spreading pubescence; texture fragile, fracture medullated. Leaves alternate, leaflets 1~3, rounded or oblong, 2.5~4.5 cm in length, 2~4 cm in width; apex slightly dented, base cordate or obtusely rounded, margin entire; the upper surface yellowish-green or grayish-green, the lower surface covered with grayish-white tomenta; lateral veins pinnate; petiole 1~2 cm in length; stipules lanceolate, about 8 mm in length. Odour slightly aromatic; taste slightly sweet.

Microscopic identification:

1. **Transverse section:**
   Stem of *Desmodium styracifolium*: The outermost layer was rectangular epidermal cells, wall thickened; inside showing cork, cells polygonal, wall thickened and suberized. Non-glandular hairs 2 types: one type is hook-like, small, 35~120 μm in length, composed of 1~3 cells; the other type is long needle-shaped, unicellular, slightly curved. Cortex composed of 6~10 layers of oblong parenchymatous cells, some cells contain red and irregular pigment masses. Pericyclic fibers composed of 3~6 layers of fibers into bundles or bands, arranged in an interrupted ring. Phloem cells irregular in shape, arranged densely, some cells contain prisms of calcium oxalate, singly scattered, 5~20 μm in diameter. Vessels singly scattered or 2~3 linked, 30~70 μm in diameter, lignified, mainly reticulate and spiral. Pith with thin walls, polygonal, 40~120 μm in diameter.
2. **Powder:** Yellowish-green. Both upper and lower epidermis of leaf irregularly polygonal, with small anomocytic stomata, subsidiary cells 2~4. Non-glandular hairs of 2 types: one type is hook-like, small, 35~120 μm in length, composed of 1~3 cells; the other type is long needle-shaped, unicellular, slightly curved. Cork cells polygonal, wall thickened and suberized. Prisms of calcium oxalate singly scattered, 5~20 μm in diameter. Pericyclic fibers with both ends acute. Xylem fibers lanceolate, the apex slightly curved. Pigment masses irregular in shape, scattered in parenchymatous cells of cortex, parenchymatous cells of pith and palisade tissue. Vessels 30~70 μm in diameter, vessels of leaf veins reticulate, scalariform or spiral, wall slightly lignified.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 0.2 g of powdered sample to 25 mL of 80% methanol, ultrasonicate for 20 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 50% methanol.
2. Reference drug solution: Take 0.2 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of schaftoside and dissolve in 50% methanol to produce a solution containing 75 μg per mL.
4. Procedure: Use polyamide as the coating substance and a solution of ethyl acetate, butanone, and formic acid (5:1:1) as the developing solvent. Apply 1 μL

of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with $AlC1_3$/EtOH TS, and dry with hot air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution correspondings in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 12.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 11.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 5.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Schaftoside:
   (1) Mobile phase: A solution of methanol and water (32:68). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of schaftoside and dissolve in 50% methanol to produce a solution containing 30 μg per mL.
   (3) Sample solution: Weigh accurately 0.2 g of the powdered sample and place it in a conical flask with stopper, accurately add 25 mL of 80% methanol, weigh, ultrasonicate for 20 minutes, cool, weigh again, replenish the loss of the weight with 80% methanol, mix well, filter, evaporate the filtrate to dryness, dissolve the residue in a quantity of 50% methanol, transfer the solution to 10-mL volumetric flask, make up to volume with 50% methanol, mix well, filter and use the filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (272 nm) and a column packing L1. The number of theoretical plates of the peak of schaftoside should not be less than 1,500.
   (5) Procedure: Inject accurately 5 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   Schaftoside (%)=0.001(r_U/r_S) (C_S) / (W)

   r_U: peak area of schaftoside of sample solution
   r_S: peak area of schaftoside of reference standard solution
   C_S: concentration of schaftoside of reference standard solution (μg /mL)
   W: weight of test sample (g) calculated with dried sample
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a dry place.
Usage: Dampness-dispelling medicinal (Dampness-draining diuretic medicinal).
Property and flavor: Cool, sweet and bland.
Meridian tropism: Liver, kidney, and bladder meridians.
Effects: Induce diuresis and relieve strangury, eliminate dampness and anti icteric, detoxicate and alleviate edema.
Administration and dosage: 15~30 g.

DIANTHI HERBA
瞿麥
Jyu Mai / Ju Mai
Pink Herb

Pink herb is the dried aerial part of *Dianthus superbus* L. or *Dianthus chinensis* L. (Fam. Caryophyllaceae).
It contains not less than 9.0% of dilute ethanol-soluble extractives and not less than 11.0% of water extractives.

Description:

1. Aerial part of *Dianthus superbus*: Stems cylindrical, branched at the upper part, 30~60 cm in length, nodes swollen; externally pale green or yellowish-green, glabrous. Leaves mostly crumpled, opposite, yellowish-green, lamina liner-lanceolate as whole, 2~10 cm in length, 0.4~1 cm in width, apex slightly curved, base short sheath shape and amplexicaul. Flowers solitary or several aggregated into cyme; calyx tubular, 2.5~3.5 cm in length, about 3/4 of flower, persistent; bracts 4~6, broadly ovate, about 1/4 in length of calyx tube, apex acute or acuminate, with regularly longitudinal striations; petals brownish-purple or brownish-yellow, 3~4 cm in length, apex deeply laciniate. Capsules cylindrical, as long as persistent calyx. Seeds minute, numerous, brown and flattened. Odourless; taste sweet.
2. Aerial part of *Dianthus chinensis*: Stem erect, cylindrical, branched, 30~50 cm in length; texture hard and fragile, fracture hollowed. Lamina strip-lanceolate as whole, 2~9 cm in length, 0.2~0.7 cm in width. Calyx tubular, 1~2 cm in length, about 1/2 of flower; bracts numerous, about 1/2 in length of calyx tube, apex acuminate, imbricate; occasionally with shrunken petals, brownish-purple or brownish-yellow, apex shallowly toothed. Odour slight; taste slightly sweet.

Microscopic identification:

1. **Powder:**
   (1) Aerial part of *Dianthus superbus*: Yellowish-green or yellowish-brown. Fibers and crystal fibers relatively numerous, 10~38 μm in diameter, pit canals indistinct, lumen narrow; some fiber bundles surrounded by cells containing clusters of calcium oxalate, forming crystal fibers. Clusters of calcium oxalate relatively numerous, 7~85 μm in diameter. Non-glandular hairs 2 types: one type (margins of bract) is 1- to 3-celled, wall thin, 5~12 μm in diameter; the other type is 1- to 2-celled, clavate, the apex obtusely rounded, 10~13 μm in diameter, with strip-shaped cutinized striations on the surface. Upper epidermal cells of leaf subpolygonal in surface view, anticlinal walls moniliform thickened, with sparsely cutinized striations on the surface. Stomata diacytic, anomocytic occasionally found. Pollen grains spheroidal, 31~75 μm in diameter, with scattered pits, 10~17, with reticular striations on the surface. Sclerenchymatous cells of pith of stem subrectangular, 3.7~9.3 μm in diameter, wall 3~8 μm thick, slightly lignified, pit canals sparse.
   (2) Aerial part of *Dianthus chinensis*: Yellowish-green. Fibers mostly in bundles, 8~22 μm in diameter, pit canals indistinct, lumen linear; some cells surrounded by cells containing clusters of calcium oxalate, forming crystal fibers. Clusters of calcium oxalate relatively numerous, 5~75 μm in diameter. Non-glandular hairs 1- to 11-celled, up to 300 μm in length, 7~33 μm in diameter, some lumens contain yellowish-brown contents. Leaf margins with cone-like protuberance. Pollen grains spheroidal, 27~53 μm in diameter, with scattered pits, 9~14, with reticular striations on the surface.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, cool, filter, make up the filtrate to 10 mL, and evaporate the solution to 3 mL.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and the supernatant of *n*-butanol, glacial acetic acid, and water (4:1:5) as the developing solvent. Apply 1 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray a solution of $AlC1_3$/EtOH TS, and dry with hot air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:

1. Loss on drying: Not more than 11.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 12.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.5 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place.
Usage: Dampness-dispelling medicinal (Dampness-draining diuretic medicinal).
Property and flavor: Cold; bitter.
Meridian tropism: Heart and small intestine meridians.
Effects: Induce diuresis and relieve strangury, break blood andpromoting menstruation.
Administration and dosage: 9~15 g.
Precaution and warning: Use cautiously during pregnancy.

DICHROAE RADIX
常山
Chang Shan/Chang Shan
Dichroa Root

Dichroa root is the dried root of *Dichroa febrifuga* Lour. (Fam. Saxifragaceae).
It contains not less than 4.0% of dilute ethanol-soluble extractives and not less than 4.0% of water extractives.

Description: Cylindrical, often twisted or branched, vary in size, 9~15 cm in length, 0.5~2 cm in diameter. Epidermis brownish yellow, longitudinal wrinkles, outer skin is easy to peel off, yellow xylem is exposed at the peeling surface, hard, not easy to break; Cross-section touch is powdery, yellowish white, medulla is white, radial, annual ring pattern is clearly visible. Odor slight, taste bitter.

Microscopic identification:
Transverse section:
Root of *Dichroa febrifuga*: The number of cork cells is narrow, phelloderm is narrow. A few cells contain resin blocks or calcium oxalate needle bundles, phloem is narrow. Parenchyma cells also contain resin blocks or needle bundles. The formation layer is irregularly wave-shaped, xylem is the main part, all are lignified, the width of the medulla is narrow, the cell type is 2~9 columns wide, catheter is polygonal, a single scattered or several convergence, mostly a scalariform vessels. The parenchyma cells contain starch granules.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 5 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of dichroine A and dissolve in methanol to produce a solution containing 10 μg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of toluene, ethyl acetate, and formic acid (6:3:0.1) as the developing solvent. Apply 5 μL of each of the sample solution and reference drug solution and 1 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 9.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 2.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 0.5% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Storage: Store in a ventilated and dry place.
Usage: Emesis medicinal.
Property and flavor: Cold; bitter and pungent.
Meridian tropism: Lung, liver, and heart meridians.
Effects: Vomit and phlegm drool, interrupt malaria.
Administration and dosage: 5~12 g.
Precaution and warning: Use cautiously during pregnancy.

DICTAMNI CORTEX
白鮮皮
Bai Sian Pi / Bai Xian Pi
Densefruit Pittany Root-bark

Densefruit pittany root-bark is the dried bark of root of *Dictamnus dasycarpus* Turcz. (Fam. Rutaceae).
It contains not less than 15.0% of dilute ethanol-soluble extractives, not less than 20.0% of water extractives and not less than 0.15% of obakunone.

Description: Quilled, 5~15 cm in length, 1~2 cm in diameter, 2~5 mm thick. Outer surface grayish-white or pale yellow, with fine wrinkles and rootlet scars, occasionally remained with cork, frequently with small protruding granular dots; inner surface almost whitish, with fine longitudinal striations. Texture fragile, easily broken, dusting on breaking. Odour muttony; taste slightly bitter.

Microscopic identification:
1. **Transverse section:**
   Bark of root of *Dictamnus dasycarpus*: Outermost layer composed of 1 layer of epidermis covered with cuticle, cells in subrectangular or subsquare, occasionally broken. Cork composed of 6~14 layers of subrectangular or subsquare cells, slightly lignified, yellowish-brown. Cortex occupy 1/4~1/5 portion of the bark of root, 12~16 layered, composed of parenchymatous cells and fibers; parenchymatous cells subrectangular, subsquare or subpolygonal, scattered with clusters of calcium oxalate; fibers individually scattered or linked by 2~3, yellow, cells subrectangular, subrounded, subovate, suboblong or subpolygonal, 24~110 μm in diameter, walls thickened, with distinct striations. Rays distinct, 2~3 layered, growing to strip cells from outer to inner, cells subrectangular, subsquare or suboblong, scattered with clefts.
2. **Powder:** Pale yellowish-white. Cork cells subsquare, subpolygonal or subrectangular, slightly lignified. Fibers or phloem fibers yellow, 24~110 μm in diameter, walls thickened, with distinct striations, stone cell-shaped. Clusters of calcium oxalate, 5~33 μm in diameter, scattered or existed in parenchymatous cells.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 2.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 15 minutes, filter and use the filtrate.
2. Reference drug solution: Take 2.0 g of the reference drug and the method of preparation is the same as which is described above.

3. Reference standard solution: Weigh accurately a quantity of fraxinellone and dissolve in methanol to produce a solution containing 0.2 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane and ethyl acetate (3:2) as the developing solvent. Apply 5 μL of each of the sample solution and reference drug solution and 2 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 15.0% dry at 105°C for 5 hours (General rule 6015).
2. Total ash: Not more than 12.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 4.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
1. Obakunone:
   (1) Mobile phase: A solution of methanol and water (55:45). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of obakunone, and dissolve in methanol to produce a solution containing 125 μg per mL.
   (3) Weigh accurately 1.0 g of powdered sample and place it in a 100-mL round bottom flask, then add 25 mL of methanol, heat under reflux for 60 minutes, cool, filter to 25-mL volumetric flask with filter paper and make up to volume with methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (236 nm) and a column packing L1. The column temperature is maintained at 23 ± 4°C. The flow rate is about 1.2 mL/min. The number of theoretical plates of the peak of obakunone should not be less than 6,000.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   Obakunone: (%)= 0.0025(r_U/r_S) (C_S) / (W)

   r_U: peak area of obakunone of sample solution

   r_S: peak area of obakunone of reference standard solution

   C_S: concentration of obakunone of reference standard solution (μg/mL)

   W: weight of test sample (g) calculated with dried sample
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place, and protect from mold.
Usage: Heat-clearing medicinal (Heat-clearing and dampness-drying medicinal).
Property and flavor: Cold; bitter.
Meridian tropism: Spleen, stomach, and bladder meridians.
Effects: Clear heat and dry dampness, purge fire and detoxicate, dispel wind and relieve itching.
Administration and dosage: 5~15 g.

DIOSCOREAE HYPOGLAUCAE RHIZOMA
粉萆薢
Fen Bei Jie / Fen Bei Jie
Hypoglaucous Collett Yam Rhizome

Hypoglaucous collett yam rhizome is the dried rhizome of *Dioscorea collettii* Hook.f. var. *hypoglauca* (Palib.) S.J.Pei & C.T.Ting (*Dioscorea hypoglauca* Palib.) (Fam. Dioscoreaceae).
It contains not less than 6.0% of dilute ethanol-soluble extractives and not less than 6.0% of water extractives.

Description: Bamboo-like or massive, subround, branched. Externally brownish-yellow, crumpled, often remained with fibrous root. Sliced pieces irregularly thin slices, edge uneven, outer bark yellowish-brown or brownish-black, 1.5~2.5 cm in diameter, 1~3 mm thick, margin brown, slightly curved, with root scars, cut surface yellowish-white, starchy, scattered with yellow dots and striations of vascular bundles. Texture loose, slightly tenacious. Odour slight; taste pungent and slightly bitter.

Microscopic identification:
1. **Transverse section:**
   Rhizome of *Dioscorea collettii* var. *hypoglauca*: Cork composed of 4~10 rows of cork cells. Cortex relatively narrow, parenchymatous cells arranged tangentially, pits distinct. Mucilage cells slightly arranged in a ring, flattened-rounded, elongated tangentially, 100~180 μm in diameter, containing

raphides of calcium oxalate. Stele well developed, parenchymatous cells large, containing abundant starch granules. Vascular bundles collateral, scattered sparsely or arranged in a ring, xylem vessels 15~60 μm in diameter, sieve tube groups of phloem slightly semicircular-shaped.

2. **Powder:** Yellowish-white. Lignified parenchymatous cells long-subfusiform or polygonal, colorless or pale yellow, 50~250 μm in length and 20~104 μm in diameter, wall slightly thickened and lignified, pits large and dense. Vessels mainly bordered-pitted, 15~60 μm in diameter. Fibers slender, 12~20 μm in diameter, wall 4~7 μm thick, with distinct pit canals. Simple starch granules subrounded or conchoidal, up to 55 μm in length and 5~40 μm in diameter, hilum indistinct, striations faintly present; compound granules composed of 2~4 components. Raphides of calcium oxalate mostly scattered in bundles, 55~120 μm in length and up to 4 μm in diameter.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 0.5 g of powdered sample to 25 mL of methanol, ultrasonicate for 30 minutes, cool, filter, evaporate the filtrate to dryness, and dissolve the residue in 2 mL of methanol.
2. Reference drug solution: Take 0.5 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and the lower layer of a solution of dichloromethane, methanol, and water (13:7:2) below 10℃ as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible, and examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:

1. Loss on drying: Not more than 11.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 3.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place, and protect from moisture and insects.
Usage: Dampness-dispelling medicinal (Dampness-draining diuretic medicinal).
Property and flavor: Neutral; bitter.
Meridian tropism: Kidney and stomach meridians.
Effects: Drain dampness turbidity, dispel wind dampness.
Administration and dosage: 9~15 g.

DIOSCOREAE RHIZOMA
山藥
Shan Yao / Shan Yao
Chinese Yam

Chinese yam is the dried rhizome of *Dioscorea polystachya* Turcz. (*Dioscorea opposita* Thunb.), *Dioscorea doryophora* Hance or *Dioscorea japonica* Thunb. (Fam. Dioscoreaceae).

Description:

1. Rhizome of *Dioscorea polystachya*: Cylindrical, the two ends even, externally white or yellowish-white, smooth, have fine brown vascular bundles striations. 15~30 cm in length, 1.3~4 cm in diameter. Texture compact and tough, fracture white and starchy. Odourless, taste weak, slightly sour, and viscous on chewing.
2. Rhizome of *Dioscorea doryophora*: Cylindrical or slightly flattened and twisted. Externally yellowish-brown, with longitudinal furrows, fibrous roots and root scars, 10~20 cm in length or longer, 1.2~3.2 cm in diameter. Texture compact and tough, fracture white, viscous.
3. Rhizome of *Dioscorea japonica*: Cylindrical or slightly twisted. Externally yellowish-brown, with longitudinal striationa, longitudinal wrinkles, fibrous roots and root scars, 10~20 cm in length or longer, 0.5~2.2 cm in diameter. Texture compact and tough, fracture white, viscous.

Microscopic identification:

1. **Transverse section:**
   (1) Rhizome of *Dioscorea polystachya*: 2~3 cm in diameter. Outermost layer composed of 12~18 layers of cork cells covered with cuticle, scattered with stone cells. Inner cork composed of large parenchymatous cells scattered with resin canals containing yellowish-brown resin. Parenchymatous cells subrounded or suboblong, filled with starch

granules. Raphides of calcium oxalate occationally present near the margin of mucilage cells. Parenchymatous cells scattered with subovoid or rounded collateral vascular bundles. Vessels in xylem lignified, suboblong, subrounded or subpolygonal, 50 μm in diameter.

(2) Rhizome of *Dioscorea doryophora*: 2~3 cm in diameter. Outermost layer composed of 12~18 layers of cork cells covered with cuticle, scattered with stone cells. Inner cork composed of large parenchymatous cells scattered with resin canals containing yellowish-brown resin. Parenchymatous cells subrounded or suboblong, filled with starch granules. raphides of calcium oxalate occationally present near the margin of mucilage cells. Parenchymatous cells scattered with subovoid or rounded collateral vascular bundles. Vessels in xylem lignified, suboblong, subrounded or subpolygonal, 20~80 μm in diameter.

(3) Rhizome of *Dioscorea japonica*: 0.8~1.0 cm in diameter. Outermost layer composed of 10~14 layers of cork cells covered with cuticle, scattered with stone cells. Inner cork composed of large subrounded or suboblong parenchymatous cells, filled with starch granules. raphides of calcium oxalate occationally present near the margin of mucilage cells. Parenchymatous cells scattered with subovoid or rounded collateral vascular bundles. Vessels in xylem lignified, 16~68 μm in diameter.

2. **Powder:** Off-white. Simple starch granules compressed-ovoid, subrounded, deltoid-ovoid or oblong, up to 48 μm long, 8~35 μm in diameter, hilum dotted, V-shaped, cruciate or shortly cleft at the small end, striations distinct; few compound starch granules, usually composed of 2~3 granules. Raphides of calcium oxalate large, existed in mucilage cells, 80~240 μm long and needle crystals 2~5 μm in diameter; apex slightly acute or truncate, slightly square in fracture surface. Bordered-pitted, reticulate, spiral and annular vessels, and a few fibers also exist.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter, evaporate the filtrate to dryness, dissolve the residue in 1 mL of methanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane and ethyl acetate (7:3) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray a solution of *p*-anisaldehyde/H_2SO_4 TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:

1. Loss on drying: Not more than 15.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 6.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 0.5% (General rule 6007).
4. Sulfur dioxide: Not more than 400 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

※Note: "When this TCM herb is sold commercially, the limits of heavy metals, sulfur dioxide and aflatoxins should follow the food standard."

Storage: Refrigerate or store in a cool and dry place, and protect from insects.
Usage: Tonifying and replenishing medicinal (Qi-tonifying medicinal).
Property and flavor: Neutral; sweet.
Meridian tropism: Spleen, lung, and kidney meridians.
Effects: Tonify qi and nourish yin, supplement spleen and nourish stomach, engender fluid and benefit lung, supplement kidney and astringent essence.
Administration and dosage: 10~30 g.

DIPSACI RADIX
續斷
Syu Duan / Xu Duan
Dipsacus Root

Dipsacus root is the dried root of *Dipsacus inermis* Wall. (Fam. Dipsacaceae).
It contains not less than 19.0% of dilute ethanol-soluble extractives, not less than 24.0% of water extractives and not less than 2.0% of asperosaponin VI.
Description: Cylindrical, slightly flattened, some slightly curved, 5~15 cm in length, 0.5~2 cm in diameter. Externally yellowish-brown or grayish-brown, with distinctly twistedly longitudinal wrinkles and furrows, showing transversal lenticels and sparse rootlet scars. Texture soft and hardened after long storage, easily broken, fracture uneven, bark dark green or brown, the outer part brown or pale brown; xylem yellowish-brown, vessel bundles arranged radially. Odour slightly aromatic; taste bitter, slightly sweet and then astringent.

Microscopic identification:

1. **Transverse section:**
   Root of *Dipsacus inermis*: Cork composed of several rows of cells. Phelloderm relatively narrow. Groups of sieve tubes sparsely scattered in the phloem. Cambium in a ring. Xylem rays broad, vessels dense near the cambium and lessened inward, usually singly scattered or 2~3 in groups. Pith small. Parenchymatous cells contain clusters of calcium oxalate.
2. **Powder:** Yellowish-brown. Clusters of calcium oxalate extremely numerous, 15~50 μm in diameter, scattered in shrunken parenchymatous cells, usually several arranged as a row. Fusiform parenchymatous cells with fine and oblique crisscross striations, wall slightly thickened. Bordered-pitted and reticulate vessels about to 72~90 μm in diameter. Cork cells pale brown, subpolygonal or elongated-polygonal in surface view, wall thin.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 15 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of asperosaponin VI and dissolve in methanol to produce a solution containing 0.5 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, methanol, and water (7:2:1) as the developing solvent. Apply 2 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 10.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 14.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 3.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Asperosaponin VI:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and water as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of asperosaponin VI, and dissolve in methanol to produce a solution containing 0.5 mg per mL.
   (3) Sample solution: Weigh accurately 0.5 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 25 mL of methanol, ultrasonicate for 30 minutes, filter with filter paper. Repeat the extraction of the residue two more times. Combine the filtrate, evaporate the filtrate to a small amount and transfer to 25-mL volumetric flask, make up to volume with methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (210 nm) and a column packing L1. The column temperature is maintained at 35℃. The flow rate is about 1 mL/min.Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of asperosaponin VI should not be less than 10,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~40	10→45	90→55
40~60	45→95	55→5

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   Asperosaponin VI (%)=2.5(r_U/r_S) (C_S) / (W)

   r_U: peak area of asperosaponin VI of sample solution

   r_S: peak area of asperosaponin VI of reference standard solution

   C_S: concentration of asperosaponin VI of reference standard solution (mg /mL)

   W: weight of test sample (g) calculated with dried sample
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from insects.
Usage: Tonifying and replenishing medicinal (Yang-tonifying medicinal).
Property and flavor: Mild warm; bitter and pungent.
Meridian tropism: Liver and kidney meridians.
Effects: Tonify liver and kidney, adjust blood vein, continue sinew and bone.
Administration and dosage: 9~15 g.

DOLOMIAEAE RADIX
川木香
Chuan Mu Siang / Chuan Mu Xiang
Common Vladimiria Root

Common vladimiria root is the dried root of *Dolomiaea souliei* (Franch.) C.Shih or *Dolomiaea souliei* (Franch.) C.Shih var. *cinerea* (Y.Ling) Q.Yuan (Fam. Compositae). It contains not less than 12.0% of dilute ethanol-soluble extractives, not less than 16.0% of water extractives and not less than 1.3% of the total amount of costunolide and dehydrocostuslactone.

Description: Cylindrical or subsemicylindrical, slightly curved, 10~30 cm in length, 1.5~3 diameter. Externally rough, yellowish-brown or dark brown, with visible dense rhomboid mesh striations composed of fiber bundles, pale yellow. Root stocks occasionally with black viscous gelatinous substance result from processing, commonly known as “Hu Tou” or “Oil Head”. Texture light, hard and fragile, uneasily broken, fracture uneven, bark yellowish-brown, wood yellow, with visible yellowish-brown oil spots (oil cavity), some of the central part rotten-wood-like. Odour slightly aromatic; taste bitter.

Microscopic identification:
1. **Transverse section:**
   Dolomiaeae radix: Cork composed of 4~6 layers of cells. Phloem relatively broad, forming regular radiated pattern with xylem. Cambium ring undulate. Fibers bundles yellow, lignified, accompanied by stone cells. Pith intact or withered. Oil cavities scattered in rays and throughout parenchyma in pith. Inulin found in parenchymatous cells.
2. **Powder:** Brownish-yellow. Fibers long-fusiform or elongate, yellow or colorless, 15~35 μm in diameter, the wall 5~15 μm thick, lignified, pits and pit canals distinct. Vessels mostly reticulate and scalariform, 15~140 μm in diameter, the walls lignified. Stone cells fibrous in shape, the walls lignified and thickened. Inulin abundant, present in fan-shaped or irregular clumps. Oil cavities mostly broken, oil droplets rarely present and few prisms of calcium oxalate.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 3.0 g of powdered sample to 10 mL of ethanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 3.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of dehydrocostuslactone and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane, ethyl acetate, and formic acid (15:5:1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 12.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 5.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:
1. Costunolide and dehydrocostuslactone:
   (1) Mobile phase: A solution of methanol and water (65:35). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of costunolide and dehydrocostuslactone, and dissolve in methanol to produce a solution containing 50 μg per mL of each.
   (3) Sample solution: Weigh accurately 0.3 g of the powdered sample and place it in a 125-mL conical flask, then add accurately 50 mL of methanol, ultrasonicate for 30 minutes, filter to 50-mL volumetric flask with filter paper, make up to volume with methanol, mix well, filter and use the successive filtrate

(4) Chromatographic system: The liquid chromatography is equipped with an UV detector (225 nm) and a column packing L1. The column temperature is maintained at 35℃. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of costunolide and dehydrocostuslactone should not be less than 6,000 of each.

(5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Costunolide or dehydrocostuslactone (%)=0.005 (r_U/r_S) (C_S) / (W)

r_U: peak area of costunolide or dehydrocostuslactone of sample solution

r_S: peak area of costunolide or dehydrocostuslactone of reference standard solution

C_S: concentration of costunolide or dehydrocostuslactone of reference standard solution (μg/mL)

W: weight of test sample (g) calculated

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place, and protect from moisture and insects.
Usage: Qi-regulating medicinal.
Property and flavor: Warm; pungent and bitter.
Meridian tropism: Spleen, stomach, large intestine, and gallbladder meridians.
Administration and dosage: 3~9 g.

DRACONIS SANGUIS
血竭
Sie Jie / Xie Jie
Dragon's Blood

Dragon's blood is the prepared resin of the fruit of *Daemonorops draco* (Willd.) Blume (Fam. Palmae).
It contains not less than 1.0% of dracorhodin.

Description: Subsquare or subrounded, externally dark red or reddish-brown, lustrous. Texture fragile and hard, fracture reddish-brown, lustrous as glass-like. Ground powder brick red, giving unpleasant smoke when burned, sand-like on chewing. Insoluble in water, softened in hot water. Odour slight; taste weak.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 3.0 g of powdered sample to 10 mL of ethanol, ultrasonicate for 1 hour, filter and use the filtrate.
2. Reference drug solution: Take 3.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of dichloromethane and methanol (19:1) as the developing solvent. Apply 10 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:

1. Total ash: Not more than 4.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 3.0% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Total heavy metals: Not more than 20.0 ppm (General rule 6301).

Assay:

1. Dracorhodin:
   (1) Mobile phase: A solution of acetonitrile and 0.05 M sodium dihydrogen phosphate solution (50:50). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately 9.0 mg of dracorhodin perchlorate and place it in a 50-mL amber volumetric flask, add accurately 50 mL of 3% phosphoric acid in methanol, and mix well. Transfer 1 mL of the mixture to a 5-mL amber volumetric flask, make up to volume with methanol, mix well, mix well (containing 26 μg of dracorhodin per mL) (the weight of dracohodin is equivalent to 1/1.377 of the weight of dracorhodin perchlorate).
   (3) Sample solution: Weigh accurately 0.05~0.15 g of powdered sample, transfer to a tube with stopper, add accurately 10 mL of 3% phosphoric acid in methanol, stopper tightly, shake for 3 minutes, filter, weigh accurately 1 mL of the successive filtrate, transfer to a 5-mL amber volumetric flask, make up to volume with methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (440 nm) and a column packing L1. The number of theoretical plates of the peak of dracorhodin should not be less than 4,000.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Dracorhodin:(%)=(5/1.377)(r_U/r_S)(C_S)/ (W)

r_U: peak area of dracorhodin of sample solution
r_S: peak area of dracorhodin of reference standard solution
C_S: concentration of dracorhodin of reference standard solution (mg/mL)
W: weight of test sample (g) calculated with dried sample

Storage: Store in a cool and dry place, and protect from moisture.
Usage: Blood-regulating medicinal (Blood-activating and stasis-dispelling medicinal).
Property and flavor: Neutral; sweet and salty.
Meridian tropism: Heart and liver meridians.
Effects: Hemostatic to promote tissue regeneration and hemostatic wound healing, activate blood and dissipate stasis to relieve pain.
Administration and dosage: 1~2 g.

DRYNARIAE RHIZOMA
骨碎補
Gu Suei Bu/Gu Sui Bu
Fortune's Drynaria Rhizome

Fortune's drynaria rhizome is the dried rhizome of *Drynaria roosii* Nakaike (Fam. Polypodiaceae).
It contains not less than 2.0% of dilute ethanol-soluble extractives and not less than 1.0% of water extractives and not less than 0.15% of naringin.

Description: Flat and long, curved, branched. 5~15 cm in leng, 1~1.5 cm in wide, 0.2~0.5 cm in thick. Scales dark brown to dark brown, soft and hairy, After burning is brown or dark brown. Both sides and the upper surface have protruding or concave circular leaf marks, a few have petiole residues and fibrous roots. Light, brittle, easy break, section reddish brown, vascular bundles are yellow dots arranged in a ring. Odor slight, taste light, slight astringent.

Microscopic identification:
1. **Transverse section:**
   Rhizome of *Drynaria roosii*: Epidermal cells 1 column, subround or oblong, outer wall is slightly thick; the scale base is located in the depression of the epidermis, the cells are 3~4 columns, wall thick, contains reddish brown pigment. Basic parenchyma cells are subround or irregularly wavy, containing a small amount of starch granules and yellow-brown granules. Endothelium surrounds the split column, cells are tangentially elongated, and the Kjeldahl point is not clear. Vascular bundle is surrounded by a tough surrounding type, 17~25 are arranged in a flat circular ring, vascular bundle has an endothelial layer on the periphery. Xylem pseudo-catheter has a polygonal shape, 6~40 μm in diameter. Middle part is larger and gradually becomes smaller toward the two ends. Phloem part is the inner and outer parts at the two ends, cell wall of the inner phloem is thickened and filled with yellow-brown secretion.
2. **Powder:** Brown. Scale fragments are reddish brown or yellowish brown, body cells are irregular or elongated, walls are straight or slightly curved, 1.5~5 μm in thick, 2 cells with hair on the edge. Terminal is often separated. Some are filled with yellowish brown oil; Stalk fragments are dark reddish brown, cells are irregularly shaped. Cortical cells are subrectangular or subpolyhedral, cells in the near epidermis are small, the walls are slightly curved, pores are sparse, cell wall near the endothelium is thick, pores are obvious. tracheid yellow, yellowish brown or colorless, main is a netting, 10 to 80 μm in diameter. Fiber is mostly bundled, orange-yellow or redish brown, fusiform,terminal tapered,18~30 μm in diameter, the wall thickness, pores are not obvious, cavity often contains brown oil.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 30 mL of methanol, heat under reflux for 1 hour, filter, evaporate the filtrate to dryness, and dissolve the residue in 1 mL of methanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of naringin and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of toluene, ethyl acetate, formic acid, and water (1:12:2.5:3) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with $AlC1_3$/EtOH TS. Examine immediately under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 12.0% dry at 105°C for 5 hours (General rule 6015).
2. Total ash: Not more than 8.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.5% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 10.0 ppm (General rule 2251, 6301)

Assay:

1. Naringin:
   (1) Mobile phase: A solution of methanol and 1.0% acetic acid (40:60). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of naringin and dissolve in methanol to produce a solution containing 25 μg per mL.
   (3) Sample solution: Weigh accurately 0.25 g of the powdered sample and place it in a conical flask with a stopper, then add accurately 40 mL of 70% methanol, heat under reflux for 1 hour, cool, transfer the solution to 50-mL volumetric flask, make up to volume with 70% methanol, mix well, filter and use the filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (283 nm) and a column packing L1. The column temperature is maintained at 25℃. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of naringin should not be less than 3,000.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Naringin (%)=0.005(r_U/r_S) (C_S) / (W)
   r_U: peak area of naringin of sample solution
   r_S: peak area of naringin of reference standard solution
   C_S: concentration of naringin of reference standard solution (μg/mL)
   W: weight of test sample (g) calculated with dried sample

Storage: Store in a ventilated and dry place.
Usage: Tonifying and replenishing medicinal (Yang-tonifying medicinal).
Property and flavor: Warm; bitter.
Meridian tropism: Liver and kidney meridians.
Effects: Supplement kidney and strengthen bone, promote tissue regeneration, activate blood to relieve pain, continue sinew and bone, hemostatic.
Administration and dosage: 3~12 g

DRYOPTERIS CRASSIRHIZOMAE RHIZOMA
貫眾
Guan Jhong/ Guan Zhong
Male Fern Rhizome

Male fern rhizome is the dried rhizome of *Dryopteris crassirhizoma* Nakai (Fam. Dryopteridaceae).
It contains not less than 10.0% of dilute ethanol-soluble extractives and not less than 8.0% of water extractives and not less than 0.02% of albaspidin AA.
Description: Long obovate, slightly curved, obtuse at the upper end, sharper at the lower end, 3~17.8 cm in length, 2.2~9.5 cm in diameter. Exterior is yellowish brown to dark brown, densely arranged with petiole residues and scales, and has curved roots, and the scales are easy to fall off. Hard, slightly flat section. Yellowish green to yellowish brown. It can be seen that 5~13 oblong or elliptical yellowish white vascular bundles (separated middle columns) are arranged in a ring, and most of the leaf vascular bundles are scattered outside. The petiole residue is oblate, 2~9 mm in diameter. Material hard and brittle, the section is slightly flat, yellowish green to yellow-brown, and 5 to 13 oval or elliptical yellow-white vascular bundles (separated middle columns) are arranged in a ring. Odor specific, tastes faint, and gradually becomes bitter and pungent.

Microscopic identification:

1. **Transverse section:**
   (1) Rhizome of *Dryopteris crassirhizoma*: Sclerenchyma consists of several layers of irregular polygonal sclerenchyma cells, brown to dark brown. The basic tissue parenchyma cells are loosely arranged, contain yellow-brown and starch granules. The leaf vascular bundle is scattered outside the basic tissue. The vascular bundle (the split middle column) is surrounded by a tough surrounding type, and 5~13 are arranged in a ring; each outer layer has 1 flat layer of small endothelial cells. Xylem is composed of a polygonal tracheid. Glandular hairs of the glandular gland are spherical or pear-shaped, sometimes containing brown secretions, which are present in the intercellular space, often broken.
   (2) Blade shank of *Dryopteris crassirhizoma*: Sclerenchyma consists of several layers of sclerenchyma cells, brown to dark brown. The basic tissue parenchyma cells are loosely arranged, contain yellowish brown and starch granules. Vascular bundle (the split middle column) is surrounded by a tough surrounding type, and 5~13 are arranged in a ring; each outer layer has a flat layer of small endothelial cells. Xylem is composed of a polygonal tracheid . Glandular hairs of the glandular gland are spherical or pear-shaped, sometimes containing brown secretions, which are present in the intercellular space, often broken.
2. **Powder:** Grayish-brown to yellowish-brown. Sclerenchyma cells are scattered or bundled, yellowish brown or brown, fibrous, 6~42 μm in diameter; pale yellow-brown to bright yellowish brown under polarizing microscope. Interstitial glandular hair cells, more broken, intact occasional, oval or long oval, base extension, and some contain yellowish-brown secretions. Tracheid are mainly scalariform, and a few are reticulate, 7~43 μm in diameter. Many starch granules, single grain subround, elliptical or oval, 2~14 μm in diameter. The umbilical point and layer are not obvious; under

the polarizing microscope, it is black cross. The fibers are bundled or scattered, sparse twill holes are visible in thicker ones.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 0.5 g of powdered sample to 20 mL of *n*-hexane, ultrasonicate for 30 minutes, filter, evaporate 10 mL of the filtrate to dryness, and dissolve the residue in 5 mL of *n*-hexane.
2. Reference drug solution: Take 0.5 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of albaspidin AA and dissolve in methanol to produce a solution containing 0.05 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of petroleum ether (30~60 ℃), ethyl acetate, and glacial acetic acid (9:15:0.5) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 13.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 4.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 0.5% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Albaspidin AA:
   (1) Mobile phase: Methanol as the mobile phase A, and a solution of sodium hydrogen phosphate and citric acid buffer solution (50 mL of 0.1M Sodium hydrogen phosphate solution and 50 mL of 0.1M citric acid in 1500 mL flask. Adjust the pH to 5.0 with 0.1 M citric acid solution) as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of albaspidin AA and dissolve in a solution of dimethyl sulfoxide and methanol (1:4) to produce a solution containing 1 μg per mL.
   (3) Sample solution: Weigh accurately 0.1 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 10 mL of a solution of dimethyl sulfoxide and methanol (1:4), ultrasonicate for 20 minutes, centrifuge for 10 minutes. Transfer the supernatant to a 25-mL volumetric flask. Repeat the extraction of the residue one more time. Combine the supernatant and make up to volume with a solution of dimethyl sulfoxide and methanol (1:4), mix well, filter and use the filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (340 nm) and a column packing L1. The column temperature is maintained at 30℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of albaspidin AA should not be less than 1,500.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~25	60→73	40→27
25~30	73→95	27→5

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Albaspidin AA (%)=0.0025(r_U/r_S) (C_S) / (W)

r_U: peak area of albaspidin AA of sample solution

r_S: peak area of albaspidin AA of reference standard solution

C_S: concentration of albaspidin AA of reference standard solution (μg/mL)

W: weight of test sample (g) calculated with dried sample

Storage: Store in a ventilated and dry place.
Usage: Heat-clearing medicinal (Heat-clearing and detoxicating medicinal).
Property and flavor: Mild cold; bitter.
Effects: Clear heat, detoxicate, kill worms, hemostatic.
Administration and dosage: 4.5~12 g.

ECLIPTAE HERBA
墨旱蓮
Mo Han Lian / Mo Han Lian
Yerbadetajo Herb

Yerbadetajo herb is the dried aerial part of *Eclipta prostrata* (L.) L. (Fam. Compositae).
It contains not less than 10.0% of dilute ethanol-soluble extractives, not less than 10.0% of water extractives and not less than 0.04%of wedelolactone.

Description: White pubescences wholly. Stems cylindrical or subsquare, with longitudinal ridges, mostly branched, about 30 cm in length, 2~6 mm in diameter; externally greenish-brown or dark green; texture compact, fracture fibrous, yellowish-white, with white and lax pith in the center or hollowed. Leaves opposite, lamina crumpled and rolled or broken, long-lanceolate as whole, margin entire or shallowly dentate, grayish-green. Heads terminal or axillary, 2~6 mm in diameter. Achenes elliptical and flattened, 2~3 mm in length, brown or black. Odour slight; taste slightly salty.

Microscopic identification:

1. **Transverse section:**
   (1) Stem of *Eclipta prostrata*: Epidermis 1 row; inside showing 3~6 rows of parenchymatous cells, subrounded or subsquare, arranged densely. Cortex composed of polygonal or subrounded cells, spongy tissue-like, cells with numerous boundaries, large fiber cells with wall lignified, subtriangular, 75~100 μm in diameter. Pericyclic fibers scattered. Phloem and cambium indistinct. Xylem relatively broad, vessels 15~25 μm in diameter, subrounded or polygonal. Fibers lignified, singly scattered or in bundles. Rays composed of 2~6 rows of parenchymatous cells, arranged radially. Pith in the center composed of large and subrounded parenchymatous cells.
   (2) Leaf of *Eclipta prostrata*: Upper epidermal cells subsquare or rectangular, cells varying in size. Lower epidermal cells relatively small, stomata numerous. Both upper and lower epidermis contain hairs. Inside upper and lower epidermis of main vein contain 2~3 rows of collenchymatous cells. Palisade cells 1 row, spongy tissue 4~5 rows. Vascular bundles of main vein 3~5 in collateral type, xylem vessels arranged in rows, phloem cells narrow.
2. **Powder:** Grayish-green. Epidermal cells with thin wall, suboblong. Cortex in spongy tissue-shaped. Fibers long-fusiform, walls thickened and lignified, singly scattered or in bundles. Spiral vessels 15~25 μm in diameter. Pith composed of large parenchymatous cells, 300~350 μm in diameter. Non-glandular hairs mostly composed of 3 cells, 260~700 μm in length.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane, ethyl acetate, and formic acid (10:7:1) as the developing solvent. Apply 10 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:

1. Loss on drying: Not more than 14.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 14.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 4.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Wedelolactone:
   (1) Mobile phase: Methanol as the mobile phase A, and a solution of 0.5% acetic acid as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of wedelolactone and dissolve in methanol to produce a solution containing 10 μg per mL.
   (3) Sample solution: Weigh accurately 1.0 g of the powdered sample and place it in a conical flask with a stopper, accurately add 50 mL of 70% ethanol, weigh, heat under reflux for 1 hour, cool, weigh again, replenish the loss of the weight with 70% ethanol, mix well, filter and use the filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (351 nm) and a column packing L1. Program the chromatographic system as follows The number of theoretical plates of the peak of wedelolactone should not be less than 6,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~10	35-59	65-41
10~20	59	41

   (5) Procedure: Inject accurately 20 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Wedelolactone (%)=0.005(r_U/r_S) (C_S) / (W)

r_U: peak area of wedelolactone of sample solution
r_S: peak area of wedelolactone of reference standard solution
C_S: concentration of wedelolactone of reference standard solution (μg /mL)
W: weight of test sample (g) calculated with dried sample

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place, and protect from moisture.
Usage: Tonifying and replenishing medicinal (Yin-tonifying medicinal).
Property and flavor: Cold; sweet and sour.
Meridian tropism: Kidney and liver meridians.
Effects: Cool the blood to hemostatic, supplement liver and kidney, clear heat and detoxicate.
Administration and dosage: 6~15 g, used an appropriate amount of the fresh one.

EPHEDRAE HERBA
麻黃
Ma Huang / Ma Huang
Ephedra Herb

Ephedra herb is the dried herbaceous stem of *Ephedra sinica* Stapf, *Ephedra intermedia* Schrenk & C.A.Mey. or *Ephedra equisetina* Bunge (Fam. Ephedraceae).
It contains not less than 13.0% of dilute ethanol-soluble extractives, not less than 10.0% of water extractives and not less than 0.8% of total alkaloids, calculated with the total amounts of ephedrine HCl and pseudoephedrine HCl.

Description:
1. Stem of *Ephedra sinica*: Slenderly cylindrical, infrequently branched, 1~2 mm in diameter. Some with a few woody stems. Externally pale green to yellowish-green, with fine longitudinal ridges. Nodes distinct, internodes 2~6 cm in length. Membranous scaly leaves on the nodes, 3~4 mm in length, with 2 lobes (rarely 3), the apex reversed, base tubular. Texture light, fragile, easily broken, dusting on breaking, fracture slightly fibrous with greenish-yellow edge and subrounded reddish-brown pith. Odour slightly aromatic; taste slightly bitter and astringent.
2. Stem of *Ephedra intermedia*: Frequently branched, 1~3 mm in diameter, with 18~28 longitudinal ridges, internodes 2~6 cm in length, externally pale green or yellowish-green, inner reddish-brown. Membranous scaly leaves 2~3 mm in length, with 3 lobes (rarely 2), about 1/3 upper apart from the stem, apex acute. Taste slightly bitter and astringent.
3. Stem of *Ephedra equisetina:* Frequently branched, 1~1.5 mm in diameter, with 13~14 longitudinal ridges, internodes 1~3 cm in length. Membranous scaly leaves 1~2 mm in length, with 2 lobes (rarely 3), about 1/4 upper part apart from the stem, short-triangular, apex infrequently reversed.

Microscopic identification:
1. **Transverse section:**
   (1) Stem of *Ephedra sinica*: Subrounded and slightly oblate, margins with ridges in an undulating formation. Epidermal cells subsquare, outer walls thickened, covered with thick cuticle, with sunken stomata located between two ridges, subsidiary cells with walls lignified. Hypodermal fiber bundles located just between two ridges. Cortex just like mesophyll, containing chloroplast, scattered with fibers. Collateral vascular bundles of young stems 8~10, while that of old ones forming intrafascicular cambium, parenchymatous cells located outside. Phloem small, outside showing fiber bundles crescent-shaped. Cambium ring subrounded. Xylem linking into a ring, triangular, cells all lignified. Parenchymatous cells of pith usually containing brownish-red masses, surrounded by a few of fibers. Epidermal cells, cortex cells and fiber walls contain fine prisms of calcium oxalate or sandy crystals.
   (2) Stem of *Ephedra intermedia*: Vascular bundles 12~15. Cambium ring subtriangular. Fibers surrounding pith scattered or in bundles.
   (3) Stem of *Ephedra equisetina*: Vascular bundles 8~10. Cambium subrounded. Without fibers surrounding pith.
2. **Powder:**
   Stem of *Ephedra sinica*: Brown or green. Epidermis fragments extremely numerous, cells rectangular, containing granular crystals, stomata peculiar, sunken, subsidiary cells dumbbell-shaped in lateral view; cuticle layer usually broken in irregularly strip-shaped masses. Fibers numerous, with thick wall, unlignified to lignified, slender, lumen narrow, usually indistinct, scattered with fine and abundant sandy and prism crystals. Parenchymatous cells of pith unlignified to lignified, usually containing reddish-purple or brown contents, mostly shedded. Tracheids with pits. Vessels occasionally found, spiral and pitted. Stone cells (nodes) relatively rare.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, heat and shake in the water bath for 5 minutes, cool, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as

which is described above.

3. Reference standard solution: Weigh accurately 10 mg of ephedrine HCl and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-butanol, glacial acetic acid, and water (7:2:4) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with ninhydrin TS and heat at 105℃ until the spots become visible. Examine under visible light. The purplish-brown spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained with the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 9.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 12.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Ephedrine HCl and pseudoephedrine HCl:
   (1) Mobile phase: A solution of methanol and 0.092% phosphoric acid solution (It contains 0.04% triethylamine and 0.02% dibutylamine) (1.5:98.5). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of ephedrine HCl and pseudoephedrine HCl and dissolve in methanol to produce a solution containing 40 μg per mL of each.
   (3) Sample solution: Weigh accurately 0.5 g of the powdered sample and place it in a conical flask with stopper, accurately add 50 mL of 1.44% phosphoric acid solution, weigh, ultrasonicate for 20 minutes, cool, weigh again, replenish the loss of the weight with 1.44% phosphoric acid solution, mix well, filter, use the filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (210 nm) and a column packing L11. The number of theoretical plates of the peak of ephedrine HCl should not be less than 3,000.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   Ephedrine HCl or pseudoephedrine HCl (%)=0.005(r_U/r_S) (C_S) / (W)

   r_U: peak area of ephedrine HCl or pseudoephedrine HCl of sample solution

   r_S: peak area of ephedrine HCl or pseudoephedrine HCl of reference standard solution

   C_S: concentration of ephedrine HCl or pseudoephedrine HCl of reference standard solution (μg/mL)

   W: weight of test sample (g) calculated
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place, and protect from moisture.
Usage: Exterior-releasing medicinal (Pungent-warm exterior-releasing medicinal).
Property and flavor: Warm; pungent and mild bitter.
Meridian tropism: Lung and bladder meridians.
Effects: Promote sweating, calm panting, promote urination.
Administration and dosage: 1.5~9 g.

EPIMEDII FOLIUM
淫羊藿
Yin Yang Huo / Yin Yang Huo
Epimedium Leaf

Epimedium leaf is the dried leaf of *Epimedium sagittatum* (Siebold & Zucc.) Maxim., *Epimedium koreanum* Nakai, *Epimedium brevicornu* Maxim. or *Epimedium pubescens* Maxim. (Fam. Berberidaceae).
It contains not less than 15.0% of dilute ethanol-soluble extractives, not less than 6.0% of water extractives and not less than 0.2% of the total amounts of icariin and epimedin C.

Description:

1. Leaf of *Epimedium sagittatum*: Leaves trifoliolate; petiole slender; leaflets oval or ovate-lanceolate, coriaceous, 4~9 cm in length, 2.5~5 cm in width, apex acuminate, upper brownish-green or grayish-green; lower grayish-green, sparsely covered with thick, short and pronated hairs or nearly glabrous; bilateral leaflets distinctly oblique at the base, outer lobe larger, margin with spinulose hairs. Odour slight; taste bitter.
2. Leaf of *Epimedium koreanum*: Leaves biternate; leaflets thin, chartaceous, ovate or elongated ovate,

apex acuminate, base cordate, margin minutely serrate, serrate spinulose.

3. Leaf of *Epimedium brevicornu*: Leaves biternate; leaflets subcoriaceous, broadly ovate or nearly rounded.
4. Leaf of *Epimedium pubescens:* Ternately compound leaf, the lower surface of lamina and petioles densely coverd with flossy pubescences.

Microscopic identification:

1. **Transverse section:**
   (1) Leaf of *Epimedium sagittatum*: In surface view, upper and lower epidermis with irregularly thickened moniliform anticlinal walls; lower epidermis with periclinal walls papilla-shaped protuberance, double circles shaped in surface view. Stomata and non-glandular hairs only presented in lower epidermis. Stomata anomocytic. Non-glandular hairs 5~23 cells, at the apex 1~7 cells, colorless, walls about 6 μm thick, apical cells extremely long, straight, blunt, turning right angle shaped, irregularly curved or twisted, lower cells pale brown, occasionally containing brown contents; a few of non-glandular hairs relatively long, up to more than 24-celled, lower cells short and flat, linking into bamboo-like shaped, all cells containing pale brown contents; a few of non-glandular hairs thick and short, 3~5 cells, wall thin with obtusely rounded apex. Idioblasts long, arranged longitudinally along veins, containing 1 to numerous column crystals of calcium oxalate, 15~40 μm in length, 4~13 μm in diameter. Clusters of calcium oxalate also visible, 9~41 μm in diameter, angles short and blunt, some composed of 1~2 prism crystals; prism crystals 5~25 μm in diameter.
   (2) Leaf of *Epimedium koreanum*: Non-glandular hairs mostly slim and short, 2~8 cells, straight or slightly curved, apical cells mostly long and acute, at the apex 1~3 cells, all cells containing yellowish-brown contents, basal cells with cutinized fine striations; the other non-glandular hairs thick and long, mainly presented in vein and leaf base, cells more than 30, mostly curved, lower cells short or flat, gradually elongated upwards, some cells shrunken or swollen, arranged alternately, apical cells with obtusely-rounded apex, some cells containing reddish-brown or yellowish- brown oil droplets. A few of non-glandular hairs 6~10 cells, apical cells with obtusely-rounded or acute apex.
   (3) Leaf of *Epimedium brevicornu*: Non-glandular hairs rare, mostly presented in vein or vein base, 3~14 cells, straight or curved, basal cells short, wall slightly thickened, cells elongated upwards, wall thin, apical cells undulated, hook-like, twisted, twisted reversely or straight, the apex obtusely-rounded, some cells shrunken, numerous or all cells containing brown contents. A few of non-glandular hairs relatively slim and short, cells rare, apical cells extremely long, the apex acute, containing brown contents.
   (4) Leaf of *Epimedium pubescens*: Lower epidermis bearing spares stomatas and numerous slender non-glandular hairs.
2. **Powder:** Greenish-brown. Upper epidermal cells of leaf in surface view, wall thin and undulating, cells irregular in shape. Lower epidermal cells of leaf in surface view, stomata with 3~6 subsidairy cells, broken scars of glandular hairs and non-glandular hairs presented. Epidermal cells of stem in longitudinal view, cells subrectangular or flatten-rectangular, 2 layers, accompanied by fibers; fibers in bundles, slender. Parenchymatous cells in longitudinal view, cells subrectangular, rectangular or subsquare.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 0.5 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 0.5 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of icariin and epimedin C, dissolve in methanol to produce a solution containing 0.2 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, formic acid, and water (7:1:1) as the developing solvent. Apply 5 μL of the sample solution and reference drug solution and 1μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 14.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 8.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 3.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).

7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 10.0 ppm (General rule 2251, 6301).

Assay:

1. Icariin and epimedin C:
   (1) Mobile phase: A solution of acetonitrile and water (30:70). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of icariin and epimedin C, dissolve in methanol to produce a solution containing 10 μg and 40 μg per mL of each.
   (3) Sample solution: Weigh accurately 0.2g of the powdered sample, add 10 mL of 50% ethanol, ultrasonicate for 30 minutes, filter, transfer the filtrate to a 25-mL volumetric flask. Repeat the extraction of the residue one more time, make up to volume with 50% ethanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (270 nm) and a column packing L1. The column temperature is maintained at 35℃. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of icariin and epimedin C should not be less than 3,000.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Icariin or epimedin C (%)=0.0025(r_U/r_S) (C_S) / (W)
   r_U: peak area of icariin or epimedin C of sample solution
   r_S: peak area of icariin or epimedin C of reference standard solution
   C_S: concentration of icariin or epimedin C of reference standard solution (μg/mL)
   W: weight of test sample (g) calculated with dried sample
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place.
Usage: Tonifying and replenishing medicinal (Yang-tonifying medicinal).
Property and flavor: Warm; pungent and sweet.
Meridian tropism: Liver and kidney meridians.
Effects: Tonify kidney and invigorate yang, strengthen sinew and bone, dispel wind and eliminate dampness.
Administration and dosage: 3~10 g.

EQUISETI HYEMALIS HERBA
木賊
Mu Zei / Mu Zei
Scouring Rush Herb

Scouring rush herb is the dried aerial part of *Equisetum hyemale* L. (Fam. Equisetaceae).
It contains not less than 8.0% of dilute ethanol-soluble extractives, not less than 8.0% of water extractives and not less than 0.2% of kaempferol.

Description: Long tubular, unbranched, varying in length. Externally grayish-green or yellowish-green, nodes distinct with blackish-brown scaly leaves, internodes with 18~30 longitudinal ridges, ridges with shiny warts, rough. Texture light, fragile, easily broken, fracture hollow. Odour slight; taste sweet, slightly bitter.

Microscopic identification:

1. **Transverse section:**
   Aerial part of *Equisetum hyemale*: Epidermis covered with undulating cuticle, surface with grooves and ridges; epidermal cells square or rectangular, wall extremely thickened, arranged neatly and densely, distinct membrane pores on cell walls play a role as connection between adjacent cells, unlignified. Fibers mostly in bundles, linked with epidermis, long-fusiform, walls thickened and unlignified. Parenchymatous cells located on both side, subrounded, ovate or oblong, thick-walled, filled with yellow contents and starch granules; starch granules relatively small, round or oblong. Vascular bundles collateral. Phloem cell extremely small and regular, rectangular, oblong or polygonal, containing yellowish-brown contents. Xylem relatively undeveloped, vessels arranged in 2 rows, each row composed of 3~6 vessels, wall thickened and lignified to slightly lignified, mainly spiral. Internal parenchymatous cells relatively large, varing in size, cell membrane undulating or incompletely broken.
2. **Powder:** Grayish-green. Epidermal cells of stem rectangular or strip-shaped in surface view, anticlinal walls extremely thickened and undulating, arranged neatly, lumen contains yellowish-brown pigment granules; flat-rectangular in sectional view, wall thickened, containing pit canals, some (on ridges) outer walls bulged, with subrounded silica protuberances. Sunken stomata arranged in longitudinal, subrounded or elliptical, with many horizontally parallel thickened strips in guard cells. Epidermal cells of leaf sheath rectangular or long-fusiform in surface view, anticlinal walls thin or slightly thickened; relatively straight in grooves or undulating on ridges; stomata subrounded. Fibers long-fusiform, 12~37 μm in diameter, wall 2~9 μm thick, pits very small, V-shaped or oblique cleft-shaped, pits canals relatively distinct. Scalariform tracheids 8~17 μm in diameter. Endodermal cells also present.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 25 mL of 75% methanol and 1 mL of hydrochloric acid, heat under reflux for 1 hour, filter and evaporate the filtrate to dryness, dissolve the residue in 10 mL of water, extract shaking twice each with 10 mL of ethyl acetate, combine the ethyl acetate extracts and evaporate to dryness, dissolve the residue in 1 mL of methanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of kaempferol and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of cyclohexane, ethyl acetate, and formic acid (1:1:0.1) as the developing solvent. Apply 5 μL of each of the sample solution and reference drug solution and 2 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 5% $AlC1_3$/EtOH TS. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 13.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 15.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 10.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Kaempferol:
   (1) Mobile phase: A solution of acetonitrile and 0.4% phosphoric acid solution (50:50). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of kaempferol and dissolve in 75% methanol to produce a solution containing 20 μg per mL.
   (3) Sample solution: Weigh accurately 0.75 g of powdered sample and place it in a round bottom flask with stopper, add accurately 50 mL of 75% methanol, stopper tightly and weigh, heat under reflux for 1 hour, cool, weigh again, replenish the loss weight with 75% methanol, mix well and filter. Take 20 mL of successive filtrate in a filter, add accurately 5 mL of hydrochloric acid, place in a water bath for 1 hour, and cool. Transfer to a 50-mL volumetric flask, make up to volume with 75 % methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (365nm) and a column packing L1. The column temperature is maintained at 23 ± 4℃. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of kaempferol should not be less than 3,000.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   Kaempferol: (%)=0.0125(r_U/r_S) (C_S) / (W)

   r_U: peak area of kaempferol of sample solution

   r_S: peak area of kaempferol of reference standard solution

   C_S: concentration of kaempferol of reference standard solution (μg/mL)

   W: weight of test sample (g) calculated with dried sample
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place.
Usage: Exterior-releasing medicinal (Pungent-cold exterior-releasing medicinal).
Property and flavor: Neutral; sweet and bitter.
Meridian tropism: Lung and liver meridians.
Effects: Disperse wind-heat, remove nebula and improve vision.
Administration and dosage: 3~11.5 g.

ERIOBOTRYAE FOLIUM
枇杷葉
Pi Pa Ye / Pi Pa Ye
Loquat Leaf

Loquat leaf is the dried leaf of *Eriobotrya japonica* (Thunb.) Lindl. (Fam. Rosaceae).
It contains not less than 16.0% of dilute ethanol-soluble extractives, not less than 10.0% of water extractives and not less than 0.7% of the total amounts of oleanolic acid and ursolic acid.

Description: Obovate or oblong, 12~25 cm in length, 5~10 cm in width. Apex acute, base cuneate, margin serrate at the upper part and entire near base. Upper surface yellowish-brown or grayish-green, lustrous, midrib on lower surface distinctly protuberant, lateral veins pinnate, 10~20 pairs, with yellowish-brown tomenta, coriaceous and fragile, petioles short. Odour slight; taste bitter.

Microscopic identification:

1. **Transverse section:**
   Leaf of *Eriobotrya japonica*: The upper and lower epidermis all covered with cuticle and non-glandular hairs. Upper epidermis composed of 3~5 rows of subsquare sclerenchymatous cells, containing round to oblong mucilage cells. Lower epidermis usually contain stomata and non-glandular hairs; unicellular non-glandular hairs 700~1700 μm in length, 30~70 μm in diameter, mostly curved into a V-shape near midrib. Palisade tissue composed of 3~5 rows of rectangular cells, spongy tissue arranged loosely, composed of subsquare or polygonal cells, both palisade tissue and spongy tissue all containing prisms and clusters of calcium oxalate. Collateral vascular bundles of midrib nearly ringed. Pericycle fiber bundles arranged in an interrupted ring, walls lignified, surrounded by parenchymatous cells containing prisms of calcium oxalate, forming crystal fibers; parenchymatous tissue scattered with mucilage cells and prisms of calcium oxalate.
2. **Powder:** Yellowish-green. Upper epidermal cells moniliform thickened, lower epidermal cells irregularly shaped. Non-glandular hairs unicellular, curved and some folded to V-shaped, blunt top and narrow base. Mucilage cells subrounded, 50~100 μm in length, 25~60 μm in diameter. Stomata oblong, 20~30 μm in diameter, with 4~8 subsidiary cells. Vessels spiral, 10~20 μm in diameter. Fibers slender, 150~350 μm in length, 10~20 μm in diameter, fiber bundles occasionally surrounded by rhombic or double conical of calcium oxalate.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of ursolic acid and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of toluene and ethyl acetate (1:1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 12.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 12.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 15.0 ppm (General rule 2251, 6301).
9. Pesticide residues:
   (1) The total DDT content: Not more than 0.2 ppm (General rule 6305).
   (2) The total BHC content: Not more than 0.2 ppm (General rule 6305).

Assay:

1. Oleanolic acid and ursolic acid:
   (1) Mobile phase: A solution of acetonitrile, methanol, and 0.5% ammonium acetate (67:12:21). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of oleanolic acid and ursolic acid and dissolve in methanol to produce a solution containing 0.05 mg and 0.1 mg per mL of each.
   (3) Sample solution: Weigh accurately 1.0 g of powdered sample and place it in a conical flask with a stopper, then add accurately 25 mL of ethanol, stopper tightly, ultrasonicate for 30 minutes, Centrifuge for 10 minutes, transfer the supernatant to a 50-mL volumetric flask. Repeat the extraction of the residue one more time. Combine the supernatant and make up to volume with ethanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (210 nm) and a column packing L1. The column temperature is maintained at 25℃. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of ursolic acid should not be less than 5,000.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample

solution into the liquid chromatography apparatus, and calculate the content.

Oleanolic acid or ursolic acid (%)=5(r_U/r_S) (C_S) / (W)

r_U: peak area of oleanolic acid or ursolic acid of sample solution

r_S: peak area of oleanolic acid or ursolic acid of reference standard solution

C_S: concentration of oleanolic acid or ursolic acid of reference standard solution (mg/mL)

W: weight of test sample (g) calculated with dried sample

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place, and protect from moisture.
Usage: Phlegm-dispelling medicinal (Cough-suppressing and panting-calming medicinal).
Property and flavor: Mild cold; bitter.
Meridian tropism: Lung and stomach meridians.
Effects: Suppress cough and to calm panting, clear lung and resolve phlegm, downbear counterflow to stop vomiting.
Administration and dosage: 6~12 g.

ERIOCAULI FLOS
穀精草
Gu Jing Cao / Gu Jing Cao
Buerger Pipewort Flower

Buerger pipewort flower is the dried inflorescence with peduncle of *Eriocaulon buergerianum* Körn. (Fam. Eriocaulaceae).

Description: Heads spheroidal, slightly flattened, 4~5 mm in diameter, grayish-white, containing of 30~40 florets, arrange densely. Involucral scale at the base of heads, arranged densely in numerous layers, discoid, pale yellowish-green, with white and fine powder, the upper margin covered with densely white pubescences. After rubbing the inflorescence, numerous black anthers and yellowish-green, unripe fruits visible. Peduncle slender, 15~18 cm in length, less than 1 mm in diameter, pale yellowish-green, bearing numerous twisted ridges, lustrous, texture pliable, uneasily broken. Odourless; taste weak.

Microscopic identification:

1. **Transverse section:**
   Inflorescence of *Eriocaulon buergerianum*: Glandular hairs with head cells suboblong or subovate, 1~4 layers of cells, with reticular striations on the surface. Non-glandular hairs long at the apex, wall thickened. Epidermal cells of scapes strip-shaped, wall thin, surface bearing longitudinal cutin striations. Cell walls of fibers thick and slender. Vessels visible.
2. **Powder:** Yellowish-green. Glandular hairs with the head elongated-rounded or strip-shaped, 1~4 layers of cells, with reticular striations on the surface. Non-glandular hairs mostly broken, long at the apex, walls thickened. Epidermal cells of scapes strip-shaped, wall thin, surface bearing longitudinal cutin striations. Stomata subrectangular, subsidiary cells reniform. Fibers with thick and slender walls. Vessels mainly reticulate.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 30 mL of ethanol, ultrasonicate for 30 minutes, filter, evaporate the filtrate to dryness, dissolve the residue in 1 mL of ethanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, formic acid, and water (19:1:1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:

1. Loss on drying: Not more than 15.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 6.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Storage: Store in a ventilated and dry place.
Usage: Heat-clearing medicinal (Heat-clearing and fire-purging medicinal).
Property and flavor: Neutral; pungent and sweet.
Meridian tropism: Liver and lung meridians.
Effects: Disperse wind-heat, remove nebula and improve vision.

Administration and dosage: 4.5~15 g.

EUCOMMIAE CORTEX
杜仲
Du Jhong / Du Zhong
Eucommia Bark

Eucommia bark is the dried bark of trunk of *Eucommia ulmoides* Oliv. (Fam. Eucommiaceae).
It contains not less than 7.0% of dilute ethanol-soluble extractives, not less than 5.0% of water extractives and not less than 0.1% of pinoresinol diglucoside.

Description: Flat pieces or pieces with two edges slightly curved inwards, 2~7 mm thick. Outer surface pale grayish-brown. Unscraped one with distinct longitudinal wrinkles, fissured and rhombus lenticels, occasionally with lichens spot. Scraped one outer surface pale brown and smooth, inner surface reddish-purples or purplish-brown, smooth. Texture fragile, easily broken, fracture linked up by fine, dense, silvery and elastic rubber threads, generally pulling off above 1 cm. Odour slight; taste slightly bitter, gum-like on chewing.

Microscopic identification:

1. **Transverse section:**
   Bark of trunk of *Eucommia ulmoides*: Rhytidome remained, inner containing several layers of cork tissue, every layer composed of cork cells arranged in order with inner walls extremely thickened and lignified. Phloem composed of 5~7 stone cell bands, each band contains 3~5 layers of stone cells, with some fibers nearby. Phloem rays 2~3 cells wide, obliquing to one side near phelloderm. White resinous masses mostly scattered in phloem. The resinous threads existed in laticiferous cells.
2. **Powder:** Brown. Stone cells numerous, mostly in groups, rectangular, subrounded or irregular, walls thickened, lumina small, pit canals distinct, some lumina contain resinous masses. Cork cells present individually or in groups, polygonal in surface view, walls unevenly thickened; rectangular in lateral view, walls thickened on three sides and thin on one side. Resinous threads stripe-shaped or twisted into masses.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 5 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of pinoresinol diglucoside and dissolve in methanol to produce a solution containing 0.5 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-butanol, glacial acetic acid, and water (7:1:2) as the developing solvent. Apply 8 μL of each of the sample solution and reference drug solution and 1 μL of the reference standard solution to the plate Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS, heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 11.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 9.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 5.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 15.0 ppm (General rule 2251, 6301).

Assay:

1. Pinoresinol diglucoside:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and water as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of pinoresinol diglucoside, and dissolve in 50% ethanol to produce a solution containing 50 μg per mL.
   (3) Sample solution: Weigh accurately 1.0 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 25 mL of 50% ethanol, ultrasonicate for 30 minutes, filter with filter paper. Repeat the extraction of the residue two more times. Combine the filtrate, Evaporate the filtrate, transfer to 25-mL volumetric flask and make up to volume with 50% ethanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (226 nm) and a column packing L1. The column temperature is maintained at 35℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of pinoresinol diglucoside should not be less than 10,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~30	10→20	90→80
30~60	20→40	80→60

(5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Pinoresinol diglucoside (%)=0.0025(r_U/r_S) (C_S) / (W)

r_U: peak area of pinoresinol diglucoside of sample solution

r_S: peak area of pinoresinol diglucoside of reference standard solution

C_S: concentration of pinoresinol diglucoside of reference standard solution (μg/mL)

W: weight of test sample (g) calculated with dried sample

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place.

Usage: Tonifying and replenishing medicinal (Yang-tonifying medicinal).

Property and flavor: Warm; sweet.

Meridian tropism: Liver and kidney meridians.

Effects: Tonify liver and kidney, strengthen sinew and bone, prevent abortion.

Administration and dosage: 6~15 g.

EUODIAE FRUCTUS
吳茱萸
Wu Jhu Yu / Wu Zhu Yu
Euodia Fruit

Euodia fruit is the dried and almost ripe fruit of *Euodia ruticarpa* (A.Juss.) Benth., *Euodia ruticarpa* (A.Juss.) Benth. var. *officinalis* (Dode) C.C.Huang or *Euodia ruticarpa* (A.Juss.) Benth. var. *bodinieri* (Dode) C.C.Huang (Fam. Rutaceae).

It contains not less than 15.0% of dilute ethanol-soluble extractives, not less than 10.0% of water extractives and not less than 0.2% of the total amounts of evodiamine and rutaecarpine.

Description: Flattened spheroidal or slightly flattened-pentagon spheroidal, 2~5 mm in diameter. Externally dark yellowish-green or greenish-black, with numerous fine depressed oil dots and tiny and fine wrinkles. A pentagon-stellate cleft present at the apex, composed of 5 follicles, 5-toothed persistent calyx, fruit stalk short with yellow tomenta at the base. Texture hard. Transverse section showing 5-locular ovary, each loculus possessing 1 yellowish-brown seed. Odour strong aromatic; taste pungent and bitter.

Microscopic identification:

Powder: Grayish-brown. Mucilage cells subrounded or oblong, 64~120 μm in diameter, occasionally mucilage contents overflowed when the walls broken. Non-glandular hairs 1~9 celled, straight or slightly curved, 62~416 μm in length, 16~48 μm in diameter, walls slightly thickened, smooth, with cuticle striations or warty protrusions, some lumina filled with brownish-red contents. Epidermal cell of pericarp polygonal, mostly containing hesperidin crystals; stomata with 4~6 subsidiary cells. Parenchymatous cells of mesocarp subrounded, also containing hesperidin crystals. Glandular hair heads composed of 7~14 cells or more, 64~96 μm in length, 24~53 μm in diameter, containing yellowish-brown or dark reddish-brown contents; stalk 1~4 celled, the cells connected with head usually containing reddish-brown contents. Clusters of calcium oxalate 16~38 μm in diameter, prisms of calcium oxalate also present. Stone cells subrounded, rectangular or fusiform, 40~64 μm in diameter, walls 8~16 μm thick, pits and pit canals distinct, lumina contain yellow contents. Pollen grains, fibers, vessels and fragments of oil cavities also present.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 25 mL of ethanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of rutaecarpine and evodiamine and dissolve in ethanol to produce a solution containing 0.2 mg and 1.5 mg per mL of each.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane: ethyl acetate, ethanol, and diethylamine (19:5:1:1) as the developing solvent. Apply 2 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 254 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 13.0% dry at 105°C for 5 hours (General rule 6015).
2. Total ash: Not more than 9.5% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).

5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Evodiamine and rutaecarpine:
   (1) Mobile phase: A solution of acetonitrile and 0.1% acetic acid (45∶55). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of evodiamine and rutaecarpine and dissolve in methanol to produce a solution containing 30 μg per mL of each.
   (3) Sample solution: Weigh accurately 0.13 g of the powdered sample and place it in a 50-mL centrifuge tube, add 50 mL of methanol, ultrasonicate for 30 minutes, centrifuge for 15 minutes, use the supernatant. Repeat the extraction of the residue one more time, combine the supernatant, transfer to a 100-mL volumetric flask, make up to volume with methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (225 nm) and a column packing L1. The column temperature is maintained at room temperature. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of evodiamine and rutaecarpine should not be less than 5,000.

   Evodiamine or rutaecarpine (%) = $0.01(r_U/r_S)\ (C_S)\ /\ (W)$

   r_U: peak area of evodiamine or rutaecarpine of sample solution
   r_S: peak area of evodiamine or rutaecarpine of reference standard solution
   C_S: concentration of evodiamine or rutaecarpine of reference standard solution (μg/mL)
   W: weight of test sample (g) calculated with dried sample
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place.
Usage: Interior-warming medicinal.
Property and flavor: Hot; pungent and bitter.
Meridian tropism: Liver, spleen, stomach, and kidney meridians.
Effects: Dissipate cold and relieve pain, soothe liver and direct qi downward, dry dampness, downbear counterflow to stop vomiting.
Administration and dosage: 1.0~7.5 g; used an appropriate amount for external use.
Precaution and warning: Used with caution in patients with yin deficiency fever.

EUPATORII HERBA
佩蘭
Pei Lan / Pei Lan
Fortune Eupatorium Herb

Fortune eupatorium herb is the dried aerial part of *Eupatorium fortunei* Turcz. (Fam. Compositae).
It contains not less than 8.0% of dilute ethanol-soluble extractives, not less than 11.0% of water extractives.

Description: Stems straight, branched less, cylindrical, 30~100 cm in length, 0.2~0.5 cm in diameter, externally yellowish-brown or yellowish-green, with distinct nodes and longitudinal ridges, internodes 3~7 cm in length; texture fragile, fracture whitish, with pith or hollow. Leaves opposite, mostly crumpled and broken, trifid or not divided as whole, segments oblong or oblong-lanceolate, margin serrate, externally greenish-brown or blackish-green. Odour aromatic; taste slightly bitter.

Microscopic identification:
Transverse section:
Leaf of *Eupatorium fortunei*: Anticlinal walls of upper epidermal cells slightly sinuous in surface view, multicellular non-glandular hairs occasionally found, non-glandular hairs on veins relatively long, 7~8 celled, 120~160 μm in length, 16~20 μm in basal diameter. Stomata anomocytic. Anticlinal walls of lower epidermal cells sinuous, with non-glandular hairs more than upper epidermis, usually 3~6 celled, 60~105 μm in length, 14~16 μm in basal diameter, some cells usually contain pale brown contents; stomata numerous, anomocytic.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, cool, filter and make up the filtrate to 10 mL.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of coumarin and dissolve in methanol to produce a solution containing 0.5 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane, ethyl acetate, and formic acid (4:1:0.1) as the developing solvent. Apply 8 μL of each of the sample solution and reference drug solution and 1 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry

in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 15.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 11.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 3.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place.
Usage: Dampness-dispelling medicinal (Dampness-resolving with aroma medicinal).
Property and flavor: Neutral; pungent.
Meridian tropism: Spleen and stomach meridians.
Effects: Resolve dampness with aroma, arouse spleen and harmonize stomach, clear summerheat.
Administration and dosage: 3~10 g.

EURYALES SEMEN
芡實
Cian Shih / Qian Shi
Euryale Seed

Euryale seed is the dried ripe kernel of *Euryale ferox* Salisb. (Fam. Nymphaeaceae).
Description: Spheroidal, 6~7 mm in diameter. One end externally white, with a round dented and yellowish-brown scar of hilum, the other end brownish-red, smooth, occasionally peeling with striations. Texture hard and fragile, fracture uneven, white, starchy. Odourless; taste weak.

Microscopic identification:
1. **Transverse section:**
Kernel of *Euryale ferox*: 4~5 layers of reticular sclerenchymatous tissue exist at the outer part of endotesta, unlignified, scattered with small spiral and reticulate vessels, 6~25 μm in diameter; inside showing 3~4 layers of parenchymatous cells, containing aleurone granules. Endosperm composed of suboblong to subpolygonal parenchymatous cells, containing numerous starch granules; compound granules composed of dozens to hundreds components, subrounded, 10~30 μm in diameter; simple granules subrounded, subpolygonal or oblong, 1~3 μm in diameter, without striations, with dotted hilum rare.
2. **Powder:** White. Starch granules mainly compound granules, subspheroidal, some oval, oblong or rounded-polygonal, composed of dozens to hundreds components, up to 31 μm in length, 12~29 μm in diameter, edge smooth, normally unbroken; the components melted after mounted by chloral hydrate TS, leaving grid-shaped traces. After compound granules broken, simple granules or groups shedded; simple granules polygonal or irregular in shape, 1~3 μm in diameter. Perisperm cells mostly broken, complete ones rectangular, long strip-shaped, long-polygonal or irregular in shape, up to 450 μm in length, 36~90 μm in diameter, wall thin, one cell filled with dozens to hundreds subspheroidal compound granules. Pigment cells fallen off, with cell boundaries indistinct, containing orange-yellow, orange-red or reddish-brown contents. Endotesta cells and vessels also present.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes then filter, evaporate the filtrate to dryness, and dissolve the residue in 1 mL of methanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane and acetone (5:1) as the developing solvent. Apply 10 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:
1. Total ash: Not more than 1.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
3. Sulfur dioxide: Not more than 400 ppm (General rule 2525, 6303).

4. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

※Note: "When this TCM herb is sold commercially, the limits of heavy metals, sulfur dioxide and aflatoxins should follow the food standard."

Storage: Refrigerate or store in a cool and dry place, and protect from mold and insects.
Usage: Astringent medicinal.
Property and flavor: Neutral; sweet and astringent.
Meridian tropism: Spleen and kidney meridians.
Effects: Tonify spleen and antidiarrheal, tonify kidney and secure essence, dispel dampness and stanch vaginal discharge, astringe.
Administration and dosage: 9~15 g.

FAGOPYRI SEMEN
蕎麥
Chiao Mai/Qiao Mai
Buckwheat

Buckwheat the dried mature seed *Fagopyrum esculentum* Moench. (Fam. Polygonaceae).
It contains not less than 4.0% of dilute ethanol-soluble extractives and not less than 5.0% of water extractives and not less than 0.01% of rutin.

Description: Most of them are triangular, few two-sided or multi-edge irregular shapes. The surface is yellowish green to yellowish brown, smooth. The apex is sharpened, and the base has 5 splits. The seed coat is hard, opposite cotyledons.
Microscopic identification:
1. **Transverse section:**
   Seed of *Fagopyrum esculentum*: The outer seed coat consists of a layer of rectangular cells with a slightly thicker wall. The outer seed is a layer of stone cells, in groups, and the wall is very thick. The inner seed coat is composed of a layer of rectangular parenchyma cells. The aleurone layer is located outside the endosperm, and the cells are square, contain aleurone particles. The endosperm consists of parenchyma cells and is rich in starch granules. Two cotyledons, slightly S-shaped, containing primary vascular bundles.
2. **Powder:** Pale yellowish-white. The outer seed cells are rectangular in shape and slightly thick in wall. The inner seed coat cells are colorless, The cross-sectional view is subsquare or tangential, radial and narrow, different in size, thin in wall and slightly curved. The inner stone cells of the seed coat are clustered, golden yellow, subround, and thick. Layers and pores are faintly visible. The catheter is a spiral catheter. Starch granules are the main body of powder, mostly single round, oval, round polygonal, umbilical point, some visible layering; rare complex granules.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 2.0 g of powdered sample to 20 mL of methanol, ultrasonicate for 30 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 1 mL of methanol.
2. Reference drug solution: Take 2.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of rutin and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of butanone, ethyl acetate, formic acid, and water (3:5:1:1) as the developing solvent. Apply 2 μL of each of the sample solution and reference drug solution and 1 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 5% $AlC1_3$/EtOH TS. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 15.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 2.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 0.2% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
Rutin:
1. Mobile phase: Acetonitrile as the mobile phase A, and 0.1% phosphoric acid as the mobile phase B.
2. Reference standard solution: Weigh accurately a quantity of rutin and dissolve in methanol to produce a solution containing 5 μg per mL.
3. Sample solution: Weigh accurately 0.5 g of powdered sample and place it in a 125-mL conical flask with a stopper, then add accurately 20 mL of methanol, heat under reflux for 30 minutes, transfer

the filtrate to a 100-mL round bottom flask. Repeat the extraction of the residue one more time, combine the filtrate and evaporate to dryness, dissolve the residue with methanol and transfer to a 10-mL volumetric flask, make up to volume with methanol, mix well, filter and use the filtrate.

4. Chromatographic system: The liquid chromatography is equipped with an UV detector (350 nm) and a column packing L1. The column temperature is maintained at 25℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of rutin should not be less than 5,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~20	15→30	85→70
20~30	30→90	70→10

5. Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Rutin (%)=0.001(r_U/r_S) (C_S) / (W)

r_U: peak area of rutin of sample solution

r_S: peak area of rutin of reference standard solution

C_S: concentration of rutin of reference standard solution (μg /mL)

W: weight of test sample (g) calculated with dried sample

Storage: Store in a cool and dry place, and protect from mold and insects.
Usage: Qi-regulating medicinal.
Property and flavor: Cold; sweet.
Effects: Fortify spleen and replenish qi, increase appetite and soothe intestine, promote digestion and remove food stagnation, eliminate dampness and direct qi downward.
Administration and dosage: 9~20 g.

FARFARAE FLOS
款冬花
Kuan Dong Hua / Kuan Dong Hua
Coltsfoot Flower Bud

Coltsfoot flower bud is the dried bud of *Tussilago farfara* L. (Fam. Compositae).
It contains not less than 25.0% of dilute ethanol-soluble extractives, not less than 30.0% of water extractives and not less than 0.07% of tussilagone.

Description: Long clavate, 1.5~3 cm in length, 0.3~1 cm in diameter. The upper part broader and the lower part gradually slender or pedicelled, enclosed by bracts. Bracts externally purplish-red or yellowish-purple, several layers, slightly triangular, inner surface and margin densely covered with white flocky hairs. Show very small ray florets and disc florets after removing bracts, less than 0.3 cm in length, with pappi. Texture light and tenacious, showing white and rubber hairs after ripping. Odour aromatic; taste slightly bitter and pungent, cotton like on chewing.

Microscopic identification:
Powder: Brown, tomentose-shaped. Non- glandular hairs extremely long, 1- to 4-celled, apical cells long, twisted into masses, 5~17 μm in diameter, wall thin. Glandular hairs slightly pestle-like in shape, 104~216 μm in length, 16~52 μm in diameter, the head slightly expanded, about 4- to 6-celled; the stalk multicellular, composed of 2 rows (1 row in lateral view). Pappi composed of several rows of branched hairs, each branch unicellular, the apex gradually acute. Pollen grains subspheroidal, 28~40 μm in diameter, with 3 germinal pores, with spiny protuberance on the surface. Cells in inner walls of pollen sac subrectangular in surface view, with thickened wall into longitudinally strip-shaped. Epidermal cells of bracts in surface view, anticlinal walls thin or slightly moniliform thickened, with sinuous and cutinized striations; epidermal cells of margins tomentose-shaped. Endodermal cells of margins of tubular corolla lobes suboblong, with cutinized striations. Epidermal cells of stigma with outer walls papillary protuberance, some cells differentiated into short tomentose-shaped. Sclerenchymatous cells, secretory cells containing yellow secretions and inulin masses also visible.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 20 mL of ethanol, ultrasonicate for 1 hour, filter, evaporate the filtrate to dryness, and dissolve the residue in 1 mL of ethyl acetate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of tussilagone and dissolve in ethyl acetate to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane and ethyl acetate (4:1) as the developing solvent. Apply 2 μL of each of the sample solution and reference drug solution and 1 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 254 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Total ash: Not more than 12.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 6.0% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).

4. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Tussilagone:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and 0.1% phosphoric acid as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of tussilagone, and dissolve in methanol to produce a solution containing 15 μg per mL.
   (3) Sample solution: Weigh accurately 0.5 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 10 mL of methanol, ultrasonicate for 30 minutes. Centrifuge for 15 minutes, filter the supernatant. Repeat the extraction of the residue one more time. Combine the filtrate and transfer to 25-mL volumetric flask and make up to volume with methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (220 nm) and a column packing L1. The column temperature is maintained at room temperature. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of tussilagone should not be less than 8,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~5	75	25
5~15	75→80	25→20
15~16	80→95	20→5

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Tussilagone (%)=0.0025(r_U/r_S) (C_S) / (W)
   r_U: peak area of tussilagone of sample solution
   r_S: peak area of tussilagone of reference standard solution
   C_S: concentration of tussilagone of reference standard solution (μg/mL)
   W: weight of test sample (g) calculated with dried sample
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from insects.
Usage: Phlegm-dispelling medicinal (Cough-suppressing and panting-calming medicinal).
Property and flavor: Warm; pungent and mild bitter.
Meridian tropism: Lung meridians.
Effects: Direct qi downward, suppress cough to resolve phlegm.
Administration and dosage: 5~12 g.

FOENICULI FRUCTUS
小茴香
Siao Huei Siang / Xiao Hui Xiang
Fennel Fruit

Fennel fruit is the dried ripe fruit of *Foeniculum vulgare* Mill. (Fam. Umbelliferae).
It contains not less than 12.0% of dilute ethanol-soluble extractives, not less than 10.0% of water extractives and nor less than 1.4% (v/w) of volatile oil.

Description: Cremocarp, slender cylindrical, some slightly curved, 3~8 mm in length, 1.5~3 mm in diameter. Externally yellowish-green or grayish-brown, apex remained with protuberant stylopodium, base occasionally with slender fruit stalk. Mericarp oval, ribs 5, commissural surface flattened, with longitudinal striations, occasionally attached with white line of thecaphore. Odour characteristically aromatic; taste slightly sweet and pungent.

Microscopic identification:

1. **Transverse section:**
   Fruit of *Foeniculum vulgare*: Exocarp composed of 1 layer of flattened cells, covered with cuticles. Mesocarp composed of several layers of parenchymatous cells, 6 vittae, with oblong or semi-rounded vita between every 2 ribs, and 2 situated in the commissural, surrounded by numerous reddish-brown and flattened secretory cells. Vascular bundles exists in the middle of ribs, consisted of 2 collateral vascular bundles and fiber bundles, surrounded by lignified and large reticulate cells; xylem consists of some small vessels; phloem exists on the both side of vessels. Endosperm composed of 1 layer of flattened thin-walled cells varying in length. The testa cells compressed and elongated, with several layers of cells in the middle of commissural, containing brown contents, consisted of small rhaphe vascular bundles. Endosperm cells polygonal, filled with numerous aleurone grains, and embedding clusters of calcium oxalate and some fatty oil.
2. **Powder:** Yellowish-brown. Epidermal cells of exocarp subpolygonal or subsquare in surface view, with slightly thickened walls. Stomata anomocytic, with 4 subsidiary cells. Reticulate cells of mesocarp subrectangular of sub-oblong, with thickened and

slightly lignified walls, pits reticulate ovate or oblong. Fragments of vittae yellowish-brown or dark reddish-brown, complete ones up to 250 μm wide, polygonal secretory cells scars visible. Endocarp inlaid layer cells slender in surface view, with thin walls, usually several cells of a group irregularly inlaid along their long axes. Endosperm cells, clusters of calcium oxalate and xylem parenchymatous cells also present.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Sample solution: Add 2.0 g of powdered sample to 30 mL of ethyl acetate, ultrasonicate for 10 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 1 mL of dichloromethane.
2. Reference drug solution: Take 2.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of *trans*-anethole and dissolve in absolute ethanol to produce a solution containing 10.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane and ethyl acetate (20:1) as the developing solvent. Apply 5 μL of each of the sample solution and reference drug solution and 1 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 254 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 13.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 10.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).
9. Aflatoxins
   (1) Aflatoxins (sum of B_1, B_2, G_1 and G_2): Not more than 10.0 ppb (General rule 6307).
   (2) Aflatoxin B_1: Not more than 5.0 ppb (General rule 6307).

※Note: "When this TCM herb is sold commercially, the limits of heavy metals, sulfur dioxide and aflatoxins should follow the food standard."

Assay:

1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).
3. Volatile oil: Carry out the method for determination of volatile oil (General rule 6013).

Storage: Store in a cool and dry place.
Usage: Interior-warming medicinal.
Property and flavor: Warm; pungent.
Meridian tropism: Liver, kidney, spleen, stomach, and bladder meridians.
Effects: Dissipate cold and relieve pain, regulates qi to harmonize stomach.
Administration and dosage: 3~11.5 g.

FORSYTHIAE FRUCTUS
連翹
Lian Ciao / Lian Qiao
Forsythia Fruit

Forsythia fruit is the dried fruit of *Forsythia suspensa* (Thunb.) Vahl (Fam. Oleaceae). Collected when nearly ripe, commonly known as "Qing Qiao"; collected when fully ripe, commonly known as "Lao Qiao"
It contains not less than 9.0% of dilute ethanol-soluble extractives, not less than 5.0% of water extractives, not less than 0.3% and 2.0% of phillyrin and forsythoside A of each of Qing Qiao and not less than 0.09% and 0.25% of phillyrin and forsythoside A of each of Lao Qiao.

Description: Elongated ovate to ovate, 1.5~2.5 cm in length, 0.5~1.3 cm in diameter. Externally with irregular longitudinal wrinkles and numerous protuberant small maculates, with a distinct longitudinal furrow on each of both surfaces. Apex acute, base with a small fruit stalk or not. "Qing Qiao" mostly indehiscent, externally greenish-brown, with less protuberant small and grayish-white maculates; texture hard; seeds numerous, yellowish-green, slender, winged at one side. "Lao Qiao" dehiscent from apex or dehiscent to two segments, outer surface yellowish-brown or reddish-brown, inner surface mostly pale yellowish-brown, smooth, with a longitudinal septum; texture fragile; seeds brown, mostly fallen off; Odour slightly aromatic; taste bitter.

Microscopic identification:

1. **Transverse section:**
   Pericarp of *Forsythia suspensa*: Exocarp composed of 1 layer of epidermal cells, outer and lateral walls thickened, covered with cuticle. Mesocarp composed of vascular bundles scattered in parenchyma at the

outside, and many layers of stone cells with fibers at the inner side, long strip-shaped, subrounded or elongated- rounded, walls varying in thickness, mostly tangentially parqueted and extended to the cells of the septum; endocarp composed of 1 layer of parenchymatous cells.

2. **Powder:** Pale yellowish-brown. Epidermis cells of Pericarp subrectangular in sectional view, 24~30 μm in diameter, outer walls cutinized thickness, 8~17 μm thick, lateral walls also thickened, occasionally into hemispheroidal. Epidermis cells of Pericarp subrectangular or subpolygonal in surface view, anticlinal walls thickened and slightly curved, outer periclinal walls with irregular or reticulate striations on the surface. Mesocarp cells brownish-yellow, rounded-polygoanl or irregular in shape, walls thickened, occasionally moniliform thickened. Lignified slender vessels and tracheids also visible. Endocarp fibers mostly in bundles, some cross-overlapping, short fusiform or irregular in shape, margins uneven or lumpy, 80~224 μm in length, 24~32 μm in diameter, wall 8~18 μm thick, lignified, pits rare, pit canals fine. Stone cells subpolygonal, subrectangular, rounded-triangular, subrounded or subsquare, 36~48 μm in diameter, wall 8~22 μm thick, some with walls relatively thin at one side, pits with different spacing, pit canals faintly visible.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter, evaporate the filtrate to dryness and dissolve the residue in 1 mL of methanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of phillyrin and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of dichloromethane and methanol (4:1) as the developing solvent. Apply 5 μL of each of the sample solution and reference drug solution and 2 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained with the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Foreign matter: Not more than 3.0% of Qingqiao, not more than 9.0% of Laoqiao (General rule 6005).
2. Loss on drying: Not more than 14.0% dry at 105℃ for 5 hours (General rule 6015).
3. Total ash: Not more than 6.0% (General rule 6007).
4. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
5. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
6. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
7. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
8. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
9. Lead (Pb): Not more than 10.0 ppm (General rule 2251, 6301).

Assay:

1. Phillyrin and forsythoside A:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and 0.4% acetic acid as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of phillyrin and forsythoside A and dissolve in 50% methanol to produce a solution containing 30 μg and 200 μg per mL of each.
   (3) Sample solution: Weigh accurately 0.25 g of the powdered sample and place it in a 50 mL centrifuge tube, accurately add 10 mL of 50% methanol, ultrasonicate for 30 minutes, centrifuge for 10 minutes, transfer the supernatant to a 25-mL volumetric flask. Repeat the extraction of the residue one more time, wash the residue with a small quantity of 50% methanol, combine the filtrate, make up to volume with 50% methanol, mix well, filter and use the filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (277 nm) and a column packing L1. The flow rate is about 0.8 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of phillyrin should not be less than 3,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~22	10→25	90→75
22~42	25→65	75→35
42~44	65→100	35→0

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Phillyrin or forsythoside A (%)
= 0.0025 (r_U/rs) (Cs) / (W)

r_U: peak area of phillyrin or forsythoside A of sample solution

rs: peak area of phillyrin or forsythoside A of reference standard solution
Cs: concentration of phillyrin or forsythoside A of reference standard solution (μg/mL)
W: weight of test sample (g) calculated with dried sample

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place.
Usage: Heat-clearing medicinal (Heat-clearing and detoxiating medicinal).
Property and flavor: Mild cold; bitter.
Meridian tropism: Lung, heart, and small intestine meridians.
Effects: Clear heat and detoxicate, disperse abscesses and nodules.
Administration and dosage: 6~15 g.

FRAXINI CORTEX
秦皮
Cin Pi / Qin Pi
Ash Bark

Ash bark is the dried bark of branch or trunk of *Fraxinus chinensis* Roxb. subsp. *rhynchophylla* A.E. Murray (*Fraxinus rhynchophylla* Hance), *Fraxinus chinensis* Roxb. (*Fraxinus szaboana* Liugelsh.), *Fraxinus szaboana* Lingelsh. or *Fraxinus stylosa* Lingelsh. (Fam. Oleaceae). It contains not less than 6.0% of dilute ethanol-soluble extractives, not less than 4.0% of water extractives and not less than 1.0% of the total amounts of aesculin and aesculetin.

Description:
1. Bark of branch of Fraxini cortex: Quilled or channeled, 10~60 cm in length, 1.5~3 mm thick. Outer surface grayish-white, grayish-brown to blackish-brown, or alternated in patches, even or slightly rough, with grayish-white and rounded dotted lenticels, and fine oblique wrinkles, some with branch scars; inner surface yellowish-white or brown, smooth. Texture hard and fragile, fracture split, easily exfoliated, yellowish-white. Odour slight; taste bitter.
2. Bark of trunk of Fraxini cortex: Slat pieces, 3~6 mm thick. Texture hard, fracture relatively fibrous. Odour slight; taste bitter.

Microscopic identification:
1. **Transverse section:**
Fraxini cortex: Cork composed of 5~10 rows of cells. Phelloderm composed of several rows of polygonal collenchymatous cells. Cortex scattered with fiber bundles and stone cell groups, stone cells branched, with walls thickened. Pericycle shows the ringed-band composed of stone cells and fiber bundles, occasionally interrupted. Phloem rays 1~3 rows of cells wide; fiber bundles and a few stone cells arranged into layers, penetrated with rays in "#" shape. Rays and phloem parenchymatous cells filled with sandy crystals of calcium oxalate, mostly distributed in ray cells.
2. **Powder:** Pale yellowish-white. Fibers straight or slightly curved, the margins sinuous or uneven, 15~40 μm in diameter, walls extremely thickened and lignified, pits indistinct, lumen linear, occasionally with irregularly oblique striations on the surface. Stone cells subrounded, subrectangular or subfusiform, irregularly branched, up to about 150~282 μm in length and 24~90 μm in diameter, walls extremely thickened, pit canals distinct. Rays 1~2 rows of cells wide, lumen filled with sandy crystals of calcium oxalate, in fine fusiform or granular forms, about 3 μm in length. Cork cells polygonal in surface view, wall slightly lignified, with sparse pits. Starch granules rare.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of aesculin and aesculetin in methanol to produce a solution containing 0.2 mg per mL of each.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of dichloromethane, methanol, and formic acid (6:1:1) as the developing solvent. Apply 2 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 7.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 8.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).

8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Aesculin and aesculetin:
   (1) Mobile phase: A solution of acetonitrile and 0.1% phosphoric acid (8:92). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of aesculin and aesculetin and dissolve in methanol to produce a solution containing 100 μg and 60 μg per mL of each.
   (3) Sample solution: Weigh accurately 0.5 g of powdered sample and place it in a conical flask with a stopper, add accurately 50 mL of methanol, stopper tightly and weigh, heat under reflux for 1 hour, cool, weigh again, replenish the loss of the weight with methanol, mix well, filter and use the filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (334 nm) and a column packing L1. The number of theoretical plates of the peak of aesculetin should not be less than 5,000.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Aesculin or aesculetin (%)=0.005(r_U/r_S) (C_S) / (W)
   r_U: peak area of aesculin or aesculetin of sample solution
   r_S: peak area of aesculin or aesculetin of reference standard solution
   C_S: concentration of aesculin or aesculetin of reference standard solution (μg/mL)
   W: weight of test sample (g) calculated with dried sample
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place.
Usage: Heat-clearing medicinal (Heat-clearing and dampness-drying medicinal).
Property and flavor: Cold; bitter and astringent.
Meridian tropism: Liver, gallbladder and large intestine meridians.
Effects: Clear heat and dry dampness, astringe and stop dysentery, stanch vaginal discharge, improve vision.
Administration and dosage: 6~12 g.

FRITILLARIAE CIRRHOSAE BULBUS
川貝母
Chuan Bei Mu / Chuan Bei Mu
Tendrilleaf Fritillary Bulb

Tendrilleaf fritillary bulb is the dried bulb of *Fritillaria cirrhosa* D.Don, *Fritillaria unibracteata* P.K.Hsiao & K.C.Hsia, *Fritillaria przewalskii* Maxim. ex Batalin, *Fritillaria delavayi* Franch., *Fritillaria taipaiensis* P.Y.Li or *Fritillaria unibracteata* P.K.Hsiao & K.C.Hsia var. *wabuensis*(S.Y.Tang & S.C.Yueh) Z.D.Liu, Shu Wang & S.C.Chen (Fam. Liliaceae). According to the different appearance traits, they are called " Song Bei", " Ching Bei" and " Lu Bei".
It contains not less than 7.0% of dilute ethanol-soluble extractives and not less than 6.0% of water extractives.

Description:

1. Bulb of Song Bei: Conical or spheroid, 0.3~0.8 cm in height, 0.3~0.9 cm in diameter. Externally whitish, the outer scale leaves 2, the size is very different, the large flap holds the small flap, the unbranched part is crescent shaped, and the top is closed. Subcylindrical and apical heart buds and small scale leaves 1~2. The apex is blunt or slightly pointed; th.e bottom is flat, slightly concave, with a taupe bulb in the middle and occasionally residual roots. Texture hard and fragile, fracture white, starchy. Odour slight; taste slightly bitter.
2. Bulb of Ching Bei: Oblate spheroidal, 0.4~1.4 cm in height, 0.4~1.6 cm in diameter. The outer scale leaves 2, The size is similar, relatively cohesive, and the top is cracked. There are heart buds and small scale leaves 2~3 and a thin cylindrical stem.
3. Bulb of Lu Bei: Long conical, in two-thirds of the expansion, 0.7~2.5 cm in height, 0.5~2.5 cm in diameter. Externally whitish (Bai Lu Bei), or light brownish yellow(Huang Lu Bei), brown spots. The outer scale leaves 2, The size is similar, the top is cracked and slightly pointed, and the base is slightly pointed or blunt.

Microscopic identification:
Transverse section:
Fritillariae cirrhosae bulbus: Epidermis with cells subrectangular, Epidermis composed of parenchymatous cells subrounded filled with starch granules, Mostly oval or scalloped, The umbilical point is mostly point shape, the layer is fine, rarely compound. Vessels mainly in spiral, scattered in parenchyma. Stomata present in epidermis, circular or oval.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 5.0 g of powdered sample to 5 mL of 25% ammonia solution and 30 mL of dichloromethane, ultrasonicate for 1 hour, filter, evaporate the filtrate to dryness, and dissolve the residue in 1 mL of methanol.

2. Reference drug solution: Take 5.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of peimisine and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, methanol, 25% ammonia solution, and water (18:2:1:0.1) as the developing solvent. Apply 12 μL of each of the sample solution and reference drug solution and 2 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Soak in the solution of 1% vanillin prepared in 10% H_2SO_4/MeOH TS and heat at 105℃ until the spots become visible. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 15.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total Acid-insoluble ash: Not more than 1.0% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 5.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).
8. ash: Not more than 5.0% (General rule 6007).

Assay:
1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place, and protect from insects.
Usage: Phlegm-dispelling medicinal (Heat-phlegm clearing and resolving medicinal).
Property and flavor: Mild cold; bitter and sweet.
Meridian tropism: Lung and heart meridians.
Effects: Clear heat to transform phlegm, moisten lung to suppress cough, dissipate binds to alleviate edema.
Administration and dosage: 3~10 g, 1~2 g for powdering.
Precaution and warning: Incompatible with *Aconitum* sp.

FRITILLARIAE THUNBERGII BULBUS
浙貝母
Jhe Bei Mu / Zhe Bei Mu
Thunberg Fritillary Bulb

Thunberg fritillary bulb is the dried bulb of *Fritillaria thunbergii* Miq. (Fam. Liliaceae). The drug is washed clean, and classified according to its size. The smaller one with the central bud is commonly known as “Zhu Bei”; the larger one without the central bud is commonly known as “Da Bei”; or classify according to its size, removed the central bud, cut into thick slice while fresh, washed clean, dried, commonly known as “Zhe Bei Pian”.
It contains not less than 5.0% of dilute ethanol-soluble extractives, not less than 5.0% of water extractives and not less than 0.08% of the total amount of peimine and peiminine.

Description:
1. Bulb of Zhu Bei: Whole bulb, oblate, 1~1.5 cm in height, 1~2.5 cm in diameter. Externally whitish, the outer scale leaves 2, plump and fleshy, slightly reniform, holding together, containing 2~3 small scale leaves and dried crumpled stem remains. Texture fragile and compact, easily broken, fracture white, starchy. Odour slight; taste bitter.
2. Bulb of Da Bei: Outer single scale leaf of bulb, one side concave, the other side convex, dumpling-shaped, 2~4 cm in diameter, 1~2.5 cm in height, 0.6~l.5 cm thick. Externally whitish to pale yellowish-white, covered with white powder. Texture hard and fragile, easily broken, fracture white, starchy. Odour slight; taste slightly bitter.
3. Bulb of Zhe Bei Pian:Slices cut from the outer single scale leaf of bulb, elliptical or subrounded, 1~2 cm in diameter, surface of edge pale yellow, cut surface even, powdery-white. Texture hard and fragile, easily broken, fracture powdery-white, starchy. Odour slight; taste slightly bitter.

Microscopic identification:
1. **Transverse section:**
   Fritillariae thunbergii bulbus: Epidermis with cells subrectangular, covered with thickened cuticle, stomata found occasionally. Mesophyll composed of 30~40 layers of parenchymatous cells, filled with starch granules, fine prisms of calcium oxalate occasionally found; vascular bundles of leaf view in closed collateral type, several vessels scattered in xylem; phloem composed of over 10 cells.
2. **Powder:** Subwhite. Starch granules mostly simple, rarely compound or semi-compound. Simple granules mostly ovate or oblong, 6~56 μm in diameter, hilum mostly pointed, cleft-shaped, V-shaped or U-shaped in the narrowed end, larger starch granules with eccentric striations. Epidermal cells subpolygonal or rectangular, anticlinal walls moniliform thickened, cuticle protuberant inwards and forming cuticle cork, rough granular-shaped. Stomata flattened-rounded, with 4~5 subsidiary cells;

epidermal cells scattered with fine crystals of calcium oxalate, mostly fine-square, fusiform or thin bacilliform-shaped. Vessels fine, mostly spiral, up to about 18 μm in diameter.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 5.0 g of powdered sample, transfer to a 50-mL conical flask, add 2 mL of 25% ammonia solution and 20 mL of ethyl acetate, ultrasonicate for 30 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 1 mL of ethyl acetate.
2. Reference drug solution: Take 5.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of peimine and peiminine and dissolve in ethyl acetate to produce a solution containing 2.0 mg per mL of each.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, methanol, and ammonia solution (17:2:1) as the developing solvent. Apply 5 μL of the sample solution and reference drug solution and 2 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with the modified Dragendorff's reagent and heat at 110℃ until the spots become visible, and examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Total ash: Not more than 7.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 5.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Peimine and peiminine:
   (1) Mobile phase: A solution of acetonitrile, water, and diethylamine (70:30:0.03). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of peimine and peiminine and dissolve in methanol to produce a solution containing 0.2 mg and 0.15 mg per mL of each.
   (3) Sample solution: Weigh accurately 2.0 g of powdered sample and place it in a flask, add 4 mL of concentrated ammonia solution, and macerate for 1 hour. Accurately add 40 mL of a solution of chloroform and methanol (4:1), weigh, heat at 80℃ under reflux for 2 hours, cool and weigh again, replenish the loss of solvent with the above mixture and filter. Measure accurately 10 mL of the successive filtrate and evaporate to dryness. Dissolve the residue in methanol, transfer to a 2-mL volumetric flask, make up to volume with methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: It is equipped with an evaporative light-scattering detector (ELSD) and a column packing L1. The number of theoretical plates of the peak of peimine should not be less than 2,000.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and use a calibration equation of logarithm alteration of two external standards calculate the content.
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from insects.
Usage: Phlegm-dispelling medicinal (Heat-clearing and phlegm-resolving medicinal).
Property and flavor: Cold; bitter.
Meridian tropism: Lung and heart meridians.
Effects: Clear heat to transform phlegm, disperse abscesses and nodule.
Administration and dosage: 4.5~10 g.
Precaution and warning: Incompatible with *Aconitum* spp.

GALLI GIGERII CORNEUM ENDOTHELIUM
雞內金
Ji Nei Jin / Ji Nei Jin
Chicken's Gizzard-membrane

Chicken's gizzard-membrane is the dried inner wall of the gizzard of *Gallus gallus domesticus* Brisson (Fam. Phasianidae).

Description: Irregular, shrunken, capsule-shaped slices, 3~6 cm in length as whole, about 3 cm in width, about 0.6 mm thick. Externally yellow or yellowish-brown, thin and slightly translucent, with numerous protuberant ridge-

shaped wrinkles. Texture light and fragile, easily broken, fracture horny, lustrous. Odour slightly stinking; taste weak and slightly bitter.

Microscopic identification:
Powder: Fragments of gizzard irregular flaky, varying in size, translucent or slightly pale yellow, the margin irregular, with shrunken and twisted striations on the surface. Sandy granules numerous, irregular polyhedrons, three-dimensional and translucent, with distinct angles.

Impurities and other requirements:
1. Loss on drying: Not more than 15.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 2.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Storage: Store in a ventilated and dry place, and protect from insects and crush.
Usage: Disgestant medicinal.
Property and flavor: Neutral; sweet.
Meridian tropism: spleen, stomach, small intestine, and bladder meridians.
Effects: Invigorate stomach and promote digestion, astringe essence stop spermatorrhea.
Administration and dosage: 3~10 g.

GARDENIAE FRUCTUS
梔子
Jhih Zih / Zhi Zi
Capejasmine Fruit

Capejasmine fruit is the dried ripe fruit of *Gardenia jasminoides* J.Ellis (Fam. Rubiaceae).
It contains not less than 12.0% of dilute ethanol-soluble extractives, not less than 15.0% of water extractives and not less than 1.8% of geniposide.

Description: Elongated ovate or ellipsoid, 2~4.5 cm in length, 0.8~2 cm in diameter. The outer surface deep red or reddish-yellow, with 5~8 longitudinal winged ribs. Apex bearing remains of sepals, base somewhat tapering and remained with a fruit stalk. Pericarp thin and fragile, the inner surface bright yellow, lustrous, with 2~3 protuberant false septa. Seeds numerous, flattened-ovate, aggregated into a mass, reddish-brown, with fine and dense warts on the surface. Immersed in water makes water dyed bright yellow. Odour slight; taste slightly sour and bitter.

Microscopic identification:
1. **Transverse section:**
   (1) Fruit of *Gardenia jasminoides*: Rounded, rib obviously protuberant. Exocarp composed of 1 layer of rectangular cells, outer wall thickened and covered with cuticle. 2~4 layers of collenchymatous cells located outside mesocarp; large elongated-rounded parenchymatous cells located inside mesocarp, containing yellow pigments, a few relatively small cells contain clusters of calcium oxalate. Collateral vascular bundles scattered sparsely, relatively large ones surrounded by lignified fiber bundles, inlaid with stone cells. Endocarp composed of 2~3 layers of stone cells, subsquare, rectangular or polygonal, wall thick, pit canals distinct, some lumens contain prisms of calcium oxalate, cluster crystal-containing parenchymatous cells occasionally inlaid.
   (2) Seed of *Gardenia jasminoides*: Flatten-rounded, one side slightly protuberant. Testa composed of 1 layer of subsquare stone cells, inner and lateral walls extremely thickened, lumen distinct, containing brownish-red contents and yellow pigments; endotesta composed of fallen off and flatten parenchymatous cells. Endosperm cells polygonal, 2 flatten cotyledons exist in the center, cells filled with aleurone grains.
2. **Powder:** Reddish-brown. Stone cells of pericarp subrectangular; pericarp fibers slender, fusiform, up to about 110 μm in length, about 10 μm in diameter, usually arranged criss-cross or inlaid obliquely. Crystal-containing stone cells subrounded or polygonal, 17~31 μm in diameter, wall thick, lumen containing prisms of calcium oxalate, about 8 μm in diameter. Stone cells of testa yellow or pale brown, elongated-polygonal, rectangular or irregular, up to 230 μm in length, 60~112 μm in diameter, wall thick, pits extremely large, lumen brownish-red. Clusters of calcium oxalate 19~34 μm in diameter.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 20 mL of methanol, heat and shake in the water bath for 30 minutes, cool, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of geniposide and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate and methanol (3:1) as the developing solvent. Apply 5

μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with vanillin/H_2SO_4 TS and heat at 105℃ until the spots become visible, and examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained with the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 8.5% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 8.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 3.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Geniposide:
   (1) Mobile phase: A solution of acetonitrile and water (15:85). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of geniposide and dissolve in methanol to produce a solution containing 30 μg per mL.
   (3) Sample solution: Weigh accurately 0.1 g of the powdered sample and place it in a conical flask with stopper, and accurately add 25 mL of methanol, ultrasonicate for 20 minutes, weigh again, replenish the loss of weight with methanol, mix well and filter. Weigh accurately 10 mL of the filtrate, transfer the solution to 25-mL volumetric flask, make up to volume with methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (238 nm) and a column packing L1. The column temperature is maintained at 25℃. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of geniposide should not be less than 1,500.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   Geniposide (%)=0.00625(r_U/r_S) (C_S) / (W)

   r_U: peak area of geniposide of sample solution
   r_S: peak area of geniposide of reference standard solution
   C_S: concentration of geniposide of reference standard solution (μg/mL)
   W: weight of test sample (g) calculated with dried sample
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place, and protect from mold.
Usage: Heat-clearing medicinal (Heat-clearing and fire-purging medicinal).
Property and flavor: Cold; bitter.
Meridian tropism: Heart, lung, and triple energizers meridians.
Effects: Purge fire and eliminates vexation, clear heatand drain dampness, drain bile and reduces jaundice, cool the blood to detoxicate, disperse swelling to relieve pain.
Administration and dosage: 3~11.5 g.

GASTRODIAE RHIZOMA
天麻
Tian Ma / Tian Ma
Gastrodia Tuber

Gastrodia tuber is the dried tuber of *Gastrodia elata* Blume (Fam. Orchidaceae).
It contains not less than 14.0% of dilute ethanol-soluble extractives, not less than 18.0% of water extractives and not less than 0.2% of gastrodin.

Description: Oblong, compressed shrunken and slightly curved, 5~13 cm in length, 2~6 cm in width, 1~3 cm thick. One side with reddish-brown dried buds, commonly known as “Ying Ge Zuei” or “Hong Xiao Ban”, or remained with stem base; other side with a rounded scar after fallen off from the stem. Bark peeling or partial residual, externally yellowish-white or pale yellowish-brown, with annulate rings, dotted scars, membranous scale leaves and longitudinal wrinkles. Texture hard, translucent, uneasily broken, fracture relatively even, horny. Odour special; taste sweet and slightly pungent. Texture hard and compact, with a “Ying Ge Zuei” (similar to the beak of parrot), fracture lustrous, solid in the center as better quality named “Dung Ma”; texture light and loose, remained with stem base, fracture dull, hollow in the center as lower quality named “Chuen Ma”.

Microscopic identification:

1. **Transverse section:**
   Tuber of *Gastrodia elata*: Occasionally remained with pale brown epidermis. Cortex cells are elongated tangentially, 1 to several layers of walls adjacent to hypodermis slightly thickened, pits

sparse. Vascular bundles scattered in stele, amphicribral or collateral; vessels arranged in 2 to several, polygonal in shape. Parenchymatous cells contain polysaccharide masses, result in dark brown or light brownish-purple color against adding of iodine solution; occasionally containing raphides of calcium oxalate.

2. **Powder:** Yellowish-white. Sclerenchyma cells polygonal or long-polygonal, 70~250 μm in diameter, pits distinct. Raphides of calcium oxalate scattered or in bundles, 25~93 μm long. Spiral, reticulate and annular vessels, 8~33 μm in diameter. Parenchymatous cells contain mucilage contents and granules; the granules ovate or oblong in shape, showing colorless when examined under a polarized microscope, some of the granules aggregated in groups, brown or pale brownish-purple color present when added iodine solution.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 0.5 g of powdered sample to 5 mL of 70% methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 0.5 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of gastrodin and dissolve in methanol to produce a solution containing 1.0 mg per mL
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-butanol, glacial acetic acid, and water (7:2:1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with *p*-anisaldehyde/H_2SO_4 TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Total ash: Not more than 4.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 0.5% (General rule 6007).
3. Sulfur dioxide: Not more than 400 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 5.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Gastrodin:
   (1) Mobile phase: A solution of acetonitrile and water (3:97). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of gastrodin and dissolve in mobile phase to produce a solution containing 20 μg per mL.
   (3) Sample solution: Weigh accurately 0.5 g of powdered sample and place it in a 50-mL centrifuge tube, then add accurately 25 mL of 50% methanol, ultrasonicate for 30 minutes. Filter with filter paper, use the filtrate. Repeat the extraction of the residue one more time. Combine the filtrate, transfer to a 50-mL volumetric flask and make up to volume with 50% methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (220 nm) and a column packing L1. The column temperature is maintained at 35℃. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of gastrodin should not be less than 5,000.
   (5) Procedure: Inject accurately 10 μL of the reference standard solution and sample solution into the liquid chromatography apparatus, and calculate the content.

   Gastrodin : (%)=0.005 (r_U/r_S) (C_S) / (W)

   r_U: peak area of gastrodin of sample solution

   r_S: peak area of gastrodin of reference standard solution

   C_S: concentration of gastrodin of reference standard solution (μg/mL)

   W: weight of test sample (g) calculated with dried sample
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from mold.
Usage: Liver-pacifying and wind-extinguishing medicinal.
Property and flavor: Neutral; sweet.
Meridian tropism: Liver meridians.
Effects: Pacify the liver to subdue yang, extinguish wind to arrest convulsions.
Administration and dosage: 3~11.5 g.

【Decoction pieces】

GASTRODIAE RHIZOMA

It contains not less than 14.0% of dilute ethanol-soluble extractives, not less than 18.0% of water extractives and not less than 0.2% of gastrodin.
Raw medicinal materials are processed to remove impurities, clean selection, soften thoroughly or steam to soften, cut into thin slices, and dry, mostly irregular thin slices, surface light yellow to light brown, the cut surface yellowish-white to light brown, scattering dotted vascular bundles, horny, translucent. Odour special, taste sweet and slight pungent.

Thin layer chromatographic identification test: The method is the same as that for crude herb.
Impurities and other requirements: Methods and specifications are the same as those for crude herb.
Assay: The method is the same as that for crude herb.
Storage: The method is the same as that for crude herb.
Usage: Liver-pacifying and wind-extinguishing medicinal.
Property and flavor: Neutral; sweet.
Meridian tropism: Liver meridians.
Effects: Pacify the liver to subdue yang, extinguish wind to arrest convulsions.
Administration and dosage: 3~11.5 g.

GECKO
蛤蚧
Ge Jie / Ge Jie
Tokay

Tokay is the dried and eviscerated body of *Gekko gecko* (Linnaeus) (Fam. Geckonidae).
It contains not less than 9.0% of dilute ethanol-soluble extractives and not less than 10.0% of water extractives.

Description: Flattened, fixed on bamboo. Head, neck and trunk 10~15 cm in length; tail 8~12 cm in length; abdomen 6~10 cm in width. Head prolate, slightly triangular, two eyes deeply sunken into holes. Tiny teeth present in the mouth at the margin of the jaw. Dorsum sliver-gray or grayish-black scattered with brown or grayish-green spots. Vertebrae and ribs of both sides protuberant. Four limbs all containing 5 digits, bearing suckers at the base. Tail narrow and strong, the joints visible, with silver-gray circular bands. Whole body densely covered with subround or polygonal tiny scales. Odour stinking, taste slightly salty.

Microscopic identification:
Powder: Scales colorless or pale grayish-green. Epidermal cells with semicircular or subrounded protuberance, tile-like arranged, 10~30 μm in diameter. Fragments of skin pale yellow, cell boundaries indistinct, scattered with brownish-black granules, usually aggregated into stellate shaped.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 0.4 g of powdered sample to 5 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 0.4 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel plate with sodium carboxymethyl cellulose as the coating substance and a solution of *n*-butanol, glacial acetic acid, and water (3:1:1) as the developing solvent. Apply 8 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 15 cm from the origin, dry in air. Spray with ninhydrin TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Spectrophotometry (General rule 1008):
Take 0.2 g of the powdered sample, add 20 mL of ethanol, stand for 12 hours, filter, dilute the filtrate with ethanol to produce a solution containing 1.0 mg per mL as the sample solution, and measure the max absorption appear at 321 ± 2, 287 ± 2, 275 ± 2, 265 ± 2 and 244 ± 2 nm.

Impurities and other requirements:
1. Loss on drying: Not more than 12.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 20.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place, and protect from moisture.
Usage: Tonifying and replenishing medicinal (Yang-tonifying medicinal).
Property and flavor: Neutral; salty.
Meridian tropism: Lung and kidney meridians.

Effects: Tonify lung qi, assist kidney yang, qi absorption to stabilize panting.
Administration and dosage: 3~6 g.

GENTIANAE MACROPHYLLAE RADIX
秦艽
Cin Jiao / Qin Jiao
Largeleaf Gentian Root

Largeleaf gentian root is the dried root of *Gentiana macrophylla* Pall., *Gentiana straminea* Maxim., *Gentiana crassicaulis* Duthie ex Burkill or *Gentiana dahurica* Fisch. (Fam. Gentianaceae).
It contains not less than 29.0% of dilute ethanol-soluble extractives, not less than 26.0% of water extractives and not less than 2.5% of the total amount of gentiopicrin and loganic acid.

Description:
1. Root of *Gentiana macrophylla*: Subconical, the upper part thick and the lower part thin, twisted, 7~30 cm in length, 1~3 cm in diameter. Externally grayish-yellow or brownish-yellow, with longitudinal or twisted wrinkles. Apex of main root swollen, composed of numerous rhizome, remained with stem bases adhered with fibrous leave. Middle of main root with twisted wrinkles and scars of fibrous roots. Texture hard and fragile, easily broken, fracture of bark yellow or brownish-yellow, xylem yellow. Odour characteristic; taste bitter and astringent.
2. Root of *Gentiana straminea*: Subconical, 8~18 cm in length, 1~3 cm in diameter. Externally brown, with reticulated pits by fissures, lower part of main root frequently branched or gathered, slightly reticulated or braided, commonly known as “Ma Hua Jiao. Texture loose and fragile, easily broken, fracture frequently rotten-wood-shaped.
3. Root of *Gentiana crassicaulis*: Subcylindrical, relatively stout, often as one, less twisted, 12~20 cm in length, 1~3.5 cm in diameter. Externally yellowish-brown or dark brown, with longitudinal and twisted wrinkles. Apex of main root remained with pale yellow petiole and fibrous vascular bundles of leaf base. Taste bitter and astringent.
4. Root of *Gentiana dahurica*: Long fusiform or cylindrical, 8~20 cm in length, 0.2~1 cm in diameter. Externally brownish-yellow or brown, with longitudinal and twisted furrows, yellow when peeled. Main root often as one, occasionally bifurcated, apex remained with stem base and fibrous leaf sheath. Texture loose and fragile, easily broken, fracture yellowish-white. Odour slight; taste bitter and astringent.

Microscopic identification:
1. **Transverse section:**
   (1) Root of *Gentiana macrophylla*: Both outer and inner periderm composed of 1 row of cork cells and several layers of phelloderm cells. Cortex composed of several rows of suboblong parenchymatous cells, containing rod-shaped crystals of calcium oxalate. Phloem scattered with phloem bundles, cells fine, mostly subrounded, arranged densely. Xylem composed of unlignified xylem parenchymatous cells and lignified vessels, vessels scattered or several in groups.
   (2) Root of *Gentiana straminea*: Both outer and inner periderm composed of 1 row of cork cells and several layers of phelloderm cells. Cortex composed of several rows of suboblong parenchymatous cells, cells larger at the outer side, with distinct intercellular spaces. Phloem cells subrounded, arranged densely. Cambium distinct, composed of 3~4 rows of flat and arranged densely parenchymatous cells, cells subrectangular or fusiform. Xylem composed of unlignified xylem parenchymatous cells and lignified vessels, vessels scattered or several in groups. Oil droplets present, rod-shaped crystals of calcium oxalate occasionally found.
   (3) Root of *Gentiana crassicaulis*: Both outer and inner periderm composed of 1 row of cork cells and several layers of phelloderm cells. Cortex composed of several rows of suboblong parenchymatous cells, cells larger at the outer side, with distinct intercellular spaces. Cambium distinct, composed of 3~4 rows of flat and arranged densely parenchymatous cells. Xylem composed of unlignified xylem parenchymatous cells and lignified vessels, vessels scattered or several in groups. Oil droplets present, rod-shaped crystals of calcium oxalate occasionally found.
   (4) Root of *Gentiana dahurica*: Outer periderm easily fallen off, remains of cork cells occasionally found. Between outer and inner periderm shows obliterate phloem tissue, scattered with lignified reticular sclerenchymatous cells or several in groups, subrectangular or fusiform, lignified, with reticular or elongated-oblique pits on the surface. Inner periderm composed of 1 row of cork cells and several rows of phelloderm cells. Cortex composed of several rows of subrounded parenchymatous cells, cells larger at the outer side, with intercellular spaces. Phloem cells mostly subrounded, cells larger at the outer side, cells in the inner side relatively small and arranged densely. Cambium distinct, composed of 3~4 rows of flat and arranged densely parenchymatous cells. Xylem composed of unlignified xylem parenchymatous cells and lignified vessels, vessels scattered or several in groups. Oil droplets and rod-shaped crystals of calcium oxalate also present.

2. **Powder:**
   (1) Root of *Gentiana macrophylla*: Yellowish-brown. Cork cells subpolygonal, subrectangular or irregular in surface view, up to 198 μm in length and 20~166 μm in diameter, wall thin and slightly curved, periclinal walls with laterally fine striations, lumen containing oil droplets visible, each cell divided irregularly into 2~12 small cells, separator wall faintly present, unevenly thickened. Raphides of calcium oxalate scattered in parenchymatous cells, 10~18 μm in length. A few of crystals are fine-fusiform, granular-shaped or flaky. Endodermal cells huge, colorless or pale yellow; intact ones subrectangular or flattened-square in surface view, 85~542 μm in length and 18~153 μm in diameter, wall thin, periclinal walls with laterally linear and fine striations, each large cell divided into 2~10 small palisade cells, and each small cell also divided into 2~5 cells. Spiral and reticulate vessels 8~67 μm in diameter.
   (2) Root of *Gentiana straminea*: Brown. Reticular sclerenchymatous cells fusiform, subtriangular or long strip-shaped, with terminal slightly large, obtuse-rounded or truncate, occasionally lateral hook-shaped at one end, 20~240 μm in length and 20~65 μm in diameter, wall slightly thickened and lignified, pits long slit-shaped, varying in density, mostly longitudinal, oblique or slightly twisted occasionally present. Raphides of calcium oxalate fine, scattering in parenchymatous cells, 3~7 μm in length. Cork cells long-fusiform, subsquare or subrectangular in surface view, up to 200 μm in length and 20~80 μm in diameter, wall thin, each cell divided into 2~8 small cells; occasionally each cell divided into 2 small cells, and each small cell also divided into 2~5 cells. Endodermal cells (rootlets) pale yellowish-green or almost colorless, long strip-shaped, both ends truncate or slightly oblique, up to about 198 μm in length and 10~20 μm in diameter, walls thickened on three sides and thin on one side, up to about 7 μm thick, with relatively sparse pit canals.
   (3) Root of *Gentiana dahurica*: Yellowish- brown. Reticular sclerenchymatous cells singly scattered or several in groups, usually linked with cork cells, pale yellow or pale greenish-yellow, cells subfusiform, subtriangular or subrectangular, 65~210 μm in length and 20~70 μm in diameter, wall spiral-shaped or reticulate-shaped thickened and lignified; occasionally with walls spiral-shaped thickened, obliquely overlapped and twisted, pits longitudinal or obliquely slit-shaped, irregularly suboblong, fine oblong or occasionally found. Crystals of calcium oxalate fine, needle-like or rod-shaped, up to about 10 μm in length, occasionally granular-shaped. Cork cells subfusiform or rectangular in surface view, up to 180 μm in length and 20~65 μm in diameter, wall thin and slightly curved, each cell divided into 2~8 small cells; occasionally each cell divided into 2 small cells, and each small cell also divided into 2~4 cells. Endodermal cells pale yellowish-green, long strip-shaped, both ends truncate or slightly oblique, up to about 315 μm in length and 10~25 μm in diameter, walls thickened on three sides and thin on one side, up to about 10 μm thick, pit canals warty protuberance, fine double circles shaped in surface view.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, cool, filter and make up the filtrate to 10 mL with methanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of gentiopicrin and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, methanol, and water (10:2:1) as the developing solvent. Apply 10 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 254 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 9.0% dry at 105°C for 5 hours (General rule 6015).
2. Total ash: Not more than 8.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 4.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
1. Gentiopicrin and loganic acid:

(1) Mobile phase: A solution of acetonitrile and 0.1% acetic acid (9:91). The ratio may be adjusted, if necessary.
(2) Reference standard solution: Weigh accurately a quantity of gentiopicrin and loganic acid and dissolve in methanol to produce a solution containing 0.5 mg and 0.3 mg per mL of each.
(3) Sample solution: Weigh accurately 0.5 g of powdered sample and place it in a conical flask with stopper, add accurately 20 mL of methanol, weigh, ultrasonicate for 30 minutes, cool, weigh again, replenish the loss of the weight with methanol, mix well, filter, use the filtrate.
(4) Chromatographic system: The liquid chromatography is equipped with an UV detector (254 nm) and a column packing L1. The number of theoretical plates of the peak of gentiopicrin should not be less than 3,000
(5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
Gentiopicrin or loganic acid (%)=2(r_U/r_S) (C_S) / (W)
r_U: peak area of gentiopicrin or loganic acid of sample solution
r_S: peak area of gentiopicrin or loganic acid of reference standard solution
C_S: concentration of gentiopicrin or loganic acid of reference standard solution (mg/mL)
W: weight of test sample (g) calculated with dried sample

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place.
Usage: Dampness-dispelling medicinal (Wind-dampness-dispelling medicinal).
Property and flavor: Mild cold; pungent and bitter.
Meridian tropism: Stomach, liver and gallbladder meridians.
Effects: Dispel wind dampness, relieve arthragia pain, clear deficiency hea.
Administration and dosage: 3~10 g.

GENTIANAE RADIX ET RHIZOMA
龍膽
Long Dan / Long Dan
Chinese Gentian Root and Rhizome

Chinese gentian root and rhizome is the dried root and rhizome of *Gentiana scabra* Bunge, *Gentiana manshurica* Kitag., *Gentiana triflora* Pall. or *Gentiana rigescens* Franch. (Fam. Gentianaceae). The former three are commonly known as ”Long Dan” and the latter is commonly known as ”Jian Long Dan”.
It contains not less than 26.0% of dilute ethanol-soluble extractives, not less than 30.0% of water extractives, and not less than 3.0% of gentiopicrin in Long Dan, not less than 1.5% of gentiopicrin in Jian Long Dan.

Description:
1. Root and rhizome of *Gentiana scabra*: Rhizomes mostly horizontal, 0.5~3 cm in length, 0.3~0.8 cm in diameter, externally grayish-brown or dark brown, with numerous remained scars of stems, the lower part with 4~30 roots, often more than 20. Roots slender and cylindrical, slightly twisted, 1~3 cm in diameter, externally grayish-white or brownish-yellow, the upper part with relatively distinct transverse striations, the lower part with longitudinal wrinkles and rootlet scars. Texture fragile, soft when moistened, fracture yellowish-brown, xylem yellowish-white and arranged in a ring, pith distinct in the center. Odour slight; taste extreme bitter.
2. Root and rhizome of *Gentiana manshurica*: Rhizome mostly straight, lump-shaped or long lump-shaped, 0.5~1.5 cm in length, 0.4~0.7 cm in diameter, the lower part tufted with 2~16 roots, often less than 10. Roots about 15 cm in length, 0.2~0.4 cm in diameter, externally yellowish-brown or grayish-brown, with twistedly longitudinal wrinkles, the upper part with distinctly finely transverse striations and few protuberant scars of rootlets.
3. Root and rhizome of *Gentiana triflora*: Rhizome mostly straight, 1~5.5 cm in length, 0.7~1.5 cm in diameter, the lower part with 4~30 roots, often more than 15. Roots 0.1~0.6 cm in diameter, externally yellowish-white, with relatively distinct transverse striations wholly.
4. Root and rhizome of *Gentiana rigescens*: Rhizome nodular, externally without transverse wrinkles but remained stems, the lower part with 4~30 roots. Roots slender and fusiform, slightly curved, 0.1~0.4 cm in diameter, externally pale brown or brown, outer later membranous and easily falling off. Wood white.

Microscopic identification:
1. **Transverse section:**
(1) Root of *Gentiana scabra*: Exodermal cells subrounded or flat-rounded, elongated tangentially, outer walls slightly thickened and suberized, usually containing fatty oil droplets. Cortex narrow; endodermis distinct, composed of 3~5 rows of cells, arranged sparsely with clefts; the inner layer 1 row, cells elongated tangentially into strip-shaped, some cells divided into several small cells. Phloem broad, with irregular clefts at the

outside; sieve tube groups fine, relatively distinct near cambium. Xylem rays varying in width, vessel bundles 8~9, occasionally V-shaped branched. Pith composed of parenchymatous cells. Parenchymatous cells contain fine raphides of calcium oxalate or prism crystals, 2.5~5 μm in length.

(2) Root of *Gentiana manshurica*: Cambium usually in a ring, crystals of calcium oxalate in parenchymatous cells 2.5~10 μm in length, also containing fatty oil droplets.

(3) Root of *Gentiana triflora*: Parenchymatous cells mostly shrunken and obliterated, parenchymatous cells inside phloem contain abundant crystals of calcium oxalate, 3~15 μm in length.

(4) Root of *Gentiana rigescens*: Exodermis and parenchymatous cells of cortex mostly fallen off. Endodermal cells divided longitudinally into several small cells. Phloem broad, cambium ring indistinct, xylem vessels well developed, distributed densely in the center, without pith.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, cool, filter, and make up the filtrate to 10 mL.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of gentiopicrin and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-butanol, glacial acetic acid, and water (7:1:2) as the developing solvent. Apply 10 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with *p*-anisaldehyde/H_2SO_4 TS. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Total ash: Not more than 8.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 4.0% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 5.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Gentiopicrin:
   (1) Mobile phase: A solution of methanol and water (25:75). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of gentiopicrin and dissolve in methanol to produce a solution containing 0.1 mg per mL.
   (3) Sample solution: Weigh accurately 0.5 g of the powdered sample, accurately add accurately 20 mL of methanol, weigh, heat under reflux for 15 minutes, cool, weigh again, replenish the loss of the weight with methanol, mix well, filter, take 2 mL of the filtrate to a 10-mL volumetric flask, make up to volume with methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (270 nm) and a column packing L1. The number of theoretical plates of the peak of gentiopicrin should not be less than 3,000.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Gentiopicrin (%)=10(r_U/r_S) (C_S) / (W)
   r_U: peak area of gentiopicrin of sample solution
   r_S: peak area of gentiopicrin of reference standard solution
   C_S: concentration of gentiopicrin of reference standard solution (mg /mL)
   W: weight of test sample (g) calculated with dried sample
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place.

Usage: Heat-clearing medicinal (Heat-clearing and dampness-drying medicinal).

Property and flavor: Cold; bitter.

Meridian tropism: Lliver and gallbladder meridians.

Effects: Purge liver and gall bladder fire, eliminate lower energizer dampness heat.

Administration and dosage: 3~7.5 g.

GINKGO SEMEN
白果
Bai Guo / Bai Guo
Ginkgo Seed

Ginkgo seed is the dried ripe seed of *Ginkgo biloba* L. (Fam. Ginkgoaceae) without the fleshly testa or the dried endosperm of *Ginkgo biloba* L. (Fam. Ginkgoaceae) without the mesotesta.
It contains not less than 5.0% of dilute ethanol-soluble extractives and not less than 6.0% of water extractives.

Description: Oval or ellipsoidal, 1.5~3 cm in length, 1~2.2 cm in width. Mesotesta (shell) bony, glossy, yellowish-white or pale yellowish-brown, a protuberant dot at the base, with a rib on each side, occasionally with 3 ribs. Endotesta membranous, reddish-brown or pale yellowish-brown. Endosperm pale yellowish-green, fleshy, starchy, with a fissure in the center, embryo tiny. Odor; slight; taste slightly sweet and bitter.

Microscopic identification:
Powder: Pale yellowish-brown. Individual starch granules oblong, round, ovate or subtriangular, 5~18 μm in length, hilum dotted, cleft-shaped, V-shaped or Y-shaped, large one with distinct striations. Stone cells scattered singly or in groups of several to over 10, subrounded, oblong, subrectangular, conchoidal or irregular, occasionally with protuberance, 61~322 μm in length, 27~125 μm in diameter, walls thickened, with distinct pits, pit canals and striations, some lumina contain yellowish-brown or reddish-brown contents. Parenchymatous cells of endotesta pale yellowish-brown or reddish-brown, subsquare, rectangular or polygonal. Parenchymatous cells of endosperm colorless, subrounded or oblong, filled with starch granules. Bordered-pitted tracheid mostly broken, 33~72 μm in diameter, acuminate or obtusely rounded at the end.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 10 g of powdered sample to 40 mL of methanol, heat under reflux for 1 hour, filter, evaporate the filtrate to dryness, dissolve the residue in 15 mL of water, filter with few cotton, apply the filtrate to a column (10~15 mm in inner diameter) packed with polyamide (80~100 mesh, 3.0 g), elute with 70 mL of water, collect the eluates, extract shaking twice each time with 40 mL of ethyl acetate, combine ethyl acetate extracts, evaporate to dryness, and dissolve the residue in 1 mL of methanol.
2. Reference drug solution: Take 10 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of ginkgolide A and ginkgolide C and dissolve in methanol to produce a solution containing 0.5 mg per mL of each.
4. Procedure: Use silica gel F_{254} mixed with a solution of sodium carboxymethyl cellulose containing 4% sodium acetates as the coating substance and a solution of toluene, ethyl acetate, acetone, and methanol (10:5:5:0.6) as the developing solvent. Apply 10 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air, Spray with acetic anhydride and heat at 140~160℃ for 30 minutes and examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Total ash: Not more than 4.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
3. Sulfur dioxide: Not more than 400 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place.
Usage: Phlegm-dispelling medicinal (Cough-suppressing and panting-calming medicinal).
Property and flavor: Neutral; sweet, bitter and astringent.
Meridian tropism: Lung and kidney meridians.
Effects: Suppress cough to stabilize panting, stanch vaginal discharge and secure essence and reduce urination.
Administration and dosage: 4.5~11.5 g.
Precaution and warning: Unprocessed one toxic.

GINSENG RADIX ET RHIZOMA
人參
Ren Shen / Ren Shen
Ginseng Root

Ginseng root is the dried root and rhizome of *Panax ginseng* C.A.Mey. (Fam. Araliaceae). The drug derived from the cultivated form is commonly known as “Yuan Shen” (garden ginseng) and the drug derived from the

wild origin is commonly known as “Shan Shen” (wild ginseng).
It contains not less than 0.3% of the total amount of ginsenoside Rg_1 and ginsenoside Re and not less than 0.2% of ginsenoside Rb_1.

Description:

1. Root and rhizome of Yuan Shen: Main roots (Senti) cylindrical, externally pale yellow, the upper part of root exhibiting transverse-striations. Rhizomes (Lutou) 2~6 cm in length, 0.5~1.5 cm in diameter, with sparse depressed-circular stem scars (Luwan) and adventitious roots. Lateral roots 2~6, branched, fibrous root. This product results in two different processing methods, upon the processing method, divide into two different kinds of ginsengs. White ginseng with sun-dried or dried by heat and red ginseng with steaming and drying. Dividing into Senpian (slide piece), Senwei (thin roots) and Senshiu (rootlets).
   (1) Root and rhizome of White Ginseng (Bai Shen): Main roots 3~10 cm in length, externally khaki, with blackish brown transverse striations and longitudinal wrinkles, lateral roots thin, fibrous scars. Texture fragile, light, fracture even, white. Odour fragrant; taste bitter.
   (2) Root and rhizome of Red Ginseng (Hung Shen): Main roots 5~20 cm in length, 0.7~2 cm in width, externally reddish-brown, translucent, with large transverse striations, indistinct annulations and scars of lateral roots. Rhizomes externally khaki, with circular stem scars 4~6. Texture hard and fragile, fracture even, horny, reddish-brown, with a pale colored center of the circle. Odour fragrant; taste slightly bitter.
2. Root and rhizome of Shan Shen: Main roots stout, as long as or shorter than rhizomes, main lateral roots 2, V-shaped, the upper part with deeply transverse annulations. Rhizomes slender, 3~9 cm in length, the upper part curved, with dense depressed-circular stem scars (Luwan), the lower part smooth. Fibrous roots less, 1~2 times longer than main roots, flexibility, uneasily broken, with distinct tubercles. Externally pale yellowish-white, smooth, lustrous. Odour strong; taste sweet and slightly bitter.

Microscopic identification:

1. **Transverse section:**
   (1) Root and rhizome of *Panax ginseng*: Outermost layer composed of 1 row of epidermal cells covered with cuticle, mostly broken, cells rectangular or subsquare. Phelloderm composed of 7~10 layers of rectangular, subrectangular or subsquare cells. Cortex narrow, composed of 3~5 layers of rectangular or flattened-rectangular cells, scattered with clusters of calcium oxalate. Phloem occupied about 1/3 portion of the root, mainly composed of parenchymatous cells filled with starch granules; cells rectangular, subrectangular, subsquare, subpolygonal or subrounded, with distinct intercellular spaces; scattered with clusters of calcium oxalate and resin canals containing yellow secretions, resin canals composed of 5~8 flat and small cells, rounded or elongated-rounded, 30~85 μm in diameter; phloem showing irregular clefts in the outer part, cells arranged densely in the inner part, relatively numerous resin canals arranged in a ring near cambium. Cambium in a distinct ring, composed of 3~5 rows of rectangular or flattened-rectangular cells. Xylem broad, occupied about 2/3 portion of the root, composed of vessels, xylem parenchymatous cells and xylem fibers; vessels huge, singly scattered or several linked, arranged interruptedly and radially, unlignified fibers occasionally found beside vessels; vessels 16~56 μm in diameter, mainly reticulate or scalariform, a few spiral, cells subrounded, subpolygonal, subovate or subsquare. Pith broad, extending to phloem, composed of subrectangular, subsquare, subpolygonal or subrounded parenchymatous cells, filled with starch granules, clusters of calcium oxalate occasionally found. Primary xylem existed in the center, scattered with few vessels, mainly composed of small parenchymatous cells.
2. **Powder:** Pale yellowish-white. Cork cells pale yellowish brown in surface view, walls thin and lignified, cells subrectangular, subsquare or flattened-rectangular, containing starch granules and parenchymatous cells with clusters of calcium oxalate, with distinct intercellular spaces, cells subrectangular, subsquare or rectangular. Resin canals 30~85 μm in diameter or larger in longitudinal view, containing yellowish-brown secretions; resin canals contain yellowish-brown secretions in sectional view, composed of 5~8 flat and small cells, rounded or elongated-rounded. Vessels huge, 16~56 μm in diameter, mainly reticulate or scalariform, a few spiral, lignified. Clusters of calcium oxalate 20~90 μm in diameter, the angles mostly blunt. Starch granules extremely abundant; simple granules subrounded, 2~20 μm in diameter, hilum dotted, V-shaped, slit-shaped or Y-shaped, striations indistinct; compound granules varying in size, composed of 2~6 components.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.

2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of ginsenoside Rg_1, ginsenoside Re, ginsenoside Rb_1 and ginsenoside Rf and dissolve in methanol to produce a solution containing 1.0 mg per mL of each.
4. Procedure: Use silica gel F_{254} as the coating substance and the lower layer of a solution of *n*-butanol, glacial acetic acid, and water (7:1:2), standing below 10℃ as the developing solvent. Apply 5 μL of the sample solution and reference drug solution and 1 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air, Spray with 10% H_2SO_4/EtOH TS, heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
2. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
3. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
4. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
5. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).
6. Pesticide residues:
   (1) The total DDT content: Not more than 1.0 ppm (General rule 6305).
   (2) The total BHC content: Not more than 0.9 ppm (General rule 6305).
   (3) The total PCNB content: Not more than 1.0 ppm (General rule 6305)

Assay:

1. Ginsenoside Rg_1, ginsenoside Re, ginsenoside Rb_1:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and water as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of ginsenoside Rg_1, ginsenoside Re and ginsenoside Rb_1 and dissolve in methanol to produce a solution containing 0.2 mg per mL of each.
   (3) Sample solution: Weigh accurately 0.5 g of powdered sample and place it in a 50-mL round bottom flask, then add accurately 25 mL of 75% methanol, heat under reflux for 4 hours, filter with filter paper. Repeat the extraction of the residue one more time, combine the filtrate, transfer the filtrate to a 100-mL round bottom flask, evaporate the filtrate to a small amount and transfer to 10-mL volumetric flask, make up to volume with 75% methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (203 nm) and a column packing L1. The column temperature is maintained at 35 ℃. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of ginsenoside Rg_1, ginsenoside Re and ginsenoside Rb_1 should not be less than 8,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~30	19	81
30~45	19→22	81→78
45~60	22→29	78→71
60~75	29	71
75~110	29→40	71→60

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Ginsenoside Rg_1, ginsenoside Re, or ginsenoside Rb_1 (%)=(r_U/r_S) (C_S) / (W)

r_U: Peak area of ginsenoside Rg_1, ginsenoside Re, or ginsenoside Rb_1 of sample solution

r_S: Peak area of insenoside Rg_1, ginsenoside Re, or ginsenoside Rb_1 of reference standard solution

C_S: Concentration of insenoside Rg_1, ginsenoside Re, or ginsenoside Rb_1 of reference standard solution (mg /mL)

W: weight of test sample (g) calculated with dried sample.

Storage: Refrigerate or store in a cool and dry place, preserve in a well-closed container, and protect from insects.

Usage: Tonifying and replenishing medicinal (Qi-tonifying medicinal).

Property and flavor: Mild warm; sweet and mild bitter.

Meridian tropism: Spleen, lung, and heart meridians.

Effects: Greatly tonify the original qi, resume pulse secure collapse, invigorating spleen for benefiting lung, engender fluid to stop thirsting, tranquillizing mind and benefiting wisdom.

Administration and dosage: 3~11.5 g.

Precaution and warning: Incompatible with Veratri Nigri Radix et Rhizoma.

【Decoction pieces】

White ginseng (Bai Shen)

It contains not less than 0.3% of the total amount of ginsenoside Rg_1 and ginsenoside Re and not less than 0.2% of ginsenoside Rb_1.
Raw medicinal materials are processed to remove impurities, clean selection, soften thoroughly, cut into thin slices, and dry, or pulverize or break to pieces before use, rounded or subrounded thin slices; externally greyish-yellow; fracture pale yellow-white or sub-white, starchy; cambium ring brownish-yellow; yellow-brown dotted resin canals and radial clefts in bark. Texture light, fragile. Odour specific aromatic; taste sweet and slightly bitter.

Thin layer chromatographic identification test: The method is the same as that for crude herb.
Impurities and other requirements: Methods and specifications are the same as those for crude herb.
Assay: The method is the same as that for crude herb.
Storage: The method is the same as that for crude herb.
Usage: Tonifying and replenishing medicinal (Qi-tonifying medicinal).
Property and flavor: Mild warm; sweet and mild bitter.
Meridian tropism: Spleen, lung and heart meridians.
Effects: Greatly tonify the original qi, resume pulse secure and relieving collapse, invigorating spleen for benefiting lung, engender fluid to stop thirsting, tranquillizing mind and benefiting wisdom.
Administration and dosage: 3~11.5 g.
Precaution and warning: Incompatible with Veratri Nigri Radix et Rhizoma.

【Decoction pieces】

Red ginseng (Hung Shen)

It contains not less than 0.3% of the total amount of ginsenoside Rg_1 and ginsenoside Re and not less than 0.2% of ginsenoside Rb_1.
Raw medicinal materials are processed to remove impurities, clean selection, soften thoroughly, cut into thin slices, and dry, or pulverize or break to pieces before use, rounded or subrounded thin slices; externally reddish-brown, translucent. Cut surface even, horny. Texture hard and fragile. Odour specific aromatic; taste sweet and slightly bitter.

Thin layer chromatographic identification test: The method is the same as that for s crude herb.
Impurities and other requirements: Methods and specifications are the same as those for crude herb.
Assay: The method is the same as that for crude herb.
Storage: The method is the same as that for crude herb.
Usage: Tonifying and replenishing medicinal (Qi-tonifying medicinal).
Property and flavor: Warm; sweet and mild bitter.
Meridian tropism: Spleen, lung and heart meridians.
Effects: Greatly tonify the original qi, resume pulse secure and relieving collapse, invigorating spleen for benefiting lung.
Administration and dosage: 3~11.5 g.
Precaution and warning: Incompatible with Veratri Nigri Radix et Rhizoma.

GLEDITSIAE FRUCTUS
皂荚
Zao Jia / Zao Jia
Chinese Honeylocust Fruit

Chinese honeylocust fruit is the dried ripe fruit of *Gleditsia sinensis* Lam. (Fam. Leguminosae), commonly known as “Zao Jiao”.
It contains not less than 25.0% of dilute ethanol-soluble extractives and not less than 30.0% of water extractives.

Description: Flattened long strip or sheath-shaped, slightly curved, slightly protuberant at the location of seeds, 12~25 cm in length, 2~4 cm in width, 1~1.5 cm thick. Externally purplish-brown or blackish-brown, covered with grayish-white wax, lustrous when remove powder, apex acute, base attenuate, with a short stalk or a stalk scar, distinct longitudinal ribbed on the both sides, soundable when shaking. Texture hard, fracture yellow, fibrous. Seed numerous, ovate, 1~1.4 cm in length, 8 mm in width, yellow-brown, smooth. Odour characteristic, with a strong irritant leading to sneezing; taste pungent.

Identification:
1. Take 1.0 g of powdered sample, add 8 mL of ethanol, heat under reflux for 5 minutes, cool, filter. Evaporate 0.5 mL of the filtrate to dryness in a small porcelain dish, cool, add 3 drops of acetic anhydride, mix well, add 2 drops of sulfuric acid along the wall of the dish, a reddish-purple color is produced gradually.
2. Take 1.0 g of powdered sample, add 10 mL of water, boil for 10 minutes, filter and shake the filtrate well, a lasting foam continuing more than 15 minutes is produced.

Impurities and other requirements:
1. Loss on drying: Not more than 14.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 6.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place, and protect from insects.
Usage: Phlegm-dispelling medicinal (Cold-phlegm warming and resolving medicinal).
Property and flavor: Warm; pungent and salty.
Meridian tropism: Lung, large intestine, and liver meridians.
Effects: Dispel recalcitrant phlegm, open the orifices, dispel wind and kill worms.
Administration and dosage: 1.5~5 g, 0.3~1.5 g for powdering.
Precaution and warning: Use cautiously in pregnancy, qi and yin deficiency and hemoptysis.

GLEDITSIAE FRUCTUS ABNORMALIS
豬牙皂
Jhu Ya Zao / Zhu Ya Zao
Chinese Honeylocust Abnormal Fruit

Chinese honeylocust abnormal fruit is the dried sterile fruit of *Gleditsia sinensis* Lam. (Fam. Leguminosae).
It contains not less than 26.0% of dilute ethanol-soluble extractives and not less than 26.0% of water extractives.

Description: Sickle-shaped, 4~12 cm in length, 0.5~1.2 cm in width, 0.3~1 cm thick. Externally purplish-brown or purplish-black, covered with grayish-white, waxy and frost-like powders, lustrous after remove powders, some scattered with fine warts and pale yellow short fissures. Apex with a beak-shaped remained stylopodium, base with a short fruit stalk scar. The curve side (ventral suture) raised as ridge-like. Texture hard and fragile, fracture brownish-yellow. Exocarp coriaceous; mesocarp fibrous; endocarp starchy, lax in the center, with grayish-green or pale brownish-yellow filiform substances. In transverse section, hollows arranged regularly, seldom with seeds. Odour slight and irritant; taste slightly bitter, pungent, and the powder cause sneezed.

Microscopic identification:
1. **Transverse section:**
   Sterile fruit of *Gleditsia sinensis*: Exocarp composed of 1 layer of subrectangular epidermal cells, covered with cuticle. Mesocarp broad, an annular band composed of stone cells located on the outer side, fiber bundles well developed in dorsal and ventral suture, stone cells occasionally present at the outer and inner side or among fiber bundles, parenchymatous cells contain prisms of calcium oxalate. Beneath fiber bundles showing vascular bundles arranged in a ring. Collateral vascular bundles with xylem vessels small, a few of fibers visible. Endocarp with several layers of fibers, arranged horizontally or obliquely. Fibers 15~25 μm in diameter, pit canals distinct, stone cells usually embedded on the outside.
2. **Powder:** Reddish-brown. Stone cells subrounded, subsquare, elongated-rounded, fusiform or irregularly strip-shaped, some cell margins sinuous or short branched, up to 160 μm in length, 12~51 μm in diameter, wall 5~22 μm thick, striations visible, pit canals mostly distinct, lumen relatively small, a few of cells contain brown contents, clusters or prisms of calcium oxalate. Fibers long-fusiform, 16~36 μm in diameter, wall 5~12 μm thick, lignified, accompanied by small and subsquare stone cells or crystal-containing sclerenchymatous cells, forming crystal fibers. Crystal-containing sclerenchymatous cells subsquare, 8~25 μm in diameter, wall unevenly thickened and lignified, lumen containing prisms of calcium oxalate or 2 prism crystals, occasionally containing cluster crystals; prisms of calcium oxalate up to 27 μm in length, 5~20 μm in diameter. Lignified parenchymatous cells and epidermal cells of pericarp also visible.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter, evaporate the filtrate to dryness, dissolve the residue in 10 mL of water, extract shaking with 10 mL of ethyl acetate, evaporate the ethyl acetate extract to dryness, and dissolve the residue in 1 mL of methanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and the lower layer of a solution of dichloromethane, methanol, glacial acetic acid, and water (18:1:0.2:0.6) as the developing solvent. Apply 10 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:
1. Loss on drying: Not more than 14.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 7.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).

5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place, and protect from insects.
Usage: Phlegm-dispelling medicinal (Cold-phlegm warming and resolving medicinal).
Property and flavor: Warm; pungent and salty.
Meridian tropism: Lung and large intestine meridians.
Effects: Dispel recalcitrant phlegm, open the orifices, dispel wind and kill worms.
Administration and dosage: 1~1.5 g; usually used in pills or powder, and used an appropriate amount for external use.
Precaution and warning: Avoid to use during pregnancy.

GLEDITSIAE SPINA
皂角刺
Zao Jiao Cih / Zao Jiao Ci
Chinese Honeylocust Spine

Chinese honeylocust spine is the dried spine of *Gleditsia sinensis* Lam. (Fam. Leguminosae), commonly known as "Zao Ci".

Description: Composed of main spines and 1~2 branched spines. Main spines conical, apex acute, 3~15 cm in length, 0.4~1 cm in diameter; branched spines 1~6 cm in length. Externally yellowish-brown, purplish-brown or brown, lustrous, with fine and small wart protuberances and longitudinal wrinkles. Texture light and hard, uneasily broken. Odour slight; taste weak.

Microscopic identification:
1. **Transverse section:**
   Spine of *Gleditsia sinensis*: Epidermis composed of 1 layer of flat-rectangular cells, covered with cuticle. Cortex composed of 2~3 layers of cells, containing brown contents. Pericycle fiber bundles arranged in an interrupted ring, the walls of fibers lignified, prisms of calcium oxalate present in the surrounding cells; clusters of calcium oxalate rare, occasionally forming crystal fibers; stone cells rare, scattering in fiber bundles. Phloem narrow; xylem relatively broad, vessels fine; xylem rays 1~2 rows cells, xylem bundles distributed to pith. Pith broad, parenchymatous cells large, small cells usually in the center, surrounded by elongated cells arranged radially, forming chrysanthemum-shaped; some cells contain reddish-brown contents.
2. **Powder:** Reddish-brown. Epidermal cells rectangular, covered with cuticle. Parenchymatous cells of cortex round or long-oblong, 15~40 μm in diameter, containing yellowish-brown contents. Fibers scattered, strip-shaped, 5~10 μm in diameter. Prisms or clusters of calcium oxalate existed in parenchymatous cells. The differences between xylem parenchymatous cells, xylem fibers and vessels indistinct, mostly flaky and extremely lignified. Vessels mostly spiral. Parenchymatous cells of pith large, round, long-oblong or polygonal, varying in size, 20~80 μm in diameter, few containing brown contents.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 1 mL of methanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and the lower layer of a solution of dichloromethane, methanol, and concentrated ammonia solution (18∶3∶0.4) as the developing solvent. Apply 8 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:
1. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
2. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
3. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
4. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
5. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Storage: Store in a dry place.
Usage: Blood-regulating medicinal (Blood-activating and stasis-dispelling medicinal).
Property and flavor: Warm; pungent.
Meridian tropism: Liver and stomach meridians.
Effects: Expel toxin and pus, activate blood to disperse abscesses, dispel windand kill worms.

Administration and dosage: 3~10 g.

GLEHNIAE RADIX
北沙參
Bei Sha Shen / Bei Sha Shen
Coastal Glehnia Root

Coastal glehnia root is the dried root of *Glehnia littoralis* F.Schmidt ex Miq. (Fam. Umbelliferae).
It contains not less than 15.0% of dilute ethanol-soluble extractives and not less than 17.0% of water extractives.

Description: Cylindrical, branching occasionally, 15~40 cm in length, 3~10 mm in diameter, externally yellowish-white, rough, fine wrinkles longitudinally, and with brownish-yellow spotted lenticels and the scars of fibrous roots. Texture hard and fragile, easily broken. Sliced pieces small pieces or transverse cut, fracture yellowish-white, cambium ring brown distinct, bark with brownish-red small spots, wood yellow and hollow. Odour slight; taste sweetish.

Microscopic identification:

1. **Transverse section:**
   Root of *Glehnia littoralis*: Cork composed of about 2~10 rows of cells, mostly removed. Cortex composed of 2~13 rows of subrounded or polygonal cells. Secretory canals subrounded, 25~120 μm in diameter, containing yellowish-brown contents. Phloem broad. Cambium distinct; in a ring. Xylem vessels arranged radially, lignified, cells subrounded, 15~40 μm in diameter. Rays composed of 2~3 rows of cells, arranged radially, 15~70 μm in length, 10~40 μm in diameter. Parenchymatous cells contain aleurone grains.
2. **Powder:** White. Secretory canals usually in fragments contain yellow secretions. Starch granules being gelatinized after processed; some ungelatinized starch granules subrounded or ovate, 2~10 μm in diameter, with hilum distinct. Vessels mainly reticulate, spiral and scalariform, 10~40 μm in diameter, lignified

Impurities and other requirements:

1. Loss on drying: Not more than 13.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 4.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place, and protect from moisture and insects.
Usage: Tonifying and replenishing medicinal (Yin-tonifying medicinal).
Property and flavor: Mild cold; sweet and mild bitter.
Meridian tropism: Lung and stomach meridians.
Effects: Nourishes yin to clears lung, resolve phlegm, boost qi.
Administration and dosage: 4.5~12 g.

GLYCYRRHIZAE RADIX ET RHIZOMA
甘草
Gan Cao / Gan Cao
Liquorice Root and Rhizome

Liquorice root and rhizome is the dried root and rhizome of *Glycyrrhiza uralensis* Fisch., *Glycyrrhiza inflata* Batalin or *Glycyrrhiza glabra* L. (Fam. Leguminosae).
It contains not less than 20.0% of the water-soluble extractives and not less than 2.0% of glycyrrhizic acid

Description: Cylindrical, 1~3 cm in diameter. The outer bark yellowish-brown or grayish-brown, with longitudinally wrinkles, buds and scale leaves. Inner externally pale yellow, fibrous. Distinct cambium ring present at the 2/3 of fracture of rhizome fibrous radius, small pith present in the center, xylem and phloem arrange radial. Fracture rough and fibrous. Odour slight and characteristic; taste sweet.

Microscopic identification:

1. **Transverse section:**
   (1) Glycyrrhizae Radix et Rhizoma: Cork composed of 10~20 layers of cells; near the outer layers of cork cells contain reddish-brown non-crystalline contents, the innermost 3~4 rows of cork cell walls relatively thickened and colorless. Cortex composed of 1~3 radially elongated layers of parenchymatous cells, containing prisms of calcium oxalate. Phloem broad, containing radially broad phloem rays; walls of phloem fibers quite thickened, usually in bundles, arranged radially, every phloem fiber bundle surrounded by crystal fibers, containing 10~35 μm in length prisms of calcium oxalate. Cambium composed of 3 to several layers of cells. Xylem arranged radially; xylem rays 3~5 cells wide; vessels yellow pitted or reticulate, 80~200 μm in diameter, surrounded by tracheids; xylem fiber bundles

also surrounded by crystal fibers. Walls of xylem parenchymatous cells relatively thickened among vessels, containing pits.

(2) Root of Glycyrrhizae Radix et Rhizoma: Pith parenchymatous cells at the center, every parenchymatous cell filled with ovate or round simple granules, about 3~20 μm in length. Root without, but rhizome with a pith at the center.

2. **Powder:** Pale yellow. Phloem fibers and xylem fibers in bundles, thick-walled, yellow, surrounded by crystal fibers. Fragments of vessels and tracheids bordered-pitted or reticulate. Starch granules mostly ovate or rounded, 3~20 μm in diameter, mostly 4~10 μm in diameter. Fragments of cork cells dark brown, but bark removed powdered sample with no existence of cork tissue.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 2.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter, and make up to 10 mL.
2. Reference drug solution: Take 2.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of glycyrrhizic acid and dissolve in methanol to produce a solution containing 2.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, formic acid, and water (7:1:1) as the developing solvent. Apply 5 μL of the sample solution and reference drug solution and 1 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air, examine under the ultraviolet light at 254 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Total ash: Not more than 10.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 2.5% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 0.3 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).
8. Pesticide residues:
   (1) The total DDT content: Not more than 1.0 ppm (General rule 6305).
   (2) The total BHC content: Not more than 0.9 ppm (General rule 6305).
   (3) The total PCNB content: Not more than 1.0 ppm (General rule 6305).
9. Aflatoxins
   (1) Aflatoxins (sum of B_1, B_2, G_1 and G_2): Not more than 10.0 ppb (General rule 6307).
   (2) Aflatoxin B_1: Not more than 5.0 ppb (General rule 6307).

Assay:

1. Glycyrrhizic acid:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and 0.05% phosphoric acid as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of glycyrrhizic acid, and dissolve in 50% ethanol to produce a solution containing 50 μg per mL.
   (3) Sample solution: Weigh accurately 0.2 g of powdered sample, add 25 mL of 50% ethanol, ultrasonicate for 30 minutes, filter and use the filtrate, transfer to 50-mL volumetric flask. Repeat the extraction of the residue one more time. Combine the filtrate, make up to volume with 50% ethanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (254 nm) and a column packing L1. The column temperature is maintained at 35℃. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of glycyrrhizic acid should not be less than 8,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~20	25→50	75→50

   (5) Procedure: Inject accurately 10μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   Glycyrrhizic acid (%)= 0.005(r_U/r_S) (C_S) / (W)

   r_U: peak area of glycyrrhizic acid of sample solution

   r_S: peak area of glycyrrhizic acid of reference standard solution

   C_S: concentration of glycyrrhizic acid of reference standard solution (μg/mL)

   W: weight of test sample (g) calculated with dried sample
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).

Storage: Preserve in a well-closed container, and protect from insects.

Usage: Tonifying and replenishing medicinal (Qi-tonifying medicinal).
Property and flavor: Neutral; sweet.
Meridian tropism: Heart, lung, spleen, and stomach meridians.
Effects: Supplements spleen and stomach to tonify qi, moisten the lung to suppress cough and dispel phlegm, relax tension to relieve pain, mitigate the sharp actions of other medicinals, harmonize other medicinals.
Administration and dosage: 2~11.5 g.
Precaution and warning: Use cautiously with Sargassum, Euphorbiae Pekinensis Radix, Knoxiae Radix, Kansui Radix, Daphnis Genkwa Flos.

【Decoction pieces】

GLYCYRRHIZAE RADIX ET RHIZOMA

It contains not less than 20.0% of the water-soluble extractives and not less than 1.8% of glycyrrhizic acid.
Raw medicinal materials are processed to remove impurities, clean selection, soften thoroughly, cut into thin slices, and dry, mostly dark yellow, with longitudinal wrinkles, cut surface showing slightly fibrous, centre yellowish-white, with distinctly radial striations. Texture compact, starchy. Odour slight; taste sweet and characteristic.

Thin layer chromatographic identification test: The method is the same as that for crude herb.
Impurities and other requirements: Methods and specifications are the same as those for crude herb.
Assay: The method is the same as that for crude herb.
Storage: The method is the same as that for crude herb.
Usage: Tonifying and replenishing medicinal (Qi-tonifying medicinal).
Property and flavor: Neutral; sweet.
Meridian tropism: Heart, lung, spleen, and stomach meridians.
Effects: Supplements spleen and stomach to tonify qi, moisten the lung to suppress cough and dispel phlegm, relax tension to relieve pain, mitigate the sharp actions of other medicinals, harmonize other medicinals.
Administration and dosage: 2~11.5 g.
Precaution and warning: Use cautiously with Sargassum, Euphorbiae Pekinensis Radix, Knoxiae Radix, Kansui Radix and Daphnis Genkwa Flos.

GRANATI PERICARPIUM
石榴皮
Shih Liou Pi / Shi Liu Pi
Pomegranate Pericarp

Pomegranate pericarp is the dried ripe pericarp of *Punica granatum* L. (Fam. Punicaceae).
It contains not less than 10.0% of tannins and not less than 0.4% of ellagic acid.

Description: Irregularly slices or gourd-shaped, vary in size, 1.5~3 mm thick. The outer surface reddish-brown, brownish-yellow or dark brown, slightly lustrous, rough, with numerous white protuberances. Apex with tubular persistent calyx, base with a fruit stalk or its scar. The inner surface yellow or brownish-yellow, remained with the dented scar of seeds and the scars of pulp vesicles. Texture hard and fragile, easily broken, fracture yellow, slightly granular. Odour slight; taste bitter and astringent.

Microscopic identification:
1. **Transverse section:**
   Pericarp of *Punica granatum*: Exocarp composed of 1 layer of epidermal cells, arranged relatively densely, covered with cuticle. Mesocarp relatively thick, parenchymatous cells contain starch granules and clusters of prisms of calcium oxalate, stone cells singly scattered or in groups, subrounded, rectangular or irregular, less branched, walls relatively thickened, lumen large with pits; vascular bundles scattered. Parenchymatous cells of endocarp relatively small, also containing starch granules and clusters or prisms of calcium oxalate; vessels arranged radially.
2. **Powder:** Reddish-brown. Stone cells subrounded, rectangular or irregular, a few branched, 27~102 μm in diameter, walls relatively thickened with pits, lumen large. Epidermal cells subrectangular or ovate, walls slightly thickened. Clusters of calcium oxalate 5~28 μm in diameter, prisms 3~18 μm in length. Spiral and reticulate vessels 12~18 μm in diameter. Starch granules subrounded, 2~10 μm in diameter.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 0.1 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 0.1 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of ellagic acid and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of toluene, ethyl acetate, and formic acid (4:4:1) as the developing solvent. Apply 2 μL of each of the sample solution and reference drug solution and 5 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 254 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
2. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
3. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
4. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
5. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Ellagic acid:
   (1) Mobile phase: Methanol as the mobile phase A, and 0.1% phosphoric acid as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of ellagic acid, and dissolve in methanol to produce a solution containing 20 μg per mL.
   (3) Sample solution: Weigh accurately 0.2 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 25 mL of methanol, ultrasonicate for 30 minutes. Centrifuge for 5 minutes, filter the supernatant. Repeat the extraction of the residue one more time. Combine the extracts, filter to 50-mL volumetric flask with filter paper and make up to volume with methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (254 nm) and a column packing L1. The column temperature is maintained at 30℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The ratio may be adjusted if necessary. The number of theoretical plates of the peak of ellagic acid should not be less than 6,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~10	35	65
10~35	35→45	65→55
35~55	45→100	55→0

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Ellagic acid: (%)= 0.005(r_U/r_S) (C_S) / (W)

r_U: peak area of ellagic acid of sample solution

r_S: peak area of ellagic acid of reference standard solution

C_S: concentration of ellagic acid of reference standard solution (μg/mL)

W: weight of test sample (g) calculated with dried sample

2. Tannins:
   (1) Sample solution: Weigh accurately 10.0 g of powdered sample (containing about 1.0 g tannins), transfer to a conical flask, add 150 mL of water, place in a water bath for 30 minutes, cool and transfer to a 250-mL volumetric flask, make up to volume with water, filter and use the filtrate.
   (2) Determination of total water soluble portion: Weigh accurately 25 mL of the sample solution, evaporate to dryness, dry the residue at 105℃ for 3 hours, and weigh it (T_1).
   (3) Determination of water soluble portion not combining with gelatin powder: Weigh accurately 100 mL of the sample solution, add 6.0 g of gelatin powder, shake for 15 minutes, filter, weigh accurately 25 mL of the filtrate, evaporate to dryness, dry the residue at 105℃ for 3 hours, and weigh it (T_2).
   (4) Determination of water soluble portion combining with gelatin powder: Weight accurately 100 mL of water, add 6.0 g of gelatin powder, shake for 15 minutes, filter, weight accurately 25 mL of the filtrate, evaporate to dryness, dry the residue at 105℃ for 3 hours, and weigh it (T_0).
   (5) Calculate the content of tannins as following formula:

$$\text{Content of tannins (\%)} = \frac{(T_1 - T_2 + T_0)\times 10}{W}\times 100$$

W is the weight of the sample taken (g).

Storage: Store in a ventilated and dry place, and protect from moisture and mold.
Usage: Astringent medicinal.
Property and flavor: Warm; sour and astringent.
Meridian tropism: Stomach and large intestine meridians.
Effects: Astringe the intestines and antidiarrheal, hemostatic, expel worms.
Administration and dosage: 3~10 g.

GYPSUM FIBROSUM
石膏
Shih Gao / Shi Gao
Gypsum

Gypsum is the mineral of hydrous calcium sulfate ($CaSO_4 \cdot 2H_2O$).
It contains not less than 95.0% of hydrous calcium sulfate.

Description: Plate-shaped or irregular fibrous aggregates, white, grayish-white, transparent or translucent. Longitudinally surface with fibrous striations, silky lustrous. Odour slight; taste weak.

Microscopic identification:
1. **Transverse section:** Under the polarized microscope, thin slices colorless and transparent, the crystals fibrous or columnar.
2. **Powder:** The shape of crystals neat and dense.

Identification:
1. Check crystal water: Take 2.0 g of sample in a test tube covered with a pored cork stopper, heat, the sample turns to opaque and the moisture is produced on the tube wall.
2. Check calcium salt: Take 0.2 g of powdered sample, add 10 mL of dilute hydrochloric acid, heat to dissolve, add ammonium oxalate solution, a white precipitate is produced and soluble in hydrochloric acid but acetic acid.
3. Check sulfate salt: Take 0.2 g of powdered sample, add 10 mL of dilute hydrochloric acid, heat to dissolve, add barium chloride solution, a white precipitate is produced and soluble in sodium acetate but hydrochloric acid or nitric acid. (General rule 2191)

Assay:
1. Hydrous calcium sulfate ($CaSO_4 \cdot 2H_2O$):
   Weigh accurately 0.2 g of powdered sample, transfer into a conical flask, add 10 mL of dilute hydrochloric acid, heat to dissolve, add 100 mL of water and 1 drop of methyl red, add dropwisely potassium hydroxide until the color turns to pale yellow, then add an excess of 5 mL of potassium hydroxide, add a small quantity of calcein indicator, titrate with disodium edentate (0.05 M) until the yellowish-green fluorescence disappears and the color turns to orange. Each mL of disodium edentate (0.05 M) is equivalent to 8.608 mg of hydrous calcium sulfate ($CaSO_4 \cdot 2H_2O$).
   Hydrous calcium sulfate(%)＝0.8608 (*V*) / (*W*)
   V: The volume of disodium edentate (mL)
   W: weight of test sample (g) calculated

Impurities and other requirements:
1. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
2. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
3. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
4. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Storage: Store in a cool and dry place, and protect from moisture.
Usage: Heat-clearing medicinal (Heat-clearing and fire-purging medicinal).
Property and flavor: Highly cold; sweet and pungent.
Meridian tropism: Lung and stomach meridians.
Effects: Release flesh amd clear heat and purge fire, eliminate vexation and relieve thirst.
Administration and dosage: 15~60 g, decocting in the earlier sequence, raw gypsum for oral administration.

HAEMATITUM
代赭石
Dai Jhe Shih / Dai Zhe Shi
Hematite

Hematite is a mineral of oxides of corundum group, containing mainly ferric oxide (Fe_2O_3), commonly known as “Zhe Shi”.

Description: Irregular flattened masses, dark brownish-red or grayish-black; streak cherry-red or reddish-brown, some with metal luster. Externally with many nailhead-like bulges, the hollows of the some size corresponding in position to nailhead-like bulges present on the bottom. Nailhead-like bulges reniform. The side fracture layer stratification. Texture hard and fragile, uneasily broken, sticky after crashing. Odour slight; taste weak.

Identification:
Take 0.1 g of powdered sample in a tube, add 2 mL of hydrochloric acid, shake and stand. Apply 2 drops of supernatant, add 1~2 drops of potassium ferrocyanide solution (potassium ferrocyanide/ H_2O TS), a blue precipitate is produced, and add 5~6 drops of 25% sodium hydroxide in the precipitate, the color turns to brown.

Storage: Protect from dust.
Usage: Liver-pacifying and wind-extinguishing medicinal.
Property and flavor: Cold; bitter.
Meridian tropism: Liver, heart and stomach meridians.
Effects: Pacify the liver to subdue yang, downbear counterflow, hemostatic.
Administration and dosage: 9~30 g.
Precaution and warning: Use cautiously during pregnancy.

HALIOTIDIS CONCHA
石決明
Shih Jyue Ming / Shi Jue Ming
Sea-ear Shell

Sea-ear shell is the dried shell of *Haliotis diversicolor* Reeve, *Haliotis discus hannai* Ino, *Haliotis ovina* Gmelin, *Haliotis ruber* Leach, *Haliotis asinina* Linnaeus or *Haliotis laevigata* Donovan (Fam. Haliotidae).

Description:
1. Shell of *Haliotis diversicolor*: Elongate ovate, inner side slightly ear-like; 7~9 cm in length, 5~6 cm in width, about 2 cm in height. The outer surface grayish-brown, with many irregular spiral ribs and fine dense growth lines; the spire small, the shell body large; more than 20 tubercular protuberances arranged towards right from the apex of the spire part, the terminal 6~9 protuberances with an

opening on the same level with the shell surface, commonly known as “Jiou Kung Bau” or “Jiou Kung Shi Jue Ming”. The inner surface smooth, with a pearl-like luster. The shell relatively thick, texture hard, uneasily broken, fracture 0.5~10 mm thick, obvious laminated. Odourless; taste slightly salty.

2. Shell of *Haliotis discus hannai*: Oblong, 8~12 cm in length, 6~8 cm in width, 2~3 cm in height. The outer surface grayish-brown, with many rough and irregular wrinkles, growth lines distinct, usually with attachments of bryozoans or spirorbis, more than 20 tubercular protuberances arranged at the margin, the terminal 3~5 protuberances with an opening above the shell surface. The shell relatively thin, fracture 0.5~5 mm thick, obvious laminated.
3. Shell of *Haliotis ovina*: Subrounded, 4~8 cm in length, 2.5~6 cm in width, 0.8~2 cm in height. The outer surface grayish-green or brown, with yellowish-white maculations. The umbo close to the mid-portion and higher than the surface of shell, the spire and the shell body each occupying about one half of the shell surface, the border of the spire bearing 2 rows of neat protuberances, more conspicuous at the upper part, the terminal 4~5 protuberances with tubiform openings.
4. Shell of *Haliotis ruber*: Flat ovate, 13~17 cm in length, 11~14 cm in width, 3.5~6 cm in height. The outer surface brick-red, the spire occupying about one half of the shell surface, the spiral ribs and growth lines wavy ridged with more than 30 tubercular protuberances, the terminal 7~9 protuberances with an opening above the shell surface.
5. Shell of *Haliotis asinina*: Long and narrow, slightly twisted, auricular, 5~8 cm in length, 2.5~3.5 cm in width, about 1 cm in height. The outer surface smooth, with maculations of jade green, purple, brown color, etc.; the spire small, the shell body large; the terminal 5~7 protuberances with an opening on the same level with the shell surface, mostly ellipsoidal. The shell thin, texture relatively fragile.
6. Shell of *Haliotis laevigata*: Ovate, 11~14 cm in length, 8.5~11 cm in width, 1~6.5 cm in height. The outer surface brick-red, smooth, the umbo higher than the shell surface, growth lines relatively conspicuous; the spire occupying about one third of the shell surface, with more than 30 tubercular protuberances, the terminal 9 protuberances with an opening on the same level with the shell surface.

Microscopic identification:

1. **Powder:**
   (1) Shell of *Haliotis diversicolor*: The ground slices and powder contain cylindrical fiber structures, strip-shaped in longitudinal view, irregularly rounded or polygonal in sectional view, 10~100 μm in diameter. Pearl structures composed of irregularly rounded and small aragonite plates, stacking into parallelly lamellar pieces. The powder pale brown, bright red or white, containing moss green fluorescence. Numerous granules snow white and bright red colors, arranged alternately, composing to coral-shaped masses, dark yellow, orange-yellow or blackish-purple granules involved.
   (2) Shell of *Haliotis discus hannai*: The ground slices and powder contain cylindrical fiber structures, strip-shaped in longitudinal view, rounded or polygonal in sectional view, 10~30 μm in diameter. Pearl structures composed of ovate or square-rounded or irregular small aragonite plates, stacking into parallelly lamellar pieces. The powder pale pink like petals, purplish-red or white, containing orange-yellow fluorescence. Numerous granules white and pale pink like petals colors, arranged alternately, composing to coral-shaped pellets, purplish-red pearl texture granules involved.

Identification:

Take 5.0 g of powdered sample in test tubes, add 25 mL of distilled water, mix well, take each 1 mL to small test tubes, add 2~3 drops of saturated solution of zinc acetate dihydrate, examine under the ultraviolet light at 365 nm, a glass green fluorescence is produced for *Haliotis diversicolor* and a pale yellowish-green fluorescence for *Haliotis discus hannai*.

Impurities and other requirements:

1. Loss on drying: Not more than 3.0% dry at 105℃ for 5 hours (General rule 6015).
2. Acid-insoluble ash: Not more than 10.0% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Storage: Store in a ventilated and dry place and preserve in a well-closed container.

Usage: Liver-pacifying and wind-extinguishing medicinal.

Property and flavor: Cold; salty.

Meridian tropism: Liver meridians.

Effects: Pacify the liver to subdue yang, clear liver to improve vision.

Administration and dosage: 5~30 g, decocted earlier.

HEDYSARI RADIX
紅耆
Hong Ci / Hong Qi
Hedysarum Root

Hedysarum root is the dried root of *Hedysarum polybotrys* Hand.-Mazz. (Fam. Leguminosae).
It contains not less than 33.0% of dilute ethanol-soluble extractives and not less than 27.0% of water extractives.

Description: Cylindrical, 10~50 cm in length, 0.8~2 cm diameter. Externally reddish-brown, with longitudinal wrinkles and yellow lenticels, cork easily exfoliated, wood and fibers exposed. Texture hard and tenacious, fracture fibrous, starchy, bark pale brown, occupying 1/3~1/2 of cross section, cambium ring brownish, wood pale yellowish-brown, with radial rays. Odour slight; taste sweetish. Sliced pieces oblique, about 1 mm thick, fracture with radial striations and distinct cambium ring.

Microscopic identification:

1. **Transverse section:**
   Root of *Hedysarum polybotrys*: Cork composed of 6~8 rows of square cells, pale yellow, occasionally fallen off. Cortex composed of several layers of parenchymatous cells, subsquare or polygonal, with distinct intercellular spaces. Phloem composed of fiber bundles, parenchymatous cells and sieve tubes. Phloem fiber bundles subsquare, subrounded or irregular in shape, surrounded by prisms of calcium oxalate, forming crystal fibers. Parenchymatous cells of phloem polygonal or subsquare, with distinct intercellular spaces, containing abundant starch granules. Cambium in a ring. Xylem composed of fiber bundles, parenchymatous cells, vessels and ray cells. Xylem fiber bundles subsquare, subrounded or polygonal, with wall thickened and slightly lignified, surrounded by prisms of calcium oxalate, forming crystal fibers. Xylem parenchymatous cells subrounded or subsquare, containing abundant starch granules. Vessels mainly bordered-pitted, reticulate occasionally visible, singly scattered or several linked, 70~130 μm in diameter.
2. **Powder:** Yellowish-brown. Fibers mostly in bundles, occasionally scattered, with walls thickened and slightly lignified, 5~20 μm in diameter, surrounded by prisms of calcium oxalate, forming crystal fibers. Vessels mainly bordered-pitted, reticulate occasionally visible, 70~130 μm in diameter. Starch granules mostly simple, compound granules composed of 2~6 components occasionally found, oval or subrounded, 2~20 μm in diameter. Prisms of calcium oxalate about 20 μm in length and 7~15 μm in diameter.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 2.0 g of powdered sample to 15 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 2.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of formononetin and dissolve in 70% methanol to produce a solution containing 0.1 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of dichloromethane, methanol, and ammonia solution (12:2:1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 254 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 15.0% dry at 105°C for 5 hours (General rule 6015).
2. Total ash: Not more than 6.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 0.3 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).
9. Pesticide residues:
   (1) The total DDT content: Not more than 1.0 ppm (General rule 6305).
   (2) The total BHC content: Not more than 0.9 ppm (General rule 6305).
   (3) The total PCNB content: Not more than 1.0 ppm (General rule 6305).
10. Aflatoxins
    (1) Aflatoxins (sum of B_1, B_2, G_1 and G_2): Not more than 10.0 ppb (General rule 6307).
    (2) Aflatoxin B_1: Not more than 5.0 ppb (General rule 6307).

Assay:

1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place, and protect from moisture and insects.

Usage: Tonifying and replenishing medicinal (Qi-tonifying medicinal).
Property and flavor: Mild warm; sweet.
Meridian tropism: Lung, spleeen meridians.
Effects: Secure exterior to check sweating, tonify qi and promote urination, expel toxin and wound healing.
Administration and dosage: 9~30 g.

HELMINTHOSTACHYDIS RADIX ET RHIZOMA
倒地蜈蚣
Dao Di Wu Gong/Dao Di Wu Gong
Ceylan Helminthostachys Root and Rhizome

Ceylan helminthostachys rhizome is the dried root and rhizome of *Helminthostachys zeylanica* (L.) Hook. (Fam. Ophioglossaceae).
It contains not less than 3.0% of dilute ethanol-soluble extractives and not less than 4.0% of water extractives.

Description: Cylindrical, dark brown, about 4~8 cm in length, about 0.5 cm in diameter, thick roots on the bottom and left and right sides, semi-circular leaf marks on the top, easy break, grayish white section, oval in the center Vascular bundle.

Microscopic identification:
Transverse section:
Root of *Helminthostachys zeylanica*: 1 column of epidermal cells, containing brown matter, parenchyma cells round, containing a large number of starch granules, some cells contain brown inclusions, 1 column of endothelial cells, slightly lignified, outer tough vascular bundle is C-shaped Arranged, mostly for the scalariform tracheid.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 5 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of toluene, ethyl acetate, and formic acid (7:2:1) as the developing solvent. Apply 2 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:
1. Loss on drying: Not more than 14.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 5.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Storage: Store in a cool and dry place.
Usage: Heat-clearing medicinal (Heat-clearing and detoxicating medicinal).
Property and flavor: Cool, bitter and sweet.
Effects: Clear heat and detoxicate.
Administration and dosage: 3~30 g.

HIRUDO
水蛭
Shuei Jhih / Shui Zhi
Leech

Leech is the dried body of *Whitmania pigra* (Whitman), *Hirudo nipponia* Whitman or *Whitmania acranulata* (Whitman) (Fam. Hirudinidae).
It contains not less than 10.0% of dilute ethanol-soluble extractives and not less than 15.0% of water extractives.

Description:
1. Body of *Whitmania pigra*: Flattened fusiform, slightly curved, 4~10 cm in length, 0.8~2 cm in width, with numerous segments. The anterior sucker inconspicuous, the posterior sucker relatively larger; dorsal side slightly convex, blackish-brown, with 5 longitudinal black stripes; ventral side even, brownish-yellow. Texture fragile, easily broken, fracture lustrous, gelatinous. Odour slightly stinking.
2. Body of *Hirudo nipponica*: Flattened cylindrical, usually curved and twisted, 2~5 cm in length, 2~3 mm in width.
3. Body of *Whitmania acranulata*: Narrow and flattened, 5~12 cm in length, 1~5 mm in width.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 5 mL of ethanol, ultrasonicate for 15 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of cyclohexane, ethyl acetate (4:1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the

origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under visible light and ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:
1. Loss on drying: Not more than 15.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 10.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 3.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Total heavy metals: Not more than 20.0 ppm (General rule 6301).
6. Aflatoxins
   (1) Aflatoxins (sum of B_1, B_2, G_1 and G_2): Not more than 10.0 ppb (General rule 6307).
   (2) Aflatoxin B_1: Not more than 5.0 ppb (General rule 6307).

Assay:
1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from moisture and insects.
Usage: Blood-regulating medicinal (Blood-activating and stasis-dispelling medicinal).
Property and flavor: Neutral; salty and bitter.
Meridian tropism: Liver meridians.
Effects: Break blood and eliminate stasis, promoting menstruation and disperse stasis.
Administration and dosage: 1~3 g.
Precaution and warning: Avoid to use during pregnancy.

HOMALOMENAE RHIZOMA
千年健
Cian Nian Jian / Qian Nian Jian
Obscured Homalomena Rhizome

Obscured homalomena rhizome is the dried rhizome of *Homalomena occulta* (Lour.) Schott (Fam. Araceae).
It contains not less than 8.0% of dilute ethanol-soluble extractives and not less than 10.0% of water extractives.

Description: Cylindrical or slightly cured and compressed, 15~40 cm in length, 0.8~2 cm in diameter. Externally reddish-brown or yellowish-brown, rough, with mostly twisted longitudinal furrows arranged in a row and yellowish-white needle fiber bundles. Texture fragile, fracture with reddish-brown spots, scattered with numerous yellow fiber bundles and round lustrous oil dots. Odour aromatic; taste pungent and slight bitter.

Microscopic identification:
Transverse section:
Rhizome of *Homalomena occulta*: Cork mostly removed. Secretory tissue mostly contains reddish-brown or pale brown masses. Clusters of calcium oxalate scattered. Mucilage cells relatively large, containing raphides of calcium oxalate. Vascular bundles scattered, collateral or amphivasal; large fiber bundles existed outside collateral vascular bundles, pale yellow, wall thickened and lignified, occasionally with pits. Oil cavities numerous and large, 180~375 μm in diameter, surrounded by 4~5 layers of cells with suberized walls.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of cyclohexane and ethyl acetate (8:2) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air, spray with 10% H_2SO_4/EtOH TS, heat at 105℃ until the spots become visible, and examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:
1. Loss on drying: Not more than 13.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 7.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).

2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place.
Usage: Dampness-dispelling medicinal (Wind-dampness-dispelling medicinal).
Property and flavor: Warm; bitter and pungent.
Meridian tropism: Liver and kidney meridians.
Effects: Dispel wind dampness, strengthen sinew and bone.
Administration and dosage: 4.5~10 g.

HORDEI FRUCTUS GERMINATUS
麥芽
Mai Ya / Mai Ya
Germinated Barley

Germinated barley is the dried and germinated ripe caryopsis of *Hordeum vulgare* L. (Fam. Gramineae).
It contains not less than 8.0% of dilute ethanol-soluble extractives and not less than 10.0% of water extractives.

Description: Fusiform, both sides acute, center obtuse, 9~15 mm in length, 2.5~3.5 mm in diameter. Externally pale yellow or yellowish-brown, base of the radicle grown with budlet and the fibrous root; budlet about 4 mm in length, yellowish-brown or yellowish-white, linear and soft; fibrous root about 2~20 mm in length, slender and curved; dorsally enveloped in lemma, 5 veined, with a long awn broken or fallen; ventrally subtended by palea. Texture hard, fracture white, starchy. Odour slight; taste slightly sweet.

Microscopic identification:
1. **Transverse section:**
   Caryopsis of *Hordeum vulgare*: Lemma and palea located at outermost layer of caryopsis, external showing sclerenchymatous cells, the base usually with non-glandular hairs; internal showing parenchymatous cells. Inside pericarp showing testa, composed of parenchymatous cells. Endosperm located inside testa, composed of 2~4 layers of sclerenchymatous cells, filled with starch granules. Embryo composed of parenchymatous cells, germ grown upward, radical grown downward.
2. **Powder:** Pale yellow or beige. Epidermal cells moniliform, with vascular bundles. Endocarp filled with abundant starch granules, elliptical or subrounded, about 8~30 μm in diameter, hilum V-shaped or slit-shaped.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 2 mL of dilute hydrochloric acid and 30 mL of ethyl acetate, ultrasonicate for 1 hour, cool, filter, evaporate the filtrate to dryness and dissolve the residue in 1 mL of methanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of toluene, ethyl acetate, and formic acid (10:3:0.5) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with α-naphthol/MeOH TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:
1. Loss on drying: Not more than 13.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 6.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).
9. Aflatoxins
   (1) Aflatoxins (sum of B_1, B_2, G_1 and G_2): Not more than 10.0 ppb (General rule 6307).
   (2) Aflatoxin B_1: Not more than 5.0 ppb (General rule 6307).
10. Budding rate: Not less than 85.0%. Take 10.0 g of sample in two portions diagonally (General rule 5001), calculate the percentage of the amount of the budding grains and of the total grains.

Assay:
1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place, and protect from moisture and insects.
Usage: Disgestant medicinal.
Property and flavor: Neutral; sweet.
Meridian tropism: Spleen and stomach meridians.
Effects: Promotes spleen and open appetite, moves qi and digest food, terminating lactation and eliminate swelling.
Administration and dosage: 10~15 g. Take 60~90 g fried Hordei Germinatus Fructus for lactifuge.

HOUTTUYNIAE HERBA
魚腥草
Yu Sing Cao / Yu Xing Cao
Heartleaf Houttuynia Herb

Heartleaf houttuynia herb is the dried herb in flowering of *Houttuynia cordata* Thunb. (Fam. Saururaceae).
It contains not less than 4.0% of dilute ethanol-soluble extractives, not less than 8.0% of water extractives and not less than 0.2% of quercitrin.

Description: Stems flat-cylindrical, twisted, 20~35 cm in length, 2~3 mm in diameter; externally yellowish- brown or dark brown, with several longitudinal ridges and distinct nodes, nodes in the lower with adventitious root; texture fragile and easily broken. Leaves alternate, rolled and crumpled, cordate or broadly ovate as whole, 3~6 cm in length, 3~5 cm in width, apex acuminate, margin entire; the upper surface dark yellowish-green to dark brown, the lower surface grayish-green or grayish-brown; petioles slender, accreted with stipule at the base, forming a sheath. Spike terminal, yellowish-brown. Odour fishy; taste slightly astringent.

Microscopic identification:

1. **Transverse section:**
   (1) Stem of *Houttuynia cordata*: Epidermis composed of 1 layer of square cells, outer walls slightly thickened. Outside cortex showing 1 layer of large parenchymatous cells arranging in order, scattered with oil cells; inside showing 1 layer of subrounded small parenchymatous cells arranging densely; inside showing cortex with thin walls, cells varying in shape, arranging sparsely, with numerous intercellular spaces. Pericycle fibers 1~2 layers, arranging in a ring, lignified, with extremely thickened walls and small lumens. Vascular bundles arranged in a ring; phloem distinct; vessels mainly spiral and reticulate, 20~50 μm in diameter. Pith broad, scattered with oil cells and clusters of calcium oxalate.
   (2) Leaf of *Houttuynia cordata*: Upper and lower epidermal cells polygonal, with densely undulated striations; stomata with 4~6 subsidiary cells; oil cells scattered, subrounded, 66~80 μm in diameter, surrounded by 6~7 epidermal cells arranging in a ring. Glandular hairs without stalk, the head 3~4 cells, containing pale brown contents, apical cells usually without secretions, occasionally shrunken; non-glandular hairs in vein 2~4 cells, with striations on the surface. Stomata distributed densely in lower epidermis; non-glandular hairs slightly numerous. Parenchymatous cells in mesophyll occasionally contain clusters of calcium oxalate, 6~16 μm in diameter.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 5.0 g of powdered sample to 50 mL of methanol, ultrasonicate for 30 minutes, stand, filter and use the filtrate.
2. Reference drug solution: Take 5.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of quercitrin and dissolve in methanol to produce a solution containing 0.5 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, acetone, formic acid, and water (24:3.6:1.5:0.9) as the developing solvent. Apply 5 μL of each of the sample solution and reference drug solution and 2 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Soak with $AlC1_3$/EtOH TS. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Total ash: Not more than 16.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 2.5% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 10.0 ppm (General rule 2251, 6301).

Assay:

1. Quercitrin:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and 0.2% acetic acid as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of quercitrin, and dissolve in 70% methanol to produce a solution containing 20 μg per mL.
   (3) Sample solution: Weigh accurately 0.5 g of the powdered sample and place it in a 50-mL conical flask, then add accurately 15 mL of 70% methanol, ultrasonicate for 20 minutes, filter to 50 mL volumetric flask with filter paper. Repeat the extraction of the residue two more times. Combine the filtrate and make up to volume with 70% methanol, mix well, filter and use the successive filtrate.

(4) Chromatographic system: The liquid chromatography is equipped with an UV detector (254 nm) and a column packing L1. The column temperature is maintained at room temperature. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~15	10→20	90→80
15~20	20	80
20~30	20→90	80→10

(5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Quercitrin (%)=0.005(r_U/r_S) (C_S) / (W)

r_U: peak area of quercitrin of sample solution

r_S: peak area of quercitrin of reference standard solution

C_S: concentration of quercitrin of reference standard solution (μg/mL)

W: weight of test sample (g) calculated with dried sample

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from insects.
Usage: Heat-clearing medicinal (Heat-clearing and detoxcating medicinal).
Property and flavor: Mild cold; pungent.
Meridian tropism: Lung meridians.
Effects: Clear heat and detoxicate, induce diuresis and relieve strangury, disperse abscesses and expel pus.
Administration and dosage: 10~30 g, not decocted for a long time and used double dosage of fresh one.

HOVENIAE SEMEN
枳椇子
Jhih Jyu Zih/Jhih Jyu Zih
Raisin Tree Seed

Raisin tree seed is the dried mature seed of *Hovenia acerba* Lindl., *Hovenia dulcis* Thunb. or *Hovenia trichocarpa* Chun & Tsiang. (Fam. Rhamnaceae).
It contains not less than 4.0% of dilute ethanol-soluble extractives and not less than 5.0% of water extractives and not less than 0.13% of dihydromyricetin.

Description:
1. Seed of *Hovenia acerba*: Dark brown or black purple, 3.2~4.5 mm in diameter.
2. Seed of *Hovenia dulcis*: Flat round, slightly raised on the back, flat on the ventral surface, 3~5 mm in diameter, 1~2 mm in thick. Epidermis reddish brown, brownish black or greenish brown, shiny. It can be seen in the concave point under the magnifying glass. The base is concave with a slight pale umbilical cord, top slightly convex joint, ventral surface longitudinal ridge. Seed coat hard, endosperm milky white, cotyledons pale yellow, both rich in oil. Odor slight, taste slight astringent.
3. Seed of *Hovenia trichocarpa*: Black, dark purple or brown, subround, 4~5.5 mm in diameter, ribbed in the middle of the ventral surface, sometimes with papillary protrusions on the back.

Microscopic identification:
1. **Transverse section:**
Seed of *Hovenia dulcis*: Outer epidermis 1 column of grid-shaped cells, about 180 μm length, about 12 μm in wide. surrounded by the stratum corneum, outer wall thin, side wall thick, cell cavity narrow and slit, inner wall is swollen, outer side has a brilliant band. A number of pigmented cells, suboval or polygonal, containing brown matter, small number of parenchyma cells on the inner side, no pigmentation. Inner epidermal cells radially elongated. Decadent endosperm cells sometimes have calcium oxalate crystals, endosperm cell wall thick, containing round clusters of small crystals and aleurone. Cotyledon cell wall thin, full of aleurone particles. Small cluster-like crystal arrangement annular inside the edge of the cotyledon.
2. **Powder:** Reddish-brown. Epidermis of the seed coat cell polygonal shape, thick wall, small cell cavity; lateral view elongated, closely arranged, outer layer horny, radiance obvious, colorful under polarized light. Pigment cells subnearly oval or polygonal, containing reddish brown. Cotyledon cells rectangular or long-ovate, thin walls, containing small clusters of crystals and oil droplets. Small cluster of crystals about 8 μm in diameter, bright white under polarized light. Calcium oxalate crystal 4~10 μm in diameter, colorful under polarized light.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of ethanol, heat in water bath for 30 minutes, cool to room temperature, filter, evaporate the filtrate to dryness, and dissolve the residue in 1 mL of ethanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of dihydromyricetin and dissolve in

ethanol to produce a solution containing 1.0 mg per mL.

4. Procedure: Use silica gel F_{254} as the coating substance and a solution of toluene, ethyl acetate, and formic acid (10:8:5) as the developing solvent. Apply 2 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 11.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 4.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 0.3% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

Dihydromyricetin:

1. Mobile phase: A solution of acetonitrile and 0.1% phosphoric acid (18:82). The ratio may be adjusted, if necessary.
2. Reference standard solution: Weigh accurately a quantity of dihydromyricetin and dissolve in methanol to produce a solution containing 40 μg per mL.
3. Sample solution: Weigh accurately 1.0 g of the powdered sample and place it in a 50-mL conical flask with a stopper, then add accurately 25 mL of methanol, ultrasonicate for 30 minutes, filter, transfer the filtrate to a 50-mL volumetric flask. Repeat the extraction of the residue one more time. Combine the filtrate and make up to volume with methanol, mix well, filter and use the successive filtrate.
4. Chromatographic system: The liquid chromatography is equipped with an UV detector (290 nm) and a column packing L1. The column temperature is maintained at 25℃. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of dihydromyricetin should not be less than 3,000.
5. Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Dihydromyricetin (%)=0.005(r_U/r_S) (C_S) / (W)

r_U: peak area of dihydromyricetin of sample solution

r_S: peak area of dihydromyricetin of reference standard solution

C_S: concentration of dihydromyricetin of reference standard solution (μg/mL)

W: weight of test sample (g) calculated with dried sample

Storage: Store in a cool and dry place.

Usage: Heat-clearing medicinal (Deficiency heat-clearing medicinal).

Property and flavor: Neutral; sweet.

Effects: Clear cool and relieve urinate, resolve alcohol intoxication, stop thirsting and eliminate vexation, engender body fluid, stop vomiting, induce urine and defecate.

Administration and dosage: 4.5~12 g.

ILICIS PUBESCENTIS RADIX ET CAULIS
毛冬青
Mao Dong Ching / Mao Dong Ching
Pubescent Holly Root and Stem

Pubescent holly root and stem is the dried root and stem of *Ilex pubescens* Hook. & Arn. (Fam. Aquifoliaceae).

It contains not less than 4.0% of dilute ethanol-soluble extractives and not less than 3.0% of water extractives and not less than 0.2% of ilexgenin A.

Description: Cylindrical, Some branches, different in length. Externally grayish brown to brown, root stock, with stem base and stem branch residues, outer skin slightly rough, with longitudinal fine wrinkles and lateral lenticels. Texture compact, uneasily broken, fracture extremely thin, xylem developed, yellowish brown to grayish white, with dense radial texture and ring pattern, Odor slight, bitter and slightly sweet. Most of the goods are in pieces, vary size. Stem subround or oblong shape, 1~4 cm in diameter. Externally grayish brown, longitudinal wrinkles and some can be seen in grayish white spots or small lenticels. Extremely thin, xylem width, whitish, visible dense radial texture, central marrow. Odor slight, bitter and slightly sweet.

Microscopic identification:

1. **Transverse section:**
   Stem of *Ilex pubescens*: Cork layer composed of 4 ~ 10 rows of flat cork cells, slightly lignified. Cortex consists of 2 ~ 4 composed of tangentially elongated parenchyma cells. phloem relatively narrow, outer side of cortex showing a ring of stone cells, Stone cells singly scattered or in a group, layer loop formed; xylem broad, pith line is straight, cells 1 ~ 4 columns wide. Pith cells polygonal, closely arranged, walls slightly thicker. Wood fiber developed.
2. **Powder**: Pale yellowish-white. Middle column sheath fiber slender, wall thick, cell linear, outer wall smooth or slightly shallow, apex tapered or

blunt; Bright yellow-white under polarizing microscope. Many wood fibers, single scattered or bundled, nearly colorless or pale yellow, wall thickness, some pits obvious; bright yellow-white or bright yellow-brown under the polarizing microscope. Stone cells scattered or 2~3 groups, rectangular, subround, subtriangular or subsquare, with obvious stratigraphic and pores. More common with pitted holes, 5~15 cm in diameter.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample (stem) to 20 mL of methanol, ultrasonicate for 30 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 2 mL of methanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of ilexgenin A and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and the lower layer of dichloromethane, ethyl acetate, methanol, formic acid, and water (10:20:10:1:5) as the developing solvent. Apply 2 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 9.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 2.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 0.5% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

Ilexgenin A:

1. Mobile phase: A solution of acetonitrile and 0.1% formic acid (60:40). The ratio may be adjusted, if necessary.
2. Reference standard solution: Weigh accurately a quantity of iIlexgenin A and dissolve in methanol to produce a solution containing 25 μg per mL.
3. Sample solution: Weigh accurately 0.5 g of the powdered sample (stem) and place it in a 50-mL centrifuge tube, then add accurately 20 mL of methanol, ultrasonicate for 30 minutes. Centrifuge for 10 minutes, transfer the supernatant to a 50-mL volumetric flask. Repeat the extraction of the residue one more time. Combine the supernatant and make up to volume with methanol, mix well, filter and use the filtrate.
4. Chromatographic system: The liquid chromatography is equipped with an UV detector (210 nm) and a column packing L1. The column temperature is maintained at 23 ± 4℃. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of iIlexgenin A should not be less than 1,000.
5. Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

$$\text{Ilexgenin A: (\%)} = 0.005(r_U/r_S)\,(C_S)\,/\,(W)$$

r_U: peak area of ilexgenin A of sample solution

r_S: peak area of ilexgenin A of reference standard solution

C_S: concentration of ilexgenin A of reference standard solution (μg/mL)

W: weight of test sample (g) calculated with dried sample

Storage: Store in a cool and dry place, and protect from insects.

Usage: Dampness-dispelling medicinal (Dampness-draining diuretic medicinal).

Property and flavor: Mild cold; bitter.

Effects: Activate blood and eliminate stasis, clear heat and detoxicate.

Administration and dosage: 6~15 g.

IMPERATAE RHIZOMA
白茅根
Bai Mao Gen / Bai Mao Gen
Lalang Grass Rhizome

Lalang grass rhizome is the dried rhizome of *Imperata cylindrica* (L.) Raeusch. (Fam. Gramineae).

It contains not less than 17.0% of dilute ethanol-soluble extractives and not less than 18.0% of water extractives.

Description: Slender and long cylindrical, branched, varying in length, 30~60 cm in length, 0.2~0.5 cm in diameter. Externally pale yellow, lustrous, with longitudinally wrinkles, varying in color, nodes distinct and slightly protuberant, internodes varying in length, usually 1.5~3 cm in length, remained with scale leaves. Texture light, tenacious, fracture white in bark, with

cracks arranged radially, stele pale yellow, with a pore in the center, easily stripped from cortex. Odour slight; taste slightly sweetish.

Microscopic identification:

1. **Transverse section:**
   Rhizome of *Imperata cylindrica*: Epidermis composed of 1 layer of subsquare small cells, occasionally containing silica bodies. Hypodermal fibers in 1~4 rows, walls thickened and lignified. Cortex relatively broad, composed of more than 10 rows of parenchymatous cells, scattered with 10 or more vascular bundles in closed collateral type, surrounded by fibers of vascular bundle sheath accompanied by clefts. Endodermal cells thickened at inner walls, some cells containing silica bodies. Pericycle composed of 1~2 layers of sclerenchyma cells, vascular bundles scattered in stele, surrounded by fibers of vascular bundles. Central part often hollowed.
2. **Powder:** Yellowish-white. Epidermal cells arranged parallelly, each row composed of one long cell alternated with two short cells, occasionally one short cell existed between two long cells, hypodermal fibers usually with transverse septa, containing oblique pits. Cortex cells subrectangular, thinned at one side walls and easily broken, thickened at the other side walls with striations and pits, also with silica bodies. Sclerenchyma cells of pericycle subrectangular; pericycle cells stone cell-shaped at the nodes of rhizome. Vessels mainly bordered-pitted and pitted, annular vessels rarely present.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 2.5 g of powdered sample to 10 mL of ethanol, ultrasonicate for 1 hour, filter and use the filtrate.
2. Reference drug solution: Take 2.5 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and dichloromethane as the developing solvent. Apply 10 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:

1. Loss on drying: Not more than 11.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 6.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 3.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 5.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a dry place, and protect from mold and insects.
Usage: Blood-regulating medicinal (Hemostatic medicinal).
Property and flavor: Cold; sweet.
Meridian tropism: Lung, stomach, and bladder meridians.
Effects: Cool the blood to hemostatic, clear heat and promote urination.
Administration and dosage: 9~30 g.

INDIGO NATURALIS
青黛
Cing Dai / Qing Dai
Natural Indigo

Natural indigo is the dried powder or masses perpared from the leaf or the stem and leaf of *Strobilanthes cusia* (Nees) Kuntze (Fam. Acanthaceae), *Polygonum tinctorium* W.T.Aiton (Fam. Polygonaceae) or *Isatis tinctoria* L. (*Isatis indigotica* Fortune) (Fam. Cruciferae). It contains not less than 2.0% of indigo and not less than 0.13% of indirubin.

Description: A pale blue to grayish-blue fine powder, or irregular porous masses, finely powdered on twisting. Texture light, puffy. Odour grassy; taste weak. The better character as light, dark blue, fine powder, floating on water and burning with prune flames.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 50.0 mg of powdered sample to 5 mL of dichloromethane, ultrasonicate for 10 minutes, filter and use the filtrate.
2. Reference drug solution: Take 50.0 mg of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of indigo and indirubin and dissolve in

dichloromethane to produce a solution containing 1 mg and 0.5 mg per mL of each.

4. Procedure: Use silica gel F_{254} as the coating substance and a solution of toluene, dichloromethane, and acetone (5:4:1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 6.0% dry at 105℃ for 5 hours (General rule 6015).
2. Acid-insoluble ash: Not more than 44.0% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Indigo:
   (1) Mobile phase: A solution of methanol and water (75:25). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately 2.5 mg of indigo and place it in a 250-mL volumetric flask, dissolve in a 220 mL solution of 2% chloral hydrate in chloroform (place chloral hydrate in a dryer for 24 hours, weigh 2.0 g and dissolve in chloroform to produce a 100 mL solution, stand until the solution turbid, dehydrate with anhydrous sodium sulfate, and filter), ultrasonicate for 90 minutes, cool, make up to volume with 2% chloral hydrate in chloroform, mix well (containing 10 μg per mL).
   (3) Sample solution: Weigh accurately 50 mg of powdered sample and place it in a 250-mL volumetric flask, dissolve in a 220 mL solution of 2% chloral hydrate in chloroform, ultrasonicate for 30 minutes, cool, make up to volume with 2% chloral hydrate in chloroform, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (606 nm) and a column packing L1. The number of theoretical plates of the peak of indigo should not be less than 1,800.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Indigo (%)=25(r_U/r_S) (C_S) / (W)
   r_U: peak area of indigo of sample solution
   r_S: peak area of indigo of reference standard solution
   C_S: concentration of indigo of reference standard solution (μg/mL)
   W: weight of test sample (g) calculated with dried sample
2. Indirubin:
   (1) Mobile phase: A solution of methanol and water (70:30). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately 2.5 mg of indirubin and place it in a 50-mL volumetric flask, dissolve in a 45 mL solution of *N,N*-dimethylformamide, ultrasonicate to dissolve, cool, make up to volume with DMF, and mix well. Weigh accurately 10 mL of the mixture to a 100-mL volumetric flask, make up to volume with DMF, mix well (containing 5 μg per mL).
   (3) Sample solution: Weigh accurately 50 mg of powdered sample and place it in a 25-mL volumetric flask, dissolve in a 20 mL of *N,N*-dimethylformamide, ultrasonicate for 30 minutes, cool, make up to volume with DMF, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (292 nm) and a column packing L1. The number of theoretical plates of the peak of indirubin should not be less than 3,000.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Indirubin (%)=2.5(r_U/r_S) (C_S) / (W)
   r_U: peak area of indirubin of sample solution
   r_S: peak area of indirubin of reference standard solution
   C_S: concentration of indirubin of reference standard solution (μg/mL)
   W: weight of test sample (g) calculated with dried sample

Storage: Refrigerate or store in a cool and dry place, and protect from mold and insects.
Usage: Heat-clearing medicinal (Heat-clearing and detoxcating medicinal).
Property and flavor: Cold; salty.
Meridian tropism: Liver meridians.
Effects: Clear heat and detoxicate, cool the blood to resolve macule, clear liver and purge fire to settle fright.

Administration and dosage: 1~3 g, usually used in pills or powder, and used an appropriate amount for external use.

INULAE FLOS
旋覆花
Syuan Fu Hua / Xuan Fu Hua
Inula Flower

Inula flower is the dried capitulum of *Inula japonica* Thunb. or *Inula britannica* L. (Fam. Compositae).
It contains not less than 8.0% of dilute ethanol-soluble extractives and not less than 8.0% of water extractives.

Description: Spheroidal or oblate, 1~2 cm in diameter, loose. Involucre semisphere, consisting of five layers of bracts, outer bracts foliaceous and longer or upper part foliaceous and lower part coriaceous; inner bracts membranous. Sometimes pedicels remaining at the base of involucre, surfaces of the bracts and pedicel covered with white tomenta. Ligulate florets 1 row, yellow, about 1 cm in length, strip-shaped, mostly rolled, with 3 terminal teeth; tubular florets numerous, brownish- yellow, about 5 mm in length, with 5 terminal teeth; at the apex of ovary scattered with a row white pappi. Texture light, easily broken and separated. Odour slight; taste bitter.

Microscopic identification:

1. **Transverse section:**
   Inulae flos: Non-glandular hairs of bracts 1~8 cells, base of the multicellular ones large, and the apical cells very long; 2~3 cells seriate non-glandular hairs located in inner layers of bracts. Pappi composed of multiseriate non-glandular hairs, margin cells slightly convex. Epidermal cells of ovary contain columnar crystals of calcium oxalate, up to about 48 μm in length, 2~5 μm in diameter; non-glandular hairs of ovary biseriated, one row unicellular and the other usually bicellular, 90~220 μm in length. Glandular hairs consist in the surface of bracts and corolla, clavate, with a multicellular head, mostly biseriate, surrounded by bursa of cutin, with a multicellular stalk, biseriated. Pollen grains subspheroidal, 22~33 μm in diameter, the outer wall with spiny, about 3 μm in length, with 3 germinal pores.
2. **Powder:** Golden-yellow. Epidermal cells of bracts with walls thickened, the base densely covered with non-glandular hairs, about 300 μm in length, composed of 3~4 parenchymatous cells. Pappi mostly composed of several sclerenchymatous cells, cells slender, walls slightly thickened, the apex acute. Epidermal cells of stigma villiform protuberance, the fragments of stigma and ovary pale brownish-yellow, filled with columnar crystals of calcium oxalate, 25~40 μm in length. Glandular hairs with a multicellular head, elongated-elliptical, 120 μm in length, containing oil droplets. Pollen grains subrounded, 24 μm in diameter, the outer wall with spiny protuberance, with 3 germinal pores.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, shake for 5 minutes, stand, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane and ethyl acetate (3:2) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with *p*-anisaldehyde/H_2SO_4 TS and heat at 105°C until the spots become visible. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:

1. Loss on drying: Not more than 15.0% dry at 105°C for 5 hours (General rule 6015).
2. Total ash: Not more than 14.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 4.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.5 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a dry place, and protect from moisture.
Usage: Phlegm-dispelling medicinal (Cold-phlegm warming and resolving medicinal).
Property and flavor: Mild warm; bitter, pungent and salty.
Meridian tropism: Lung, stomach, and large intestine meridians.
Effects: Direct qi downward to move water and resolve phlegm, downbear counterflow to stop vomiting.
Administration and dosage: 3~10 g, wrap-decocted.

IRIS RHIZOMA
射干
Ye Gan / Ye Gan
Blackberry-lily Rhizome

Blackberry-lily rhizome is the dried rhizome of *Iris domestica* (L.) Goldblatt & Mabb. (*Belamcanda chinensis* (L.) DC.) (Fam. Iridaceae).
It contains not less than 12.0% of dilute ethanol-soluble extractives, not less than 12.0% of water extractives and not less than 0.1% of irisflorentin.

Description: Nodular and irregularly branched, varying in length, about 5 cm in length, 1~1.5 cm in diameter. Externally crumpled, upper part with some larger dish-shaped scars of stem, about 1.5 cm in diameter, with annular scars of leaves, occasionally apex remained with stem bases and leaf bases, the lower and lateral scattered with numerous scars of fibrous roots. Fibrous roots tenacious, about 1~2 mm in diameter, brownish-yellow, wax-luster. Texture hard, fracture granular, yellow. Odour slight; taste slightly pungent.

Microscopic identification:

1. **Transverse section:**
   Rhizome of *Iris domestica*: Cork composed of several layers of cells, covered with epidermis occasionally remained. Cortex scattered with some leaf-trace vascular bundles in collateral type; endodermis indistinct. Vascular bundles of stele amphivasal or collateral type, scattered. Parenchymatous cells contain starch granules, as well as columnar crystals of calcium oxalate, a few of cells contain oil droplets.
2. **Powder:** Yellow. Columnar crystals of calcium oxalate usually broken, intact crystals 49~315 μm in length and 15~49 μm in diameter, tetrahedral or prism-polyhedral, extremity acute or blunt. Starch granules mostly gelatinized, simple ungelatinized starch granules round or oblong, 2~14 μm in diameter, hilum pointed; compound granules composed of 2~5 components. Reticulate, bordered-pitted and spiral vessels 15~49 μm in diameter. Cork cells yellow or pale yellow, polygonal in surface view, with thin and sinuous walls. Hypodermal cells slender, relatively truncate at the both ends, a few of cells irregular in shape, 63~380 μm in length and 22~43 μm in width, wall 3~9 μm thick, occasionally slightly curved. Fibers (stem) mostly in bundles, relatively long, extremity obtuse-rounded or truncated, 9~43 μm in diameter, wall about 3 μm thick, lignified, pit apertures of bordered-pits obliquely slit-shaped or V-shaped.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and make up the filtrate to 10 mL.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, methanol, and water (10:2:1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 254 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:

1. Loss on drying: Not more than 10.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 8.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).
9. Aflatoxins
   (1) Aflatoxins (sum of B_1, B_2, G_1 and G_2): Not more than 10.0 ppb (General rule 6307).
   (2) Aflatoxin B_1: Not more than 5.0 ppb (General rule 6307).

Assay:

1. Irisflorentin:
   (1) Mobile phase: A solution of methanol and 0.2% phosphoric acid (53:47). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of irisflorentin and dissolve in methanol to produce a solution containing 10 μg per mL.
   (3) Sample solution: Weigh accurately 0.1 g of powdered sample and place it in a conical flask with a stopper, add accurately 25 mL of methanol, weigh, heat under reflux for 1 hour, cool, weigh again, replenish the loss of the weight with methanol, mix well, filter and use the filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (266 nm) and a column packing L1. The number of theoretical plates of the peak of irisflorentin should not be less than 8,000.
   (5) Procedure: Inject accurately 10 μL of the reference standard solution and sample

solution into the liquid chromatography apparatus, and calculate the content.

Irisflorentin (%)=0.0025(r_U/r_S) (C_S) / (W)

r_U: peak area of irisflorentin of sample solution

r_S: peak area of irisflorentin of reference standard solution

C_S: concentration of irisflorentin of reference standard solution (μg/mL)

W: weight of test sample (g) calculated with dried sample

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place.
Usage: Heat-clearing medicinal (Heat-clearing and detoxcating medicinal).
Property and flavor: Cold; bitter.
Meridian tropism: Lung meridians.
Effects: Clear heat and detoxicate, dispel phlegm and soothe the throat.
Administration and dosage: 3~10 g.
Precaution and warning: Use cautiously during pregnancy.

ISATIDIS FOLIUM
大青葉
Da Cing Ye / Da Qing Ye
Indigowoad Leaf

Indigowoad leaf is the dried leaf of *Isatis tinctoria* L. (*Isatis indigotica* Fortune) (Fam. Cruciferae).
It contains not less than 8.0% of dilute ethanol-soluble extractives, not less than 10.0% of water extractives and not less than 0.02% of indirubin.

Description: Mostly crumpled, occasionally broken, oblong-oblanceolate or oblong as whole, 5~20 cm in length, 2~6 cm in width, margin entire or slightly undulate, dark brownish-green, base attenuate and decurrent into the petiole appearing wing-shaped, petioles 4~10 cm in length. Texture fragile, easily broken. Odour aromatic; taste slightly sour, bitter and astringent.

Microscopic identification:

1. **Transverse section**:
   Leaf of *Isatis tinctoria*: Upper epidermis covered with cuticle. Palisade tissue indistinct and slightly oblong in shape. Vascular bundles collateral, 3~7 in number. Secretory cells containing myrosinase occurred in parenchymatous tissue of mesophyll and midrib, cells suborbicular, 10~40 μm in diameter, smaller than parenchymatous cells. Pigment bodies brownish-black, scattered in the secretory cells. In surface view, upper epidermal cells covered with cuticle, anticlinal walls straight; anticlinal walls of lower epidermal cells slightly sinuous and moniliform. Stomata anomocytic, with 3~4 subsidiary cells, present in both upper and lower epidermis.
2. **Powder:** Dark grayish-brown. Epidermal cells elongated-polygonal, subrectangular, subsquare or long strip-shaped in surface view, anticlinal walls relatively straight or slightly curved, moniliform thickened; lower epidermal cells with more stomata, anisocytic, with 3~4 subsidiary cells, occasionally 2~3 stomata aggregated with same subsidiary cells. Collenchymatous cells long strip-shaped in longitudinal view, up to 14 μm thick at the corner. Indigo crystals blue, existing in mesophyll cells, occasionally found in epidermal cells, fine granular-shaped or flaky, usually aggregated. Hesperidin-like crystals existed in mesophyll or epidermal cells, subrounded or irregular in shape, occasionally clustered needle-like, 3~22 μm in diameter. Reticulate and spiral vessels 7~54 μm in diameter.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 0.5 g of powdered sample to 20 mL of dichloromethane, heat under reflux for 1 hour, filter, evaporate the filtrate to dryness, and dissolve the residue in 1 mL of dichloromethane.
2. Reference drug solution: Take 0.5 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of indigo and indirubin and dissolve in dichloromethane to produce a solution containing 1.0 mg per mL of each.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of toluene, dichloromethane, and acetone (5:4:1) as the developing solvent. Apply 5~10 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Assay:

1. Indirubin:
   (1) Mobile phase: A solution of methanol and water (75:25). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of indirubin and dissolve in methanol to produce a solution containing 2 μg per mL of each.
   (3) Sample solution: Weigh accurately 0.25 g of powdered sample, transfer to a Soxhlet extractor, and add appropriate quantity of chloroform to macerate for 15 hours, heat

under reflux to the extract colorless and the solvent to dryness, dissolve the residue in methanol and transfer to a 100-mL volumetric flask, make up to volume with methanol, mix well, filter and use the filtrate.

(4) Chromatographic system: The liquid chromatography is equipped with an UV detector (289 nm) and a column packing L1. The number of theoretical plates of the peak of indirubin should not be less than 4,000.

(5) Procedure: Inject accurately 20 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Indirubin (%)=0.01 (r_U/r_S) (C_S) / (W)

r_U: peak area of indirubin of sample solution

r_S: peak area of indirubin of reference standard solution

C_S: concentration of indirubin of reference standard solution (μg/mL)

W: weight of test sample (g) calculated with dried sample

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Impurities and other requirements:

1. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
2. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
3. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
4. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
5. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Storage: Refrigerate or store in a cool and dry place, and protect from mold.
Usage: Heat-clearing medicinal (Heat-clearing and detoxcating medicinal).
Property and flavor: Cold; bitter.
Meridian tropism: Heart, stomach meridians.
Effects: Clear heat and detoxicate, cool the blood to resolve macule.
Administration and dosage: 9~15 g.

ISATIDIS RADIX
北板藍根
Bei Ban Lan Gen / Bei Ban Lan Gen
Indigowoad Root

Indigowoad root is the dried root of *Isatis tinctoria* L. (*Isatis indigotica* Fortune) (Fam. Cruciferae).

It contains not less than 24.0% of dilute ethanol-soluble extractives, not less than 24.0% of water extractives and not less than 0.02% of epigoitrin.

Description: Cylindrical, slightly tortuous, 10~20 cm in length, 0.5~1 cm in diameter. Externally pale grayish-yellow or pale brownish-yellow, with longitudinally wrinkles, transversely lenticels, and rootlet scars. Root stock slightly expanded, exhibiting dark green or dark brown petiole-bases arranged in whorls, and dense tubercles. Texture compact and soft, fracture yellowish-white in bark and yellow in wood. Odour slight; taste sweet then bitter and astringent.

Microscopic identification:
Transverse section:
Root of *Isatis tinctoria*: Cork composed of several layers of cells. Cortex narrow. Phloem broad, with distinct rays. Cambium present as a ring. Xylem vessels yellow, subrounded, about 80 μm in diameter; xylem fibers also exist. Parenchymatous cells contain starch granules.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of boiling water, ultrasonicate for 1 hour, centrifuge, filter, evaporate the supernatant to dryness, and dissolve the residue in 1 mL of methanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of toluene and ethyl acetate (1:1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 254 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:

1. Loss on drying: Not more than 12.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 8.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Epigoitrin:
   (1) Mobile phase: A solution of methanol and 0.01% phosphoric acid (7:93). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of epigoitrin, and dissolve in water to produce a solution containing 10 μg per mL.
   (3) Sample solution: Weigh accurately 1.0 g of powdered sample and place it in a 100-mL conical flask with a stopper, then add accurately 25 mL of water, heat under reflux for 60 minutes, cool, transfer to a 50-mL centrifuge tube, centrifuge for 10 minutes, filter with filter paper. Repeat the extraction of the residue one more time. Combine the extracts, transfer to a 50 mL volumetric flask, make up to volume with water, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (240 nm) and a column packing L1. The column temperature is maintained at 23 ± 4°C. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of epigoitrin should not be less than 5,000.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Epigoitrin: (%)= 0.005(r_U/r_S) (C_S) / (W)
   r_U: peak area of epigoitrin of sample solution
   r_S: peak area of epigoitrin of reference standard solution
   C_S: concentration of epigoitrin of reference standard solution (μg/mL)
   W: weight of test sample (g) calculated with dried sample
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from mold and insects.
Usage: Heat-clearing medicinal (Heat-clearing and detoxicating medicinal).
Property and flavor: Cold; bitter.
Meridian tropism: Heart, stomach meridians.
Effects: Clear heat and detoxicate, cool the blood to soothe throat.
Administration and dosage: 9~15 g.

JUJUBAE FRUCTUS
大棗
Da Zao / Da Zao
Jujube Fruit

Jujube fruit is the dried ripe fruit of *Ziziphus jujuba* Mill. (Fam. Rhamnaceae).
It contains not less than 50.0% of dilute ethanol-soluble extractives and not less than 50.0% of water extractives.

Description: Ellipsoidal or spheroidal, 2~3.5 cm in length, 1.5~2.5 cm in diameter. Externally dark red or purplish-red, slightly lustrous, with irregular wrinkles. Apex dented, with a small protuberant scar of style; base dented, with a short fruit stalk or its round scar. Exocarp thin, mesocarp brownish-yellow or pale brown, fleshly, soft, sugary and oily. Kern fusiform, both ends acute. Texture hard. Odour slightly aromatic; taste sweet, viscous on chewing.

Microscopic identification:
1. **Transverse section:**
   Pulp of *Ziziphus jujuba*: The outermost layer of exocarp composed of tangentially elongated epidermal cells, lumen filled with brownish-red contents with granules, covered by 5~7.5 μm thick cuticles; inner side of epidermis composed of 4~6 layers of collenchymatous cells, usually containing colorless translucent masses. Mesocarp composed of subrounded parenchymatous cells, with large intercellular spaces, some cells mucilage cavity-shaped, scattered irregularly with small vascular bundles; parenchymatous cells contain granular masses, prisms and clusters of calcium oxalate.
2. **Powder:** Brownish-yellow. Epidermal cells of exocarp brownish-red in surface view, rounded-polygonal, about 20 μm in diameter, the longer ones, up to 45 μm in diameter, mostly containing 1 to several subspheroidal granules.Parenchymatous cells of mesocarp contain prisms and clusters of calcium oxalate; prisms of calcium oxalate 3~50 μm in diameter; each cluster of calcium oxalate usually covered with cellulose membrane, 10~38 μm in diameter. Occasionally with large anomocytic stomata, vessels mostly spiral, very small, 5~15 μm in diameter.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of oleanolic acid and betulinic acid and dissolve in methanol to produce a solution containing 1.0 mg per mL of each.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of toluene, ethyl acetate,

and glacial acetic acid (14:4:0.5) as the developing solvent. Apply 5 μL of each of the sample solution and reference drug solution and 2 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Total ash: Not more than 2.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
3. Sulfur dioxide: Not more than 400 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).
8. Pesticide residues:
   (1) The total DDT content: Not more than 0.2 ppm (General rule 6305).
   (2) The total BHC content: Not more than 0.2 ppm (General rule 6305).
9. Aflatoxins
   (1) Aflatoxins (sum of B_1, B_2, G_1 and G_2): Not more than 10.0 ppb (General rule 6307).
   (2) Aflatoxin B_1: Not more than 5.0 ppb (General rule 6307).

Assay:

1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from mold and insects.
Usage: Tonifying and replenishing medicinal (Qi-tonifying medicinal).
Property and flavor: Warm; sweet.
Meridian tropism: Spleen stomach meridians.
Effects: Tonify middle and replenish qi, nourish blood and tranquilize.
Administration and dosage: 6~30 g.

JUNCI MEDULLA
燈心草
Deng Sin Cao / Deng Xin Cao
Rush Pith

Rush pith is the dried pith in the stem of *Juncus effusus* L. (Fam. Juncaceae).
It contains not less than 2.0% of dilute ethanol-soluble extractives and not less than 2.0% of water extractives.

Description: Slender cylindrical, up to 90 cm in length, 0.1~0.3 cm in diameter. Externally white or pale yellowish-white, with raised fine longitudinal striations and spongy fine pores. Texture light and soft, slightly tenacious, easily broken, fracture white. Odourless; tasteless.

Microscopic identification:

1. **Transverse section:**
   Pith in the stem of *Juncus effusus*: All composed of ventilate parenchyma tissue. The parenchymatous cells stellate in shape, with several branches, 8~60 μm in length, 7~20 μm in diameter, wall about 1.7 μm thick, each cell branch is connected with branches of other stellate cells to form air cavities, mostly in triangular shape, occasionally subquadrilateral.
2. **Powder:** Off-white. All composed of stellate parenchymatous cells, connected with branches of other stellate cells to form air cavities mostly in large triangular shape or subquadrilateral, branches 4~8, 5~51 μm in length, 5~12 μm in width, wall slightly thickened, fine pits occasionally observed, occasionally 1~2 moniliform thickened.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 30 mL of methanol, heat under reflux for 1 hour, cool, filter, evaporate the filtrate to dryness, wash the residue with 2 mL of ethyl ether, discard the ethyl ether solutions, and dissolve the residue in 1 mL of methanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of petroleum ether (30~60°C) and ethyl acetate (10:7) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% phosphomolybdic acid/EtOH TS and heat at 105°C until the spots become visible. Examine under the ultraviolet light at 254 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:
1. Loss on drying: Not more than 12.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 3.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place, and protect from insects.
Usage: Dampness-dispelling medicinal (Dampness-draining diuretic medicinal).
Property and flavor: Mild cold; sweet and bland.
Meridian tropism: Heart, lung, and small intestine meridians.
Effects: Induce diuresis and relieve strangury, clear heart to eliminate vexation.
Administration and dosage: 1~3 g.

KAEMPFERIAE RHIZOMA
山柰
Shan Nai / Shan Nai
Kaempferia Rhizome

Kaempferia rhizome is the dried rhizome of *Kaempferia galanga* L. (Fam. Zingiberaceae).
It contains not less than 9.0% of dilute ethanol-soluble extractives, not less than 10.0% of water extractives, not less than 4.5% (v/w) of volatile oil and not less than 1.5% of ethyl *p*-methoxycinnamate.

Description: Subrounded, 1.5~2 cm in diameter, 2~6 mm thick. Externally yellowish-brown, shrunken, with scars of roots and scale leaves and annulations. Texture fragile, easily broken, fracture grayish-white, starchy, smooth and delicate, occasionally with distinct endodermis, stele slightly protuberant than cortex. Odour aromatic; taste pungent.

Microscopic identification:
1. **Transverse section:**
Rhizome of *Kaempferia galanga*: Epidermal cells composed of 1~2 layers of cells, subrectangular or subsquare, covered with cuticle, mostly broken, containing reddish-brown contents. Rhytidome composed of 12~15 layers of cells, rectangular, subrectangular or subsquare. Cortex broad, cells rectangular, flat-rectangular, subsquare, subrounded or subpolygonal, with distinct intercellular spaces, containing numerous starch granules, occasionally with oil cells and yellowish-brown masses. Endodermis composed of 1 layer of distinct cells, rectangular, subrectangular or subsquare. Vascular bundles in a ring, phloem and xylem arranged alternately, respectively. Bark cells relatively small, rectangular, subrectangular, subsquare, subpolygonal or subrounded. Xylem mainly composed of spiral, scalariform or annular vessels; vessels singly scattered or linked by several, 16~38 μm in diameter, extremely long, a few vessels developing towards the pith. Pith broad, occupying 1/2~2/3 portion of the rhizome, composed of large parenchymatous cells, subrounded, suboblong, rectangular, subrectangular, subsquare or subpolygonal, with distinct intercellular spaces, containing abundant starch granules; occasionally with oil cells and yellowish-brown masses.
2. **Powder:** Pale yellowish-brown. In surface view, cork cells reddish-brown, subrectangular, subsquare or subpolygonal, with slightly lignified and thickened walls, containing reddish-brown masses. Parenchymatous cells of cortex subrectangular, subsquare or rectangular, with intercellular spaces distinct, contain abundant starch granules with large oil cells with pale yellow or pale reddish-brown oil droplets, and cells containing reddish-brown masses. Vessels extremely long, 14~76 μm in diameter, mainly spiral, scalariform or annular. Starch granules abundant, mainly individual, spheroid, ellipsoidal or subtriangular, mostly flattened, 4~33 μm in diameter, hilum and striations indistinct. Colored masses subrounded, ellip-rectangular or irregular, yellow or yellowish-brown.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 10 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of ethyl *p*-methoxycinnamate and dissolve in methanol to produce a solution containing 2.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane and ethyl acetate (5:1) as the developing solvent. Apply 1 μL of each of the sample solution and reference drug solution and 2 μL of the reference standard solution

to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 254 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Total ash: Not more than 7.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
3. Sulfur dioxide: Not more than 400 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Ethyl *p*-methoxycinnamate:
   (1) Mobile phase: A solution of acetonitrile and water (55:45). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of ethyl *p*-methoxycinnamate, and dissolve in methanol to produce a solution containing 50 μg per mL.
   (3) Sample solution: Weigh accurately 0.1 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 20 mL of 50% methanol, ultrasonicate for 30 minutes, filter to a 50-mL volumetric flask with filter paper. Repeat the extraction of the residue one more time. Combine the extracts and make up to volume with 50% methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (308 nm) and a column packing L1. The column temperature is maintained at 25℃. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of nüzhenide should not be less than 6,000.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   Ethyl *p*-methoxycinnamate (%) = 0.005 (r_U/r_S) (C_S)/(W)

   r_U: peak area of ethyl *p*-methoxycinnamate of sample solution
   r_S: peak area of ethyl *p*-methoxycinnamate of reference standard solution
   C_S: concentration of ethyl *p*-methoxycinnamate of reference standard solution (μg/mL)
   W: weight of test sample (g) calculated with dried sample
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).
4. Volatile oil: Carry out the method for determination of volatile oil (General rule 6013).

Storage: Store in a cool and dry place.
Usage: Interior-warming medicinal.
Property and flavor: Warm; pungent.
Meridian tropism: Stomach meridians.
Effects: Move qi and warm the middle, promote digestion, relieve pain.
Administration and dosage: 6~9 g, 1~3 g for powdering.

KAKI CALYX
柿蒂
Shih Di / Shi Di
Persimmon Calyx and Receptacle

Persimmon calyx and receptacle is the dried persistent calyx of *Diospyros kaki* L.f. (Fam. Ebenaceae).
It contains not less than 5.0% of dilute ethanol-soluble extractives, not less than 5.0% of water extractives and not less than 0.03% of gallic acid.

Description: Dish shaped, 1.5~2.5 cm in diameter, 1~4 mm thick. Outer surface reddish-brown, with yellowish-brown tomenta, lustrous, inner surface yellowish-brown and pubescent, arranged in radial. Middle part relatively thick, 4-lobed, lobes broadly triangular, 1~1.5 cm in length, about 2 cm in width, frequently reflexed, with fruit stalk or its scars in the center. Texture hard and fragile. Odour slight; taste astringent.

Microscopic identification:
Powder: Brown. Epidermal cells polygonal or subsquare. Unicellular non-glandular hairs 150~300 μm in length, 20~25 μm in diameter, wall thick, containing brown contents. Glandular hairs occasionally visible, with head 2~3 celled, about 30 μm in diameter, containing reddish-brown contents. Stone cells mostly branched, 80~150 μm in diameter, pits and pit canals distinct. Prisms of calcium oxalate 5~25 μm in diameter.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 5 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of gallic acid and dissolve in methanol to produce a solution containing 0.2 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of toluene, ethyl acetate, and formic acid (5:4:1) as the developing solvent. Apply 5 μL of the sample solution and reference drug solution and 2 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 254 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 13.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 9.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Gallic acid:
   (1) Mobile phase: A solution of methanol and 0.1% phosphoric acid (7:93). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of gallic acid and dissolve in water to produce a solution containing 10 μg per mL.
   (3) Sample solution: Weigh accurately 1.0 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 25 mL of 75% methanol, vortex oscillation for 30 seconds, ultrasonicate for 30 minutes. Centrifuge for 15 minutes, filter the supernatant. Repeat the extraction of the residue one more time. Combine the supernatant, transfer to a 50-mL volumetric flask, make up to volume with 75% methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (217 nm) and a column packing L1. The column temperature is maintained at room temperature. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of gallic acid should not be less than 4,000.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Gallic acid (%)=0.005(r_U/r_S) (C_S) / (W)
   r_U: peak area of gallic acid of sample solution
   r_S: peak area of gallic acid of reference standard solution
   C_S: concentration of gallic acid of reference standard solution (μg/mL)
   W: weight of test sample (g) calculated with dried sample
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place, and protect from moisture.
Usage: Qi-regulating medicinal.
Property and flavor: Neutral; bitter and astringent.
Meridian tropism: Stomach meridians.
Effects: Direct qi downward to relieve hiccup.
Administration and dosage: 4.5~12 g.

KANSUI RADIX
甘遂
Gan Suei / Gan Sui
Kansui Root

Kansui root is the dried root tuber of *Euphorbia kansui* S.L.Liou ex S.B.Ho (Fam. Euphorbiaceae).
It contains not less than 14.0% of dilute ethanol-soluble extractives and not less than 12.0% of water extractives.

Description: Hypertrophy root tuber long fusiform or oblong, tapered at both ends, constricted as moniliform in the middle, 2~10 cm in length, 0.6~1.5 cm in diameter, externally yellowish-white, often with brownish-red patches of cork adhering, especially in constricted place with several fibrous roots scars. Slender root tuber slightly rod-shaped and curved, 3~5 mm in diameter, almost all brownish-red of cork remain and distinct longitudinal groove and several long transverse lenticels. Texture light, fracture bark thick and whitish, wood pale yellow and with slightly radial-striated. Odour slight; taste slightly sweetish and pungent, irritant.

Microscopic identification:

1. **Transverse section:**
   Root tuber of *Euphorbia kansui*: The outermost epidermis covered with cuticle, 1 layer, mostly broken, rectangular or subsquare. Phelloderm composed of 6~9 layers of cells, rectangular, subrectangular or subsquare. Cortex slightly narrow, composed of 5~8 layers of cells, rectangular to flat-rectangular, scattered with sclerenchyma cells, subtriangular, subrectangular, subsquare or irregular, slightly lignified or unlignified, 66~110 μm in length, 24~26 μm in diameter. Phloem broad, occupying about 2/3 portion of the root, mainly composed of parenchymatous cells filling with starch granules, rectangular, subrectangular, subsquare, subpolygonal or subrounded, with distinct intercellular spaces; occasionally non-articulated laticiferous tubes containing yellow secretions present; cells gradually small near cambium, with small cribrose (sieve) cells present. Cambium in a ring, slightly distinct, 3~5 layered, rectangular to flat-rectangular shaped. Xylem slightly broad, occupying about 1/3 portion of the root, composed of, xylem parenchymatous cells of vessels and xylem fibers; vessels slightly large, singly scattered or linked by several, arranged interruptedly and radially, 18~65 μm in diameter, mainly bordered-pitted and pitted, cells subrounded, subpolygonal, subovate or subsquare, occasionally with unlignified fibers adjacent to vessels. Rays relatively broad, growing to phloem, composed of parenchymatous cells, subrectangular, subsquare, subpolygonal or subrounded, containing numerous starch granules. Primary xylem existed at the center, composed of vessels and small parenchymatous cells.
2. **Powder:** Yellowish-white. Simple granules subrounded or elliptical, 4~36 μm in diameter; hilum stellated, cruciate, Y-shaped, slit-shaped or dotted, the larger one with distinct striations; compound granules numerous, composed of 2~14 components, rare semi-compound granules present. Sclerenchyma cells subpolygonal, subtriangular, subsquare, conchoidal or irregular, 36~208 μm in length, 18~56 μm in diameter, walls thickened unevenly, unlignified, pit canals relatively broad. Bordered-pitted vessels, 13~79 μm in diameter, vessel elements generally short, some irregular in shape and cross-overlapped. Xylem fibers slender, edge uneven, oblique, acuminate, obtusely rounded or short branches at the end, some twisted, 15~27 μm in diameter, walls slightly thickened, unlignified, with sparse oblique simple pits. Non-articulated laticiferous tubes 11~18 μm in diameter.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of ethanol, ultrasonicate for 30 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 1 mL of ethanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of euphadienol and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of petroleum ether (30~60℃) and acetone (5:1) as the developing solvent. Apply 2 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS, and heat at 105℃ until the spots become visible. Examine under visible light and ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 14.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 5.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place, and protect from insects.

Usage: Purgative medicinal (Offensive purgative and water-expelling medicinal).

Property and flavor: Cold; bitter; toxic.

Meridian tropism: Lung, kidney, and large intestine meridians.

Effects: Drain water and expel rheum, remove swelling and disperse stagnation.

Administration and dosage: 0.5~1.5 g; used an appropriate amount for external use.

Precaution and warning: Unprocessed one toxic, store with caution and processed before application. Forbit to use during pregnancy. Incompatible with Glycyrrhizae Radix et Rhizoma.

KOCHIAE FRUCTUS
地膚子
Di Fu Zih / Di Fu Zi
Belvedere Fruit

Belvedere fruit is the dried ripe fruit of *Kochia scoparia* (L.) Schrad. (Fam. Chenopodiaceae).
It contains not less than 10.0% of dilute ethanol-soluble extractives and not less than 10.0% of water extractives.

Description: Oblate-spheroidal, five-pointed star shape, 0.1~0.3 cm in diameter, surrounded by a persistent perianth. Externally grayish-green or pale brown, with 5 triangular membranous winglets, the center of dorsal surface with a protuberance of pointed fruit stalk scar and 5~10 radial veins; membranous pericarp present when the perianth stripped, translucent, with dot striations. Seed 1, flattened-ovate, about 0.1 cm in length, black. Odour slight; taste slightly bitter.

Microscopic identification:

1. **Transverse section:**
   Fruit of *Kochia scoparia*: Persistent perianth composed of 1 layer of parenchymatous cells, stone cells present occasionally. Pericarp composed of 1 layer of U-shaped sclerenchymatous cells, containing numerous small prisms of calcium oxalate. Testa composed of 1 layer of cells, yellowish-brown. Perisperm composed of polygonal parenchymatous cells, filled with minute starch granules. Radicle relatively small, composed of parenchymatous cells, filled with aleurone grains. Cotyledons relatively large, the cells containing aleurone grains and oil droplets. Epicotyl located at the center of the cotyledons.
2. **Powder:** Grayish-green or yellowish-brown. Non-glandular hairs composed of 2~3 cells, occasionally walls warty. Walls of stone cells slightly thickened, pits rarely present; some stone cells short fiber-like, 65~150 μm in length, walls relatively thickened and lignified. Epidermal cells of persistent perianth polygonal in surface view; stomata subrounded and yellowish-brown, anomocytic, with 4~5 subsidiary cells. Anticlinal walls of pericarp cells slightly undulate, cells filled with small prisms of calcium oxalate, 3~13 μm in diameter, occasionally with clusters. Testa cells yellowish-brown, slightly rectangular or square, mostly shrunken.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Weigh accurately 1.0 g of powdered sample, transfer to a 10-mL volumetric flask, dissolve in 10 mL of methanol, ultrasonicate for 30 minutes, cool and filter, and add methanol to volume.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-butanol, glacial acetic acid, and water (7:1:2) as the developing solvent. Apply 10 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with *p*-anisaldehyde/H_2SO_4 TS and heat at 105℃ until the spots become visible. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:

1. Loss on drying: Not more than 13.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 10.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 3.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place, and protect from insects.
Usage: Dampness-dispelling medicinal (Dampness-draining diuretic medicinal).
Property and flavor: Cold; pungent and bitter.
Meridian tropism: Kidney and bladder meridians.
Effects: Clear heat and induce diuresis, dispel wind and relieve itching.
Administration and dosage: 9~15 g; used an appropriate amount for external use. It can be decocted for fuming-washing therapy.

LABLAB SEMEN ALBUM
白扁豆
Bai Bian Dou / Bai Bian Dou
White Hyacinth Bean

White hyacinth bean is the dried ripe seed of *Lablab purpureus* (L.) Sweet (*Dolichos lablab* L.) (Fam. Leguminosae).

It contains not less than 8.0% of dilute ethanol-soluble extractives and not less than 9.0% of water extractives.

Description: Flattened-ellipsoidal, flattened-ovate or reniform, 8~13 mm in length, 6~9 mm in width, 4~6 mm thick. Externally yellowish-white or pale yellow, smooth, slightly lustrous, occasionally scattered with brownish-black dots, with a white and protuberant caruncle at the edge of one side. Caruncle crescent-shaped, 7~10 mm in length, commonly known as "Bai Mei". Sunken hilum present after the removal of caruncle, micropyle near the hilum, raphe short occurring on the other side. Testa thin and fragile, 2 cotyledons, plump. Odor slight; taste weak, bean-like on chewing.

Microscopic identification:

1. **Transverse section:**
   Seed of *Lablab purpureus*: Epidermal cells of testa composed of 1 layer of palisade cells, 2 layers at the hilum, lateral walls gradually thickened from inner to outer; brace cells 1 layered, 3~5 layers at the hilum, dumbbell-shaped; parenchymatous cells composed of more than 10 layers of cells, mostly elongated tangentially, with obliterated cells at the inner side. Epidermal cells of cotyledon subsquare; mesophyllous cells contain numerous starch granules. Strophiole existed at the outer side of the palisade cells of hilum, cells subrounded or irregularly long cylindrical, containing numerous starch granules; inside showing tracheid, with reticulate-thickened walls; stellated tissue existed on the both sides of tracheid, cells stellated, with large intercellular spaces.
2. **Powder:** Yellowish-white. Simple granules subrounded, ovate, wide-ovate, reniform, circularly triangular or irregular, 3~39 μm in diameter, up to 46 μm in length. In sectional view, palisade cells of testa 26~214 μm in length, 5~6 μm in width, external walls extremely thickened, with many longitudinal ridges, lateral walls thickened on the upper part, slightly thickened on the middle and lower parts, internal walls thin with a light line near the margin; on the top view, the cells subpolygonal, showing the extremely thick walls and fine pit canals; in the bottom view, the cells subrounded with thick walls and large lumina. Brace cells of testa present in groups or individually scattered, dumbbell-shaped in the lateral view, 20~125 μm in length, with thin inner and outer walls, up to 14 μm thick at the middle part of lateral walls; subrounded or ovate on the surface view, 20~68 μm in diameter, with annularly thickened walls of the middle part of lateral walls, lumina distinct. Strophiole cells palisade-shaped, suboblong or irregular, up to 280 μm in length, 9~70 μm in diameter, walls slightly thickened, occasionally with tangentially small pits, lumen filled with small starch granules. Asteroid cells with wide and short branches, walls slightly thickened, lumen contains brown contents. Cotyledon cells also present.

Identification:
Check steroid: Evaporate the 70% ethanol extract to dryness, add drops of acetic anhydride-sulfuric acid, a yellow color is produced and turns to red, purplish-red and dark green gradually.

Impurities and other requirements:

1. Loss on drying: Not more than 12.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 4.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from moisture and insects.
Usage: Tonifying and replenishing medicinal (Qi-tonifying medicinal).
Property and flavor: Mild warm; sweet.
Meridian tropism: Spleen and stomach meridians.
Effects: Fortify spleen and transform dampness, harmonizes the center disperse summerheat.
Administration and dosage: 9~15 g.

LAMINARIAE THALLUS
ECKLONIAE THALLUS
昆布
Kun Bu / Kun Bu
Kelp

Kelp is the dried thalline of *Laminaria japonica* Aresch. (Fam. Laminariaceae) or *Ecklonia kurome* Okam. (Fam. Alariaceae).
Laminaria japonica contains not less than 4.0% of dilute ethanol-soluble extractives, not less than 5.0% of water extractives and not less than 0.35% of iodine. *Ecklonia kurome* contains not less than 0.2% of iodine .

Description:

1. Thalli of *Laminaria japonica*: Slender strap, entire, often crumpled and winded up into masses or bundles. Blackish-brown, greenish-brown or

brownish-green, externally with white frost-like powder. After soaking in water, swollen into a flattened long strap, 50~150 cm in length, 10~40 cm in width, relatively thick in the center, thinner and undulate on the edges, coriaceous, externally slimy, remained with compressed-cylindrical stalk, fracture fibrous. Odour seaweed-like; taste salty.

2. Thalli of *Ecklonia kurome*: Crumpled and winded up into irregular masses. Black, externally with white frost-like powder, thin. After soaking in water, swollen into a flattened phylloid, 15~26 cm in length, 15~26 cm in width, about 1.6 mm thick, pinnatipartite at the both sides, lobes long-ligulate, margin serrate or entire. Texture soft and smooth. Odour seaweed-like; taste salty.

Identification:

1. Thick, swollen on soaking in water, surface smooth and viscous with transparent mucilage. When twisted by fingers, *Laminaria japonica* is not laminated but *Ecklonia kurome*.
2. Macerate about 10.0 g of powdered sample in 200 mL of distilled water for 4 hours, filter, and evaporate the filtrate to about 100 mL. Take 2~3 mL of the evaporated solution, add 1 drop of nitric acid and several drops of silver nitrate, a yellow colloidal precipitate is produced and slightly soluble in ammonia but nitric acid.

Impurities and other requirements:

Laminariae Thallus

1. Loss on drying: Not more than 18.0% of thalline of *Laminaria japonica* dry at 105℃ for 5 hours (General rule 6015).
2. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
3. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
4. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Eckloniae Thallus

5. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Iodine:
   (1) Sample solution: Macerate about 10.0 g of the small pieces to a crucible, ignite gently, keep for 10 minutes whenever the temperature raise to 100℃, and keep for 40 minutes at 400~500℃. Cool and place the residue in a beaker. Add 100 mL of water, boil for about 5 minutes and filter. Treat the residue with further 2 quantities of 100 mL of water, filter and combine the filtrates, wash the residue with 3 quantities of hot water, combine the washings and use the filtrate, and evaporate to about 80 mL. Cool, transfer to a 100-mL volumetric flask and make up to volume with water.
   (2) Procedure: Transfer accurately 5 mL to a conical flask with stopper, add 50 mL of water and 2 drops of methyl red, add drops of dilute sulfuric acid solution until the solution color turn to red. Add 5 mL of freshly prepared bromine, heat to boil, add 5 mL of a 20% solution of sodium formate along the flask wall, and heat for 10~15 minutes again. Wash the flask wall with hot water, cool, add 5 mL of dilute sulfuric acid and 5 mL of a 15% solution of potassium iodide, titrate immediately with sodium thiosulfate (0.01 M) is equivalent to 0.2215 mg of iodine.

   Iodine（%）＝0.423 (*V*) / (*W*)

   V: The volume of sodium sulfate titrant (0.01 M) (mL)

   W : weight of test sample (g) calculated with dried sample
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place.

Usage: Phlegm-dispelling medicinal (Heat-phlegm clearing and resolving medicinal).

Property and flavor: Cold; salty.

Meridian tropism: Liver, stomach, and kidney meridians.

Effects: Eliminate phlegm and soften hardness, induce diuresis to alleviate edema.

Administration and dosage: 6~12 g for *Laminaria japonica*; 3~10 g for *Ecklonia kurome*.

LEONURI FRUCTUS
茺蔚子
Chong Wei Zih / Ching Wei Zi
Motherwort Fruit

Motherwort fruit is the dried ripe fruit of *Leonurus japonicus* Houtt. (Fam. Labiatae).

It contains not less than 4.0% of dilute ethanol-soluble extractives and not less than 5.0% of water extractives.

Description: Trihedral, one side slightly broad, the other side attenuate, with dented scar of fruit stalk, 0.2~0.3 cm in length, 0.15 cm in width. Externally grayish-brown, with dark-colored maculates, dull. Pericarp thin, brown, endosperm and cotyledon grayish-white, oily. Odour slight; taste bitter.

Microscopic identification:

1. **Transverse section:**
   Fruit of *Leonurus japonicus*: Pericarp composed of 1 row of pale yellow and elongated radially cells, mesocarp composed of 2~3 rows of subsquare parenchymatous cells, cells contain prisms of calcium oxalate near endocarp. Endocarp hard, composed of 1 row of radially elongated and subovate or subsquare stone cells. Epidermal cells of testa subsquare, wall slightly thickened, lumen containing pale yellowish-brown contents. Endosperm and cotyledon cells contain aleurone grains and fatty oil.
2. **Powder:** Brownish-yellow. Pericarp cells elongated radially in sectional view, varying in length, forming numerous protuberant ridges with yellow reticulated cells in the center, walls unlignified and with lateral pits; subpolygonal in surface view, wall slightly thickened with strip-horny striations. Mesocarp cells subpolygonal in surface view, with thin and sinuous walls. Inner walls of endocarp extremely thickened, with pit canals, outer walls thin, lumen containing prisms of subsquare or subrhombic calcium oxalate, about 18 μm in diameter.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 5.0 g of powdered sample to 20.0 mL of methanol, ultrasonicate for 1 hour, filter and use the filtrate.
2. Reference drug solution: Take 5.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of stachydrine hydrochloride and dissolve in ethanol to produce a solution containing 5.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-butanol, hydrochloric acid, and water (4:1:0.5) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with the modified Dragendorff's reagent until the spots become visible, and examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 8.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 10.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 4.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place.
Usage: Blood-regulating medicinal (Blood-activating and stasis-dispelling medicinal).
Property and flavor: Mild cold; pungent and bitter.
Meridian tropism: Pericardium and liver meridians.
Effects: Invigorate blood to regulate menstruation, clear liver to improve vision.
Administration and dosage: 4.5~11.5 g.
Precaution and warning: Used with caution in mydriasis.

LEONURI HERBA
益母草
Yi Mu Cao / Yi Mu Cao
Motherwort Herb

Motherwort herb is the dried aerial part of *Leonurus japonicus* Houtt. (Fam. Labiatae).
It contains not less than 8.0% of dilute ethanol-soluble extractives and not less than 8.0% of water extractives.

Description: Stems quadrangular, branched less, pubescent. Leaves pubescent, opposite, pinnatifid, mostly 3-lobed, lobe narrowly, upper surface green, lower surface whitish, petioled. Inflorescences verticillate cymes, axillary, bracteoles subulate, calyx 5-lobed, corolla 2-lipped, white or reddish-purple, lower lip 3-lobed, with dark purple striations, stamen didynamous, filaments white with red spots, ovary 4-lobed, 4-locular, one ovule in each loculus. Nutlets brown, triangular, 2~5 mm in length, smooth, calyx persistent. Odour slight; taste slightly bitter.
Leonuri herba

Microscopic identification:

1. **Transverse section:**
   (1) Stem of *Leonurus japonicus*: Epidermis with thickened outer wall, cutinized, a few of trichomes and stomata occasionally found. Hypodermis composed of 6~8 layers of collenchymatous cells. Parenchymatous cells of cortex contain chloroplast and starch granules, small raphides and prism crystals also present. Endodermis with large cells.

Phloem relatively narrow, with few pericycle fiber bundles scattered outside the phloem, young stem with fiber bundles few or none. Cambium composed of 1~3 layers of cells, occasionally indistinct. Xylem well developed in the angular region, vessels up to 40 μm in diameter, with all kinds of striations. Xylem fibers with walls slightly thickened but highly lignified. Xylem parenchymatous cells lignified. Pith with large cells, containing small raphides and prisms.

(2) Leaf of *Leonurus japonicus*: Lower epidermis with stomata, both upper and lower epidermis contain trichomes. Palisade tissue composed of 1 layer of cells, spongy tissue composed of several rows of cells, mesophyllous cells contain small raphides and cluster crystals.

2. **Powder:** Pale greenish-brown. Epidermal cells with wavy walls, lower epidermal cells with stomata, mainly anomocytic, diacytic stomata occasionally present. Non-glandular hairs extremely numerous, mostly composed of 2 cells, slightly curved, up to 310 μm in length and about 20 μm thick, cells at the apex extremely long, occupying more than 2/3 portion of the hair. Trichomes with thickened and slightly warty cell walls, lumen fine and narrow at the top, the base surrounded by 3~6 slightly protuberant epidermal cells. Unicellular or up to 5-celled long non-glandular hairs occasionally found. Glandular hairs rare, labiatae type, the head flattened-spheroidal, composed of 8 cells, about 55 μm in diameter, stalk extremely short. Glandular hairs with head 1~4 celled and extremely short stalk are rare, about 22 μm in diameter. Small raphides and cluster crystals, existed in mesophyllous cells.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of stachydrine hydrochloride and dissolve in methanol to produce a solution containing 3.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of propanol, methanol, and formic acid (1:10:1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air and expose to iodine vapor until the spots become visible. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 14.0% dry at 105°C for 5 hours (General rule 6015).
2. Total ash: Not more than 12.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 4.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place.
Usage: Blood-regulating medicinal (Blood-activating and stasis-dispelling medicinal).
Property and flavor: Mild cold; bitter and pungent.
Meridian tropism: Liver, pericardium, and bladder meridians.
Effects: Activate blood and eliminate stasis, promoting menstruation and induce diuresis, clear heat and detoxicate.
Administration and dosage: 9~30 g.
Precaution and warning: Use cautiously during pregnancy.

LEPIDII SEMEN
DESCURAINIAE SEMEN
葶藶子
Ting Li Zih / Ting Li Zi
Pepperweed Seed
Tansymustard Seed

Pepperweed seed and tansymustard seed is the dried ripe seed of *Lepidium apetalum* Willd. or *Descurainia sophia* (L.) Webb ex Prantl (Fam. Cruciferae). The former is commonly known as “Bei Ting Li Zih”, and the latter is commonly known as “Nan Ting Li Zih”.
It contains not less than 7.5% of dilute ethanol-soluble extractives, not less than 9.0% of water extractives and not less than 0.075% of quercetin-3-*O*-*β*-D-glucopyranosyl-7-*O*-*β*-D-gentiobioside.
Description:

1. Seed of *Lepidium apetalum*: Flattened-ovoid, 1~1.5 mm in length, 0.5~1 mm in width. Externally brown or reddish-brown, slightly lustrous, with 2 longitudinally furrows, one furrow relatively

distinct. One end obtusely rounded, the other end acute and slightly concave, hilum whitish and situated at the concave end. Odourless; taste slightly bitter and pungent, relatively viscous when moistened.

2. Seed of *Descurainia sophia*: Oblong, slightly flattened, 0.8~1.2 mm in length, about 0.8 mm in width. Externally yellowish-brown, with finely reticulate wrinkles and 2 longitudinally shallow furrows. One end obtuse, the other slightly concave or relatively truncate, hilum situated at the concave end. Odour slight; taste slightly pungent, slightly viscous when moistened.

Microscopic identification:

1. **Transverse section:**
   (1) Seed of *Lepidium apetalum*: The outermost layer was epidermis differentiated into mucilage layer, up to 216 μm thick, inner walls with sedimentary cellulose forming cellulose columns extended radially, 24~34 μm in length, the apex obtusely rounded, oblique or truncate, surrounded by mucilage striations. Palisade cells 1 row, slightly square, 26~34 μm in width, lateral and inner walls thickened, strongly lignified. Pigment layer with cells obliterated, inside showing 1 row of flatten endosperm cells, containing aleurone grains. Cotyledons occupied the most part of the seed, cells irregularly polygonal, wall slightly thickened, and containing aleurone grains.
   (2) Seed of *Descurainia sophia*: Mucilage layer of the outer walls of mucilage cells relatively thin, about 100 μm thick, cellulose columns of inner walls 8~28 μm in length, the base with relatively large papillary protuberance, lignified and red. The other characters are same as *Lepidium apetalum*.
2. **Powder:**
   (1) Seed of *Lepidium apetalum*: Yellowish-brown. Epidermis of testa composed of subsquare mucilage cells. Cellulose columns distinct visible, 26~34 μm in length, subrounded, surrounded by mucilage striations. Endodermal cells of testa yellow, polygonal.
   (2) Seed of *Descurainia sophia*: Yellowish-brown. Epidermal cells of testa slightly rectangular, cellulose columns relatively short. Endodermal cells of testa rectangular-polygonal.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of 70% methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, formic acid, and water (3:1:1) as the developing solvent. Apply 2 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:

1. Loss on drying: Not more than 9.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 7.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 3.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Quercetin-3-*O*-*β*-D-glucopyranosyl-7-*O*-*β*-D-gentiobioside:
   (1) Mobile phase: A solution of acetonitrile and 0.1% acetic acid (11:89). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of quercetin-3-*O*-*β*-D-glucopyranosyl-7-*O*-*β*-D-gentiobioside, and dissolve in methanol to produce a solution containing 15 μg per mL.
   (3) Sample solution: Weigh accurately 0.5 g of the powdered sample and place it in a 50-mL conical flask, then add accurately 25 mL of 50% methanol, ultrasonicate for 30 minutes, filter with filter paper. Repeat the extraction of the residue one more time. Combine the filtrate, evaporate the filtrate to a small amount and transfer to 25-mL volumetric flask, make up to volume with 50% methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (254 nm) and a column packing L1. The column temperature is maintained at 35℃. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of quercetin-3-*O*-*β*-D-glucopyranosyl-7-*O*-*β*-D-gentiobioside should not be less than 5,000.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample

solution into the liquid chromatography apparatus, and calculate the content.

Quercetin-3-*O*-*β*-D-glucopyranosyl-7-*O*-*β*-D-gentiobioside (%)=0.0025(r_U/r_S) (C_S) / (W)

r_U: peak area of quercetin-3-*O*-*β*-D-glucopyranosyl-7-*O*-*β*-D-gentiobioside of sample solution

r_S: peak area of quercetin-3-*O*-*β*-D-glucopyranosyl-7-*O*-*β*-D-gentiobioside of reference standard solution

C_S: concentration of quercetin-3-*O*-*β*-D-glucopyranosyl-7-*O*-*β*-D-gentiobioside of reference standard solution (μg /mL)

W: weight of test sample (g) calculated with dried sample

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place.
Usage: Phlegm-dispelling medicinal (Heat-phlegm clearing and resolving medicinal).
Property and flavor: Cold; pungent and bitter.
Meridian tropism: Lung and bladder meridians.
Effects: Drain lung to calm panting, induce diuresis to alleviate edema.
Administration and dosage: 3~10 g, wrap-decocted.

LIGUSTICI RHIZOMA ET RADIX
藁本
Gao Ben / Gao Ben
Ligusticum Rhizome and Root

Ligusticum rhizome and root is the dried rhizome and root of *Ligusticum sinense* Oliv. or *Ligusticum jeholense* (Nakai & Kitag.) Nakai & Kitag. (Fam. Umbelliferae).
It contains not less than 15.0% of dilute ethanol-soluble extractives, not less than 15.0% of water extractives and not less than 0.05% of ferulic acid.

Description:
1. Rhizome and root of *Ligusticum sinense*: Rhizomes irregulary tubercular cylindrical, slightly branched and twisted, 3~8 cm in length, 1~3 cm in diameter; externally brown, rough and shrunken, with irregular longitudinal wrinkles and annulations. The upper part remained with round and hollowed stem bases; the lower part bearing with numerous dotted and protuberant root scars. Bark easily exfoliated. Texture hard, easily broken; fracture pale yellow, fibrous. Odour aromatic; taste pungent, bitter and slightly numbing.
2. Rhizome and root of *Ligusticum jeholense*: Rhizomes in irregular masses or columnar, 1~6 cm in length, 0.5~2 cm in diameter, with numerous slender and curved roots; externally grayish-brown, with protuberant nodes and root scars, fracture fibrous, yellowish-white, scattered with brown cavities, pith in the center.

Microscopic identification:
1. **Transverse section:**
   (1) Rhizome of *Ligusticum sinense*: Cork composed of 10~15 rows of subsquare cork cells, yellowish-brown. Cortex subsquare or polygonal, wall slightly thickened, containing oil cavities, 70~150 μm in diameter. Phloem with abundant secretory cavities, 70~200 μm in diameter, containing yellowish-brown secretions. Cambium arranged in a ring. Xylem less developed, xylem fibers mostly in bundles, 10~30 μm in diameter, brownish-yellow, wall thickened. Vessels mainly reticulate and spiral, 15~40 μm in diameter, yellow and lignified. Rays distinct, arranged radially, 6~12 rows. Pith large, containing abundant secretory canals. Parenchymatous cells contain starch granules.
   (2) Rhizome and root of *Ligusticum jeholense*: The characters are similar to rhizome and root of *Ligusticum sinense*. Phloem with numerous oil cavities. Xylem fibers relatively numerous, wall thickened, arranged alternately with vessels.
2. **Powder:**
   (1) Rhizome and root of *Ligusticum sinense*: Grayish-brown. Cork cells subrectangular in sectional view, subpolygonal or subrectangular in surface view, anticlinal walls 5~10 μm thick, slightly curved. Xylem fibers fusiform, 10~30 μm in diameter, wall 4~10 μm thick, pits small, pale yellow. Stone cells oblong, polygonal or subsquare, 50~100 μm in length, 30~60 μm in diameter, wall 5~18 μm thick. Secretory cavities huge, mostly broken, containing yellowish-brown contents. Vessels mainly reticulate and spiral, bordered-pitted and scalariform vessels occasionally found, 15~40 μm in diameter, yellow and lignified.
   (2) Rhizome and root of *Ligusticum jeholense*: Grayish-brown. Cork cells subsquare or rectangular. Stone cells elongated-polygonal, subsquare or oblong, 15~50 μm in diameter. Xylem fibers fusiform, 10~30 μm in diameter, pits fine-dotted, with horizontal clefts. Reticulate and scalariform vessels 10~65 μm in diameter, reticular-spiral vessels 16~27 μm in diameter.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of ethanol, heat under reflux for 30 minutes, cool, filter, make up the filtrate to 10 mL.
2. Reference drug solution: Take 1.0 g of the reference

drug and the method of preparation is the same as which is described above.

3. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane and ethyl acetate (7:3) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with *p*-anisaldehyde/H_2SO_4 TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:

1. Total ash: Not more than 8.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 3.0% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Ferulic acid:
   (1) Mobile phase: A solution of methanol and water (40:60) (adjust pH value to 3.5 with phosphoric acid). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of ferulic acid and dissolve in methanol to produce a solution containing 15 μg per mL.
   (3) Sample solution: Weigh accurately 0.1 g of the powdered sample, transfer to a 10-mL centrifuge tube, accurately add 5 mL of methanol, weigh, stand overnight, ultrasonicate for 20 minutes, weigh again, replenish the loss of the weight with methanol, mix well, centrifuge, filter the supernatant and use the filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (320 nm) and a column packing L1. The number of theoretical plates of the peak of ferulic acid should not be less than 2,500.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   Ferulic acid (%)=0.0005 (r_U/r_S) (C_S) / (W)

   r_U: peak area of ferulic acid of sample solution
   r_S: peak area of ferulic acid of reference standard solution
   C_S: concentration of ferulic acid reference standard solution (μg /mL)
   W: weight of test sample (g) calculated with dried sample
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place, and protect from moisture and insects.
Usage: Exterior-releasing medicinal (Pungent-warm exterior-releasing medicinal).
Property and flavor: Warm; pungent.
Meridian tropism: Bladder meridians.
Effects: Resolve exterior and disperse cold, dispel wind and eliminate dampness and relieve pain.
Administration and dosage: 3~11.5 g.

LIGUSTRI LUCIDI FRUCTUS
女貞子
Nyn Jhen Zih / Nu Zhen Zi
Glossy Privet Fruit

Glossy privet fruit is the dried ripe fruit of *Ligustrum lucidum* W.T.Aiton (Fam. Oleaceae).
It contains not less than 17.0% of dilute ethanol-soluble extractives, not less than 15.0% of water extractives and not less than 0.70% of nuzhenide.

Description: Ovate, ellipsoidal or reniform, 5~10 mm in length, 4~5 mm in diameter. Externally blackish-purple or brownish-black, with irregular reticulate wrinkles, base often with persistent calyx and the scar of fruit stalk. Exocarp thin, mesocarp relatively loose, endocarp woody, yellowish-brown, with longitudinal ribs. In cross section, 2-locularovary, each loculus containing a seed, commonly with one seed undeveloped. Seeds reniform, reddish-brown, Odour slight; taste slightly bitter and astringent.

Microscopic identification:

1. **Transverse section:**
   Fruit of *Ligustrum lucidum*: Exocarp composed of 1 layer of subpolygonal epidermal cells, containing oil droplets, the cuticle covering the outer and lateral walls thickened. Mesocarp consists of 10~20 layers of parenchymatous cells, scattered with vascular bundles near the bulge of the endocarp. Endocarp consists of 4~8 layers of lignified fibers. Epidermal cells of testa are elongated tangentially, often with secretory cells on the ridges. Parenchymatous cells of testa are brown. Endosperm contains two cotyledons.
2. **Powder:** Grayish-brown or blackish-gray. Epidermal cells of pericarp depressed-rounded,

yellowish-brown or purplish-brown, with the rounded accrued cuticle of the outer wall thickened, separated the lumina by several arris; in surface view, epidermal cells of pericarp sub-oblate, with the cuticle of the outer wall thickened, divided into 4~10 irregular small lumina by several arris, containing yellowish-brown or purplish-brown masses. Fibers of endocarp in bundles or single, cross-overlapping in bundles; the single fiber has a band or a strip-shape, mostly curved, straight or twisted, tapering, blunt or branched at one end, some fibers are enlarged, boot-shaped. Epidermal cells of testa slight slender, pale brown or brown in color, scattered with secretory cells, occasionally linked by several. Secretory cells round or oblong, 45~100 μm in diameter, containing yellowish-brown secretion and oil droplet. Endodermal cells of pericarp, mesocarp cells, endosperm cells and crystals of calcium oxalate also present.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of oleanolic acid and dissolve in methanol to produce a solution containing 0.1 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane, acetone, ethyl acetate, and formic acid (5∶2∶0.5∶0.1) as the developing solvent. Apply 1 μL of each of the sample solution, reference drug solution and reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 13.0% dry at 105°C for 5 hours (General rule 6015).
2. Total ash: Not more than 5.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0 % (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).
9. Aflatoxins
   (1) Aflatoxins (sum of B_1, B_2, G_1 and G_2): Not more than 10.0 ppb (General rule 6307).
   (2) Aflatoxin B_1: Not more than 5.0 ppb (General rule 6307).

Assay:

1. Nuzhenide:
   (1) Mobile phase: Methanol as the mobile phase A, and water as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of nuzhenide, and dissolve in 50% ethanol to produce a solution containing 0.1 mg per mL.
   (3) Sample solution: Weigh accurately 0.5 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 50 mL of 50% ethanol, ultrasonicate for 30 minutes. Centrifuge for 15 minutes, filter the supernatant, and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (224 nm) and a column packing L1. The column temperature is maintained at room temperature. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of nüzhenide should not be less than 3,500.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~21	35	65
21~21.1	35→100	65→0
21.1~26	100	0

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   Nuzhenide (%)=5 (r_U/r_S) (C_S) / (W)

   r_U: peak area of nuzhenide of sample solution
   r_S: peak area of nuzhenide of reference standard solution
   C_S: concentration of nuzhenide of reference standard solution (mg/mL)
   W: weight of test sample (g) calculated with dried sample
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a dry place, and protect from mold and insects.

Usage: Tonifying and replenishing medicinal (Yin-tonifying medicinal).
Property and flavor: Cool, sweet and bitter.
Meridian tropism: Liver and kidney meridians.
Effects: Supplement liver and kidney, strengthen waist and knees, blacken beard and hair.
Administration and dosage: 6~12 g.

LILII BULBUS
百合
Bai He / Bai He
Lily Bulb

Lily bulb is the dried fleshly scale leaf of bulb of *Lilium lancifolium* Thunb., *Lilium brownii* F.E.Br. var. *viridulum* Baker or *Lilium pumilum* Redouté (Fam. Liliaceae).
It contains not less than 10.0% of dilute ethanol-soluble extractives and not less than 18.0% of water extractives.

Description:
1. Scale leaf of bulb of *Lilium lancifolium*: Elongated ellipsoidal, apex slightly acute, base relatively broad, margins undulate, slightly curved inwards, 2~3.5 cm in length, l~1.5 cm in width, 1~3 mm thick. Externally whitish or pale yellowish-brown, smooth, translucent, with 3~8 longitudinal striations. Texture hard, easily broken, fracture relatively even, horny. Odourless; taste slightly bitter.
2. Scale leaf of bulb of *Lilium brownie* var. *viridulum*: 1.5~3 cm in length, 0.5~l cm in width, up to 4 mm thick, with 3~5 striations, occasionally indistinct.
3. Scale leaf of bulb of *Lilium pumilum*: 5.5 cm in length, 2.5 cm in width, 3.5 mm thick, color dark, most striations indistinct.

Microscopic identification:
1. **Powder:**
   (1) Scale leaf of bulb of *Lilium lancifolium*: Pale yellow. In commercial material medica, starch granules mostly gelatinized. Ungelatinized starch granules long-ovate, subrounded, reniform or irregular, some acute at one end; up to 46 μm in length, 4~29 μm in diameter; hilum indistinct, V-shaped or short cleft-shaped, mostly located at the small end; striations faintly present. Anticlinal walls of epidermal cells slightly thickened, occasionally moniliform; stomata subrounded, 60~69 μm in diameter, with 3~5 subsidiary cells, subsidiary cells contain striations. Spiral and reticulate vessels up to 30 μm in diameter.
   (2) Scale leaf of bulb of *Lilium browinii* var. *viridulum*: Grayish-white. Ungelatinized starch granules long-ovate or oblong, both ends blunt or slightly truncate, occasionally angle-like protuberance at one side, up to 88 μm in length, 5~50 μm in diameter; hilum V-shaped, U-shaped or Y-shaped; striations relatively distinct. Walls of epidermal cells thin, slightly undulated; subrounded stomata 51~61 μm in diameter, flat-rounded ones 56~67 μm in diameter, oblong ones 45~61 μm in length, 40~48 μm in diameter, with 3~5 subsidiary cells. Spiral vessels up to about 25 μm in diameter.
   (3) Scale leaf of bulb of *Lilium pumilum*: Grayish-white. Ungelatinized starch granules subovoid, oval, pear-shaped or slightly conchoidal, slightly acute at the small end, occasionally angle-like protuberance at one or two sides, 3~48 μm in diameter, 72 μm in length; hilum V-shaped, dotted or short cleft-shaped; striations relatively distinct; compound granules composed of 2~4 components; occasionally semi-compound granules present. Walls of epidermal cells undulate; stomata subrounded, 44~52 μm in diameter, with 4~5 subsidiary cells, subsidiary cells contain striations. Spiral vessels up to about 21 μm in diameter.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 20 minutes, filter, and evaporate the filtrate to 1 mL
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and the upper layer of petroleum ether (30~60℃), ethyl acetate, and formic acid (15:5:1) as the developing solvent. Apply 10 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% phosphomolybdic Acid/EtOH TS and heat at 105℃ until the spots become visible. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:
1. Loss on drying: Not more than 13.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 5.5% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 400 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.5 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

※Note: "When this TCM herb is sold commercially, the limit of heavy metals and sulfur dioxide should follow the food standard."

Assay:
1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from mold and insects.
Usage: Tonifying and replenishing medicinal (Yin-tonifying medicinal).
Property and flavor: Mild cold; sweet.
Meridian tropism: Heart and lung meridians.
Effects: Moisten lung to suppress cough, clear heart to tranquilize.
Administration and dosage: 6~12 g.

LINDERAE RADIX
烏藥
Wu Yao / Wu Yao
Combined Spicebush Root

Combined spicebush root is the dried root tuber of *Lindera aggregata* (Sims) Kosterm. (Fam. Lauraceae).
It contains not less than 7.0% of dilute ethanol-soluble extractives, not less than 4.0% of water extractives and not less than 0.4% of norisoboldine.

Description: Cylindrical or fusiform, slightly curved, some constricted in the middle to be moniliform, commonly known as "Wu Yao Ju", 5~15 cm in length, 1~3 cm in diameter. Externally yellowish-brown, with longitudinal wrinkles and transverse striations, bark easily exfoliated, exposing fibrous xylem. Texture hard, uneasily broken, fracture brownish-white, color of the center part dark, with radial rays and annual rings. Odour aromatic; taste slightly bitter and pungent, with a cooling sensation.

Microscopic identification:
1. **Transverse section:**
   Root tuber of *Lindera aggregata*: Cork composed of 5~6 rows of cork cells, mostly broken. Cortex composed of 4~5 rows of subrounded parenchymatous cells, oil cells singly scattered or several in a group, suboblong, containing volatile oil droplets. Primary phloem indistinct, secondary phloem composed of sieve tubes, parenchymatous cells and phloem fibers, oil cells and phloem fibers present among the phloem, usually singly scattered and lignified, a few of lumina contain yellowish-brown contents. Cambium in a ring. Xylem occupied the major portion of the root, annual ring distinct; vessels mainly bordered-pitted, spiral and reticulate rare; xylem fibers pale yellow, with simple pits, lumen relatively large, wall relatively thin; xylem rays composed of 1~3 rows of parenchymatous cells, lignified, wall with simple pits. Parenchymatous cells contain numerous starch granules, oil droplets and yellow resin masses.
2. **Powder:** Pale brown. Starch granules extremely abundant, simple granules subrounded or ovate, 5~40 μm in diameter, hilum dotted or simple cleft-shaped, striations faintly visible; compound granules composed of 2~5 components. Phloem fibers usually singly scattered, long-subfusiform, 11~17 μm in diameter, with walls thickened and slightly lignified, pit canals indistinct, a few of lumina contain yellowish-brown contents. Bordered-pitted vessels 20~30 μm in diameter. Xylem fibers mostly in bundles, slender and mostly broken, 20~30 μm in diameter, walls thickened and with simple pits, lumen containing starch granules. Xylem rays with cells subsquare or subpolygonal, usually several rows overlapped, with relatively dense pits.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 30 mL of petroleum ether (30~60℃) for 30 minutes, ultrasonicate for 10 minutes (keeping the water temperature lower than 30℃) then filter, evaporate the filtrate to dryness, dissolve the residue in 1 mL of ethyl acetate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of linderane and dissolve in ethyl acetate to produce a solution containing 0.75 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of toluene and ethyl acetate (15:1) as the developing solvent. Apply 4 μL of the sample solution and reference drug solution and 3 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 1% vanillin/H_2SO_4 TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 13.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 2.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule

2211, 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
1. Norisoboldine:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and a solution of water (contain 0.1% trimethylamine and 0.5% formic acid) as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of norisoboldine, and dissolve in a solution of 0.5% hydrochloric acid and methanol (1:2, v/v) to produce a solution containing 0.2mg per mL.
   (3) Sample solution: Weigh accurately 1.0 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 25 mL of 0.5% hydrochloric acid and methanol (1:2, v/v), ultrasonicate for 30 minutes, filter with filter paper. Repeat the extraction of the residue one more time. Combine the filtrate, evaporate the filtrate to a small amount and transfer to a 25-mL volumetric flask, make up to volume with 0.5% hydrochloric acid and methanol (1:2, v/v), mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (280 nm) and a column packing L1. The column temperature is maintained at 35℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of norisoboldine should not be less than 8,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~15	10→20	90→80
15~25	20	80

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Norisoboldine (%)=2.5(r_U/r_S) (C_S) / (W)
   r_U: peak area of norisoboldine of sample solution
   r_S: peak area of norisoboldine of reference standard solution
   C_S: concentration of norisoboldine of reference standard solution (mg/mL)
   W: weight of test sample (g) calculated with dried sample
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place, and protect from insects.
Usage: Qi-regulating medicinal.
Property and flavor: Warm; pungent.
Meridian tropism: Lung, spleen, kidney, and bladder meridians.
Effects: Warm the middle to dissipate cold, smooth qi and relieve pain.
Administration and dosage: 3~11.5 g.

LIQUIDAMBARIS FRUCTUS
路路通
Lu Lu Tong / Lu Lu Tong
Beautiful Sweetgum Fruit

Beautiful sweetgum fruit is the dried ripe infructescence of *Liquidambar formosana* Hance (Fam. Hamamelidaceae).
It contains not less than 0.15% of betulonic acid.

Description: Collective fruit composed of numerous small capsules, spheroidal, 2~3 cm in diameter, with a short fruit stalk at the base, externally grayish-brown, bearing with numerous acute spines and small beaked obtuse spines, formed from persistent style and the calyx teeth around ovary, 0.5~1 cm in length, often broken. Small capsules split at apex, showing hollowed; seeds numerous, fine and flattened, pale brown, lustrous, often fallen. Texture light and hard, uneasily broken. Odour slight; taste weak.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.5 g of powdered sample to 10 mL of ethyl acetate, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.5g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of betulonic acid and dissolve in ethyl acetate to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of petroleum ether (60~80 ℃), ethyl acetate, and formic acid (8:2:0.1) as the developing solvent. Apply 10 μL of each of the sample solution and reference drug solution and 2 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with vanillin/H_2SO_4 TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and

color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Total ash: Not more than 7.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 3.0% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
Betulonic acid:
1. Mobile phase: Acetonitrile as the mobile phase A, and 0.1% phosphoric acid as the mobile phase B.
2. Reference standard solution: Weigh accurately a quantity of betulonic acid, and dissolve in ethanol to produce a solution containing 0.1 mg per mL.
3. Sample solution: Weigh accurately 1.0 g of the powdered sample and place it in a 100-mL conical flask, then add accurately 20 mL of absolute ethanol, ultrasonicate for 30 minutes. Centrifuge for 10 minutes, maintained at room temperature, filter with filter paper. Repeat the extraction of the residue two more times. Combine the filtrate and evaporate the filtrate to dryness. Dissolve the residue with absolute ethanol, transfer to a 20-mL volumetric flask and make up to volume with absolute ethanol, mix well, filter and use the successive filtrate.
4. Chromatographic system: The liquid chromatography is equipped with an UV detector (210 nm) and a column packing L1. The column temperature is maintained at 35℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~25	64	36
25~40	64→80	36→20
40~60	80	20

5. Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Betulonic acid (%)=2(r_U/r_S) (C_S) / (W)

r_U: peak area of betulonic acid of sample solution
r_S: peak area of betulonic acid of reference standard solution
C_S: concentration of betulonic acid of reference standard solution (mg /mL)
W: weight of test sample (g) calculated with dried sample

Storage: Store in a ventilated and dry place.
Usage: Dampness-dispelling medicinal (Wind-dampness-dispelling medicinal).
Property and flavor: Neutral; pungent and bitter.
Meridian tropism: Liver and kidney meridians.
Effects: Dispel wind to free collateral vessels, Induce diuresis and eliminate dampness.
Administration and dosage: 5~10 g.

LITCHI SEMEN
荔枝核
Li Jhih He / Li Zhi He
Lychee Seed

Lychee seed is the dried seed of *Litchi chinensis* Sonn. (Fam. Sapindaceae).
It contains not less than 10.0% of dilute ethanol-soluble extractives and not less than 9.0% of water extractives and not less than 0.01% of protocatechuic acid.

Description: Oblong or ovoid, slightly flat, 1.5~2.2 cm in length, 1~1.5 cm in diameter. Epidermis brownish red or purple-brown, smooth, shiny, slightly concave and finely corrugated, a round yellow-brown umbilicus at one end, 7 mm in diameter. Hard. Odor slight, taste slightly sweet, bitter, and astringent.

Microscopic identification:
1. **Transverse section:**
Seed of *Litchi chinensis*: Lateral view of the outer skin of the seed coat is grid-like, cells rectangular, elongated in the radial direction. About 10-15 columns of sclerenchyma cells, wall is thickened by microwave, cells are tangentially elongated, cell gap is obvious. Brown oil cells subround or oblong, sometimes present in sclerenchyma. Mosaic layer is often connected to the thick-walled structure, microwave-shaped. Composed of several cells, embedded in an irregular direction with its long axis. Vascular bundles are arranged intermittently into a ring. Decadent layer is composed of several layers of parenchyma cells, cells shrink, gap is large. Stone cells are scattered or single scattered, pits and pores are sparse, exist in the waste layer. Inner epidermis is 1 row of parenchyma cells, flat and varying lengths. Cotyledons are composed of parenchyma cells that are subround to irregular polygons, filled with starch granules and oil droplets. Primary vascular bundle is scattered in the cotyledons.
2. **Powder:** Yellowish-brown. Mosaic cells are yellowish-brown, long strip shape. Cells are grouped by several cells, embedded in an irregular direction. Outer surface of the epidermal cells of the seed coat is polygonal, and the vertical wall is unevenly thickened; the side cells are 1 column, grid thick, wall thickened, outer layer is the stratum corneum.

Stone cells are scattered or single scattered, subround, subsquare, subpolygonal, rectangular or oblong, many protrusions or branches. Pit and colporate are sparse, layers are not obvious. Starch granules are mostly single, subspheroidal, oval, elliptical or round triangle; less compound and semi-compound. Catheter is interspersed between the parenchyma cells and the waste layer, about 8~10 μm in diameter. Cotyledon cells are subround or subround polygon, filled with starch granules.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of ethanol, ultrasonicate for 30 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 1 mL of ethanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of protocatechuic acid and dissolve in ethanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of toluene, dichloromethane, ethyl acetate, and formic acid (3:5:6:1) as the developing solvent. Apply 8 μL of each of the sample solution and reference drug solution and 2 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 254 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 14.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 3.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 0.5% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

Protocatechuic acid:

1. Mobile phase: Methanol as the mobile phase A, and 0.2% phosphoric acid as the mobile phase B.
2. Reference standard solution: Weigh accurately a quantity of protocatechuic acid and dissolve in 50% ethanol to produce a solution containing 5 μg per mL.
3. Sample solution: Weigh accurately 1.0 g of the powdered sample and place it in a 100-mL round bottom flask, then add accurately 20 mL of 50% ethanol, heat under reflux for 30 minutes, stand to cool, filter. Transfer the filtrate to 25-mL volumetric flask, make up to volume with 50% ethanol, mix well, filter and use the successive filtrate.
4. Chromatographic system: The liquid chromatography is equipped with an UV detector (260 nm) and a column packing L1. The column temperature is maintained at 30℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of protocatechuic acid should not be less than 3,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~25	5→10	95→90
25~40	10→60	90→40

5. Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Protocatechuic acid (%)=0.0025(r_U/r_S) (C_S) / (W)

r_U: peak area of protocatechuic acid of sample solution

r_S: peak area of protocatechuic acid of reference standard solution

C_S: concentration of protocatechuic acid of reference standard solution (μg/mL)

W: weight of test sample (g) calculated with dried sample

Storage: Store in a ventilated and dry place, and protect from insects.

Usage: Qi-regulating medicinal.

Property and flavor: Warm; sweet and mild bitter.

Meridian tropism: Liver and kidney meridians.

Effects: Move qi to dissipate binds, dispel cold and relieve pain.

Administration and dosage: 5~12 g.

LITSEAE FRUCTUS
華澄茄
Bi Cheng Jia/ Bi Cheng Jia
Mountain Spicy Tree Fruit

Mountain spicy tree fruit is the dried mature fruit of *Litsea cubeba* (Lour.) Pers. (Fam. Lauraceae), commonly known as “Shan Hu Jiao”

It contains not less than 10.0% of dilute ethanol-soluble extractives and not less than 7.0% of water extractives and not less than 0.4% of linoleic acid

Description: Spherical, the appearance is brown to brownish black, the skin is shrunk, the reticular corrugations are bulging, and the base often has fruit stalks. The peel is easily peeled off, contains volatile oil. The endocarp is dark brownish red and the peel is firm and brittle. Open the endocarp, there are 2 hypertrophic cotyledons, rich in oil, and the root embryo is very small, located at one end. A strong and penetrating aroma, cool and spicy taste.

Microscopic identification:
Transverse section:
Fruit of *Litsea cubeba*: The outer pericarp cells are 1 column, and the outer layer is thick cuticle. The mesocarp cells are suboval in shape, and the stone cells are scattered or aggregated. The endocarp is a fusiform stone cell, arranged in a palisade, and the cell cavity contains a cubic crystal. Cotyledon cells are subround, with aleurone and fine crystals.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 25 mL of ethanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of linoleic acid and dissolve in ethanol to produce a solution containing 0.5 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane, ethyl acetate, and formic acid (7:2:0.2) as the developing solvent. Apply 2 μL of each of the sample solution and reference drug solution and 1 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 9.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 5.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
Linoleic acid:
1. Mobile phase: A solution of acetonitrile containing 0.1% formic acid as the mobile phase A, and 0.1% formic acid as the mobile phase B.
2. Reference standard solution: Weigh accurately a quantity of linoleic acid and dissolve in methanol to produce a solution containing 0.2 mg per mL.
3. Sample solution: Weigh accurately 1.0 g of the powdered sample and place it in a 100-mL conical flask with stopper, then add accurately 25 mL of methanol, ultrasonicate for 30 minutes, filter. Repeat the extraction of the residue one more time, combine the filtrate, evaporate the filtrate to a small amount and transfer to 25-mL volumetric flask, make up to volume with methanol, mix well, filter and use the successive filtrate.
4. Chromatographic system: The liquid chromatography is equipped with an UV detector (210 nm) and a column packing L1. The column temperature is maintained at 35℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of linoleic acid should not be less than 10,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~3	55	45
3~26	55→87	45→13
26~35	87→100	13→0

5. Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Linoleic acid (%)=2.5(r_U/r_S) (C_S) / (W)

r_U: peak area of linoleic acid of sample solution
r_S: peak area of linoleic acid of reference standard solution
C_S: concentration of linoleic acid of reference standard solution (mg /mL)
W: weight of test sample (g) calculated with dried sample

Storage: Store in a cool and dry place.
Usage: Interior-warming medicinal.
Property and flavor: Warm; pungent.
Meridian tropism: Spleen, stomach, kidney, and bladder meridians.
Effects: Warm spleen and kidney, nvigorate stomach and promote digestion.
Administration and dosage: 1~6 g.

LONICERAE FLOS
山銀花
Shan Yin Hua/ Shan Yin Hua
Wild Honeysuckle Flower Bud

Wild honeysuckle flower bud is the dried flower bud or with opening flower of *Lonicera macrantha* (D.Don) Spreng. or *Lonicera hypoglauca* Miq. (Fam. Caprifoliaceae).

It contains not less than 22.0% of dilute ethanol-soluble extractives, not less than 24.0% of water extractives and not less than 1.5% of chlorogenic acid.

Description:

1 Flower of *Lonicera macrantha*.: Clavate and slightly curved, 3-4.5 cm long, about 2 mm in diameter in upper part and 1 mm in diameter in lower part. Externally yellow or yellowish-green. Pedicels aggregated in clusters, the length of lobes of corolla shorter than the 1/2 of the whole length of opened flowers. Texture slightly hard and as squeezed. Odour delicately aromatic, taste slightly bitter and sweet.

2 Flower of *Lonicera hypoglauca*: 2.5-4.5 cm long, 0.8-2 mm in diameter. Externally yellowish-white to yellowish-brown, calyx tube glabrous, lobes pubescent, 5-lobed at the apex,lobes long-triangular, pubescent; the lower lip of corolla recurved when open, style glabrous. Odour delicately aromatic, taste slightly bitter and sweet.

Microscopic identification:

1. **Transverse section:**

(1) Flower of *Lonicera macrantha*: Epidermis of corolla extremely thin, the cells subrectangular. Glandular hairs few, thick-walled non-glandular hairs relatively numerous on the epidermis. Head of glandular hairs mostly disk-shaped or inverted conical, top flat or slightly retuse, 5to16-celled in the lateral view, arranged in 1-3 layers, 37-125 μm in diameter, cells contain pale brown to yellowish-brown contents; stalk of glandular hairs 3 to 5-celled, 2 (-3) cells parallelly arranged at the junction with the head, 30-168 μm long, 12-25 μm in diameter. Thick-walled non-glandular hairs unicellular, horn-shaped, 15-347 μm long, with few warty protuberances on the surface, spiral striations occasionally visible, lumen of the cells of short horn-shaped hairs relatively narrower compared with those of the long hairs; base slightly enlarged, 8-35 μm in diameter. Pollen grains usually adhered to the surface, yellow, subrounded to rounded-triangular. Clusters of calcium oxalate occasionally found, mainly scattered in lower layer of epidermal cells of corolla.

(2) Flower of *Lonicera hypoglauca*: Epidermis of corolla with few glandular hairs, sparse thick-walled non-glandular hairs sparse, or nearly glabrous. Head of glandular hairs shield-like and large, mainly 13 to 20-celled in top view, 8 to 18-celled in lateral view, arranged in 1-2 layers, 71-150 μm in diameter, containing reddish-brown, brown or pale brown contents; stalk of glandular hairs 1 to 3-celled, extremely short, 15-60 μm long, 10-40 μm in diameter. Thick-walled non-glandular hair, 35-575 μm long, with small and dense warty protuberance on the surface, base 15-40 μm in diameter.

2. **Powder**:

(1) Flower of *Lonicera macrantha*: Colour yellowish-green to pale yellow. Pollen grains relatively numerous, yellow, rounded-triangular or subrounded, 50-87 μm in diameter, with fine granular sculptures visible on the surface, with 3 furrows. Non-glandular hairs 2 types, first type thick walled non-glandular hairs on outer surface of corolla, unicellular, short horn-shaped, 8-35 μm in diameter, usually broken, with few warty protuberances on the surface; second type thin-walled non-glandular hairs on inner surface of corolla, long and curved, 15-25 μm in diameter, usually fragmented, with few fine warty protuberances on the surface. Clusters of calcium oxalate relatively abundant, scattered in parenchymatous cells, 10-30 μm in diameter; Spiral vessels frequently found, 5-10 μm in diameter. Fibrous layer of anther reticulate, with thickened walls. Glandular hairs occasionally found, with disk-shaped or inverted conical heads.

(2) Flower of *Lonicera hypoglauca*: Colour pale yellow. Pollen grains relatively numerous, roundedtriangular or subrounded, 50-90 μm in diameter. Thick-walled non-glandular hairs on outer surface of corolla straight, 15-40 μm in diameter, usually broken, with small and dense warty protuberances on the surface; 15-40 μm in diameter. Inner surface of corolla non-glandular hair straight, 15-30 μm in diameter. Clusters of calcium oxalate 12-30 μm in diameter; polychromatic under the polarized microscope. Spiral vessels 5-10 μm in diameter. Glandular hairs occasionally found, with shieldlike and large heads.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 0.5 g of powdered sample to 5 mL of methanol, ultrasonicate for 20 minutes, filter, evaporate the filtrate to 1 mL.
2. Reference drug solution: Take 0.5 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of chlorogenic acid and dissolve in

methanol to produce a solution containing 1.0 mg per mL.

4. Procedure: Use silica gel F254 as the coating substance and the upper layer of butyl acetate, formic acid, and water (7:2.5:2.5) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
2. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
3. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
4. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
5. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Chlorogenic acid:
   (1) Mobile phase: A solution of methanol and 1% formic acid (20:80). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of chlorogenic acid, transfer to a brown volumetric flask and dissolve in 50% methanol to produce a solution containing 0.2 mg per mL.
   (3) Sample solution: Weigh accurately 0.5 g of powdered sample and place it in a conical flask with stopper, then add accurately 50 mL of 50% methanol, weigh, ultrasonicate for 30 minutes, cool, weigh again, replenish the loss of the weight with 50% methanol, mix well, filte, transfer 5 mL of filtrate to a 25-mL brown volumetric flask, make up to volume with 50% methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (330 nm) and a column packing L1. The column temperature is maintained at 25℃. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of chlorogenic acid should not be less than 1,000.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   Chlorogenic acid (%)=0.025 (r_U/r_S) (C_S)/(W)

   r_U: peak area of chlorogenic acid of sample solution

   r_S: peak area of chlorogenic acid of reference standard solution

   C_S: concentration of chlorogenic acid of reference standard solution (μg/mL)

   W: weight of test sample (g) calculated with dried sample.
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011)

Storage: Refrigerate or store in a cool and dry place, and protect from insects.
Usage: Heat-clearing medicinal (Heat-clearing and detoxcating medicinal).
Property and flavor: Sweet; cold.
Meridian tropism: Lung and stomach meridians.
Effects: Heat-clearing and detoxcating, disperse wind-heat.
Administration and dosage: 6~30 g.

LONICERAE JAPONICAE CAULIS
忍冬藤
Ren Dong Teng / Ren Dong Teng
Japanese Honeysuckle Stem

Japanese honeysuckle stem is the dried stem and branch of *Lonicera japonica* Thunb. (Fam. Caprifoliaceae).
It contains not less than 13.0% of dilute ethanol-soluble extractives, not less than 6.0% of water extractives, not less than 0.10% of chlorogenic acid and not less than 0.1% of loganin.

Description: Slender cylindrical, 1.5~6 mm in diameter. Externally reddish-brown or dark red, nodes remained with leaf scars or branch scars, internodes 5~8 cm in length, with fine longitudinal wrinkles, old branches glabrous, young branches with pale yellow hairs. Outer bark often fallen off, with grayish-white inner surface. Texture hard, easily broken, fracture yellowish-white or grayish-white, fibrous, hollow in the pith. Leaves yellowish-green, usually broken. Odour slight; taste weak.

Microscopic identification:

1. **Transverse section:**
   Stem and branch of *Lonicera japonica*: Epidermis composed of 1 row of rectangular cells. Non-glandular hairs unicellular, walls thickened with warty protrusions. Cortex cells subsquare or polygonal, outer mostly composed of compressed parenchymatous cells, walls yellowish-brown, followed by 1~2 rows of large cortex fibers on the inner side, walls slightly thickened and lignified. Inside showing relatively small cortex cells, subsquare or oblong, 20~60 μm in diameter, parts of the cells formed cork, the cork cells elongated radially, occasionally curved, walls thin. Phloem contains clusters of calcium oxalate, occasionally with few fibers present. Cambium in a ring. Xylem well developed, vessels subrounded, 10~35 μm in

diameter, mainly spiral, others as xylem fibers; xylem rays composed of 1~2 rows of cells, containing pits. Pith large with cells round, 10~50 μm in diameter, walls slightly lignified, hollowed in the center.

2. **Powder:** Brown. Epidermal cells rectangular. Non-glandular hairs unicellular with walls thickened. Cortex cells subsquare or subrounded, mostly shrunken, filled with yellowish-brown contents. Cortex fibers with walls slightly thickened and lignified, 5~25 μm in diameter. Phloem cells mostly compressed, containing clusters of calcium oxalate. Spiral vessels of xylem are visible, 10~50 μm in length, 10~35 μm in diameter. Pith cells round, 10~50 μm in diameter, walls slightly lignified.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 5 mL of methanol, shake for 5 minutes, centrifuge and use the supernatant.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately 1.0 mg of chlorogenic acid and dissolve in methanol to produce a solution containing 0.5 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, formic acid, and water (6:1:1) as the developing solvent. Apply 10 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with vanillin/H_2SO_4 TS and heat at 105℃ until the spots become visible. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 11.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 4.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Chlorogenic acid:
   (1) Mobile phase: A solution of acetonitrile and 0.4% phosphoric acid (10:90). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of chlorogenic acid in a brown volumetric flask and dissolve in 50% methanol to produce a solution containing 40 μg per mL.
   (3) Sample solution: Weigh accurately 1.0 g of powdered sample and place it in a conical flask with a stopper, add accurately 25 mL of 50% methanol, weigh, ultrasonicate for 30 minutes, cool, weigh again, replenish the loss of the weight with 50% methanol, mix well and filter, use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (327 nm) and a column packing L1. The number of theoretical plates of the peak of chlorogenic acid should not be less than 1,000.
   (5) Procedure: Inject accurately 10 μL of the reference standard solution and sample solution into the liquid chromatography apparatus, and calculate the content.
   Chlorogenic acid (%)=0.0025(r_U/r_S) (C_S) / (W)
   r_U: peak area of chlorogenic acid of sample solution
   r_S: peak area of chlorogenic acid of reference standard solution
   C_S: concentration of chlorogenic acid of reference standard solution (μg/mL)
   W: weight of test sample (g) calculated
2. Loganin:
   (1) Mobile phase: A solution of acetonitrile and 0.4% phosphoric acid (12:88). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of loganin and dissolve in 50% methanol to produce a solution containing 40 μg per mL.
   (3) Sample solution: Weigh accurately 1.0 g of powdered sample and place it in a conical flask with a stopper, add accurately 25 mL of 50% methanol, weigh, ultrasonicate for 30 minutes, cool, weigh again, replenish the loss of the weight with 50% methanol, mix well and filter, use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (236 nm) and a column packing L11. The number of theoretical plates of the peak of loganin should not be less than 3,000.
   (5) Procedure: Inject accurately 10 μL of the reference standard solution and sample solution into the liquid chromatography apparatus, and calculate the content.
   Loganin (%)=0.0025(r_U/r_S) (C_S) / (W)
   r_U: peak area of loganin of sample solution

r_S: peak area of loganin of reference standard solution
C_S: concentration of loganin of reference standard solution (μg/mL)
W: weight of test sample (g) calculated with dried sample

3. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
4. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place, and protect from moisture.
Usage: Heat-clearing medicinal (Heat-clearing and detoxcating medicinal).
Property and flavor: Cold; sweet.
Meridian tropism: Lung and stomach meridians.
Effects: Clear heat, detoxicate, free collateral vessels.
Administration and dosage: 9~30 g.

LONICERAE JAPONICAE FLOS
金銀花
Jin Yin Hua / Jin Yin Hua
Honeysuckle Flower Bud

Honeysuckle flower bud is the dried flower bud and infant flower of *Lonicera japonica* Thunb. (Fam. Caprifoliaceae).
It contains not less than 22.0% of dilute ethanol-soluble extractives, not less than 24.0% of water extractives and not less than 1.5% of chlorogenic acid.

Description: Clavate, slender, slightly curved, 1.3~5.5 cm in length, stout in upper part, 2~3 mm in diameter. Externally pale yellow or yellowish-brown, gradually darken on keeping, with densely scabrous and long glandular. Calyx tiny, calyx tube subspheroidal, about 1 mm in length, glabrous, 5-lobed at the apex, lobes ovate-deltoid, pubescent. Corolla tubular, slight dehiscence at the apex, flowering occasionally, 2-lipped apex, about 5 cm in length; 5 stamens, epipetalous; 1 pistil, 1 style. Odour delicately aromatic; taste sweet and slightly bitter.

Microscopic identification:
1. **Transverse section:**
Flower bud of *Lonicera japonica*: Glandular hairs 2 types: first type with head obconical, apex flattened, 10~33 cells in lateral view, arranged to 2~4 layers, 48~108 μm in diameter, stalk 1~5 celled, 70~700 μm in length; second type with head subrounded or rounded discoid, 4~20 celled, 30~64 μm in diameter, stalk 2~4 celled, 24~80 μm in length. Sclerenchymatous non-glandular hairs unicellular, 45~900 μm in length, 14~37 μm in diameter, walls 5~10 μm thick, slightly warty or bubble-shaped protuberance in surface, occasionally spiral striations visible. Parenchymatous non-glandular hairs unicellular, extremely long, curved or shrunken, slightly warty in surface. Clusters of calcium oxalate 6~45 μm in diameter, angles fine and acute. Pollen grains subrounded or rounded-triangular, with 3 pit canals, with dense short-spines and fine or granule-like striations on the surface.
2. **Powder:** Pale yellow. Glandular hairs 2 types: first type with head obconical, apex slightly flattened, 10~30 cells arranged to 2~4 layers, 52~130 μm in diameter, stalk 2~6 celled, 80~700 μm in length; second type with head inverted triangular, relatively small, composed of 4~20 cells, 30~80 μm in diameter, stalk 2~4 celled, 25~64 μm in length. The head cells of glandular hair contain yellowish-brown secretions. Non-glandular hairs unicellular with 2 types: first type long and curved, walls thin with slightly warty; second type relatively short, walls slightly thickened with warty on surface, occasionally with single or double-helix striations. Pollen grains abundant, yellow, spheroidal, 60~70 μm in diameter, short spine-like warty on the outer wall, with 3 germinal apertures. Epidermal cells of the stigma head villus-shaped. Parenchymatous cells contain fine clusters of calcium oxalate, 6~45 μm in diameter.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 0.5 g of powdered sample to 5 mL of methanol, ultrasonicate for 20 minutes, filter, evaporate the filtrate to 1 mL.
2. Reference drug solution: Take 0.5 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of chlorogenic acid and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and the upper layer of butyl acetate, formic acid, and water (7:2.5:2.5) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 12.0% dry at 105°C for 5 hours (General rule 6015).
2. Total ash: Not more than 10.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 5.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).

6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Chlorogenic acid:
   (1) Mobile phase: A solution of methanol and 1% formic acid (20:80). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of chlorogenic acid, transfer to a brown volumetric flask and dissolve in 50% methanol to produce a solution containing 50 μg per mL.
   (3) Sample solution: Weigh accurately 0.5 g of powdered sample and place it in a conical flask with stopper, then add accurately 50 mL of 50% methanol, weigh, ultrasonicate for 30 minutes, cool, weigh again, replenish the loss of the weight with 50% methanol, mix well, filte, transfer 5 mL of filtrate to a 25-mL brown volumetric flask, make up to volume with 50% methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (330 nm) and a column packing L1. The column temperature is maintained at 35℃. The flow rate is about 1 mL/min. The column temperature is maintained at room temperature. The flow rate is about 1.0 mL/min. The number of theoretical plates of the peak of chlorogenic acid should not be less than 1,000.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   Chlorogenic acid (%)=0.025(r_U/r_S) (C_S)/(W)

   r_U: peak area of chlorogenic acid of sample solution
   r_S: peak area of chlorogenic acid of reference standard solution
   C_S: concentration of chlorogenic acid of reference standard solution (μg/mL)
   W: weight of test sample (g) calculated with dried sample
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from insects.

Usage: Heat-clearing medicinal (Heat-clearing and detoxcating medicinal).
Property and flavor: Cold; sweet.
Meridian tropism: Lung and stomach meridians.
Effects: Clear heat and detoxicate, disperse wind-heat.
Administration and dosage: 6~30 g.

LOPHATHERI HERBA
淡竹葉
Dan Jhu Ye / Dan Zhu Ye
Common Lophatherum Herb

Common lophatherum herb is the dried culm and leaf of *Lophatherum gracile* Brongn. (Fam. Gramineae).
It contains not less than 9.0% of dilute ethanol-soluble extractives and not less than 10.0% of water extractives.

Description: Leaf blades crumpled, 3~22 cm in length, 1~3.5 cm in width, externally pale yellowish-green, veins parallel, bearing lateral veinlets, more distinct on the lower surface, both surfaces scattered with sparse tomenta. Culms pale yellow, cylindrical, about 25~60 cm in height, about 1 mm in diameter, with nodes scattered with leaf sheaths.

Microscopic identification:

1. **Transverse section:**
   Culm and leaf *Lophatherum gracile*: Upper epidermis composed of 1 layer of subrectangular cells, varying in size, the cells near fibers relatively small, about 8 μm in diameter and length; the cells far away from fibers relatively large, linked vertically into fan-shaped, about 88 μm in diameter and length, the outer periclinal walls cutinized. Lower epidermal cells relatively small, arranged neatly, subrectangular, anticlinal walls curved, the outer periclinal walls cutinized. Stomata and unicellular non-glandular hairs mostly presented in lower epidermis. Mesophyll composed of palisade tissue and spongy tissue. Palisade tissue composed of 1~2 rows of short columnar cells, arranged neatly; spongy tissue composed of 2~4 rows of parenchymatous cells, cell walls slightly curved. Vascular bundles in closed collateral type, subrounded by 1~2 rows of subrounded fibers, xylem vessels rare, with 1~3 rows of fibers between the phloem and xylem, xylem located above phloem, vessels subrounded; phloem cells relatively small, subrounded or elongated-rounded.
2. **Powder:** Pale grayish-green. Stomata and non-glandular hairs mostly presented in the lower epidermis, upper epidermis rare, non-glandular hairs usually singly scattered, mostly unicellular, subsickle-shaped curved. Stomata mainly presented in the lower epidermis, numerous, subsidiary cells slender, dumbbell-shaped. Fibers mostly in bundles, slender, about 450 μm in length, about 7~25 μm in diameter, with indistinct pit canals. Vessels mainly spiral.

Identification:

1. Check steroids: Add 1.0 g of powdered sample to 20 mL of ethanol, ultrasonicate for 1 hour, and filter. Weigh accurately 5 mL of the filtrate, evaporate the filtrate to dryness, dissolve the residue in 1 mL of acetic anhydride, and add 1~2 drops of concentrated sulfuric acid, a red color is produced and turns to purplish-red, bluish-purple and dark green gradually.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of 70% ethanol, ultrasonicate for 15 minutes, filter, make up the fitrate to 10 mL, and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, acetone, acetic acid, and water (1:1:0.4:0.3) as the developing solvent. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 254 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:

1. Loss on drying: Not more than 11.0% dry at 105°C for 5 hours (General rule 6015).
2. Total ash: Not more than 11.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 5.5% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 10.0 ppm (General rule 2251, 6301).

Assay:

1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from mold and insects.
Usage: Heat-clearing medicinal (Heat-clearing and fire-purging medicinal).
Property and flavor: Cold; sweet and bland.
Meridian tropism: Heart, stomach, and small intestine meridians.
Effects: Clear heat and eliminate vexation, benefit urine.
Administration and dosage: 6~12 g.

LYCII FRUCTUS
枸杞子
Gou Ci Zih / Gou Qi Zi
Wolfberry Fruit

Wolfberry fruit is the dried ripe fruit of *Lycium chinense* Mill. or *Lycium barbarum* L. (Fam. Solanaceae).
It contains not less than 35.0% of dilute ethanol-soluble extractives and not less than 40.0% of water extractives.
Description: Narrowly ovate or ellipsoid, 10~20 mm in length, 3~8 mm in diameter. Externally red or dark red, with irregular wrinkles, slightly lustrous, apex with a protuberant stylopodium, with a white and dented scar of fruit stalk at the other end. Texture pliable, sarcocarp fleshy, viscous. Seeds 25~50, flattened reniform, up to 2.5 mm in length, up to 2 mm in width, brownish-yellow, with some fine dented dots, hilum at the dented edge. Odour slight; taste sweet and slightly sour.

Microscopic identification:

1. **Transverse section:**
   Lycii fructus: Exocarp composed of 1 layer of cells, lateral wall thickened, unlignified or slightly lignified, covered with cuticle, the margin serrate-shaped. Mesocarp composed of over 10 layers of cells, containing abundant orange-red pigment granules, occasionally containing sandy crystals of calcium oxalate; vascular bundles bicollateral, numerous, arranged in a ring, vessels small and rare. Endocarp composed of 1 layer of cells, subrounded or elongated tangentially, arranged undulately. Parenchymatous tissue of septum and axial placentation scattered with vascular bundles, some vascular bundles with numerous vessels.
2. **Powder:** Yellowish-orange or dark red. Stone cells of testa flaky, irregularly polygonal or long-polygonal in surface view, anticlinal walls undulated or wave-curved, 37~117 μm in diameter, up to 196 μm in length, wall 5~27 μm thick; subsquare or flattened-square in sectional view, lateral and inner walls thickened, inner wall slightly curved, outer wall mucilaginous. Exocarp cells subpolygonal in surface view, anticlinal walls wave-curved or straight, the outer periclinal walls with dense and parallel cuticle striations. Sandy crystals of calcium oxalate filled in mesocarp parenchymatous cells, a few of small prisms present. Parenchymatous cells of mesocarp contain orange-red or reddish-brown pigment granules. Endosperm cells contain fatty oil droplets and aleurone grains.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and make up the filtrate to 10 mL.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of toluene and acetone (4:1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:

1. Total ash: Not more than 5.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
3. Sulfur dioxide: Not more than 400 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).
8. Aflatoxins
   (1) Aflatoxins (sum of B_1, B_2, G_1 and G_2): Not more than 10.0 ppb (General rule 6307).
   (2) Aflatoxin B_1: Not more than 5.0 ppb (General rule 6307).

※Note: "When this TCM herb is sold commercially, the limit of heavy metals, sulfur dioxide and aflatoxins should follow the food standard."

Assay:

1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from moisture and insects.
Usage: Tonifying and replenishing medicinal (Yin-tonifying medicinal).
Property and flavor: Neutral; sweet.
Meridian tropism: Liver and kidney meridians.
Effects: Supplement liver and kidney, replenish essence to improve vision.
Administration and dosage: 6~15 g.

LYCII RADICIS CORTEX
地骨皮
Di Gu Pi / Di Gu Pi
Wolfberry Rootbark

Wolfberry rootbark is the dried bark of root of *Lycium chinense* Mill. or *Lycium barbarum* L. (Fam. Solanaceae). It contains not less than 8.0% of dilute ethanol-soluble extractives and not less than 10.0% of water extractives.
Description: Quilled, channeled or irregular quills, 0.5~2 cm in diameter, 1~3 mm thick. Outer surface brownish-yellow to grayish-yellow, rough, with irregularly longitudinal fissures, easily exfoliated to scaly. Inner surface yellowish-white or grayish-yellow, with fine longitudinal striations. Texture light and fragile, fracture two layers, outer layers (cork) thick, brownish-yellow, inner layers grayish-white. Odour slight; taste sweetish and then bitter.

Microscopic identification:

1. **Transverse section:**
   Lycii radicis cortex: Rhytidome relatively thick; inside showing cork, arranged in a complete ring. Phloem occupied about half portion of the bark of root, phloem rays 1~2 rows of cells wide. Parenchymatous cells contain starch granules, occasionally containing sandy crystals of calcium oxalate. Fibers singly scattered or few in bundles; occasionally stone cells present.
2. **Powder:** Pale yellow. Sandy crystals of calcium oxalate scattered, some parenchymatous cells filled with sandy crystals, forming sandy crystal sacs. Fibers usually connected with ray cells, fusiform in shape, 110~230 μm in length, 17~48 μm in diameter, walls 3~11 μm thick, lignified or slightly lignified, containing sparsely oblique pits, some lumen contains yellowish-brown contents. Individual starch subrounded or ovate, 5~22 μm in diameter; compound granules composed of 2~8 components. Occasionally with subrounded, fusiform or subrectangular stone cells, cork cells and parenchymatous cells of cork.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 5 mL of methanol, ultrasonicate for 30 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 1 mL of methanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of scopoletin and scopolin and dissolve in methanol to produce a solution containing 0.2 mg per mL of each.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-butanol, acetic acid, and water (7:1:2) as the developing solvent. Apply 8 μL of each of the sample solution and reference

drug solution and 2 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 14.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 15.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 5.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 5.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a dry place, and protect from mold and insects.
Usage: Heat-clearing medicinal (Deficiency heat-clearing medicinal).
Property and flavor: Cold; sweet and bland.
Meridian tropism: Lung, liver, and kidney meridians.
Effects: Cool the blood and eliminate steaming, clear lung and downbear fire.
Administration and dosage: 9~15 g.

LYCOPI HERBA
澤蘭
Ze Lan / Ze Lan
Hiraute Shiny Bugleweed Herb

Hiraute shiny bugleweed herb is the dried aerial herb of *Lycopus lucidus* Turcz. var. *hirtus* Regel or *Lycopus lucidus* Turcz. & Benth. (Fam. Labiatae).
It contains not less than 14.0% of dilute ethanol-soluble extractives and not less than 14.0% of water extractives.

Description:
1. Stem of *Lycopus lucidus* var. *hirtus*: Stems square, shallowly furrowed longitudinally on four sides, 50~100 cm in length, 0.2~0.6 cm in diameter; externally yellowish-green or slightly purplish, nodes apparently purple, internode 2~11 cm; texture fragile, easily broken, fracture yellowish-white, pith hollowed. Leaves opposite, lamina mostly crumpled, lanceolate or oblong as whole, margin serrate; the upper surface blackish-green, the lower surface grayish-green and densely glandular-dotted, pubescent on both surfaces. Vertisillaster axillary, corolla mostly fallen off, bracts and calyx persistent. Odour slight; taste weak.
2. Stem of *Lycopus lucidus*: Stem and leaves relatively smooth, and the other characters simile to *Lycopus lucidus* var. *hirtus*.

Microscopic identification:
1. **Transverse section:**
   (1) Stem of *Lycopus lucidus* var. *hirtus*: Epidermal cells rectangular, with striped cuticle; glandular hair heads composed of 1~2 cells, stalk unicellular; head of glandular scales 56~60 μm in diameter, and composed of 6~8 cells. Stomata rare. Non-glandular hairs sometimes visible.
   (2) Stem of *Lycopus lucidus*: Epidermal cells Polygonal or rectangular, with looming striped cuticle. Containing glandular hair and glandular scales. Unicellular non-glandular hairs 20~28 μm in length, there are many non-glandular hairs at the edge of the stem, length can reach 750 μm, also with warty protrusions on the surface.
2. **Powder:** Brown. Lower epidermal cells polygonal or irregular in shape. Unicellular non-glandular hairs mostly present in main and lateral vein. Glandular hairs present in lower epidermis, the head composed of 1~2 cells, the stalk unicellular. Vessels pitted and spiral. Fibers slender. Subsidiary cells diacytic.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of ursolic acid and dissolve in methanol to produce a solution containing 0.5 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane, dichloromethane, ethyl acetate, and formic acid (20:5:8:0.1) as the developing solvent. Apply 1 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under the ultraviolet light at 365 nm. The

spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 14.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 10.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 3.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place.
Usage: Blood-regulating medicinal (Blood-activating and stasis-dispelling medicinal).
Property and flavor: Mild warm; bitter and pungent.
Meridian tropism: Liver and spleen meridians.
Effects: Invigorate blood to regulate menstruation, induce diuresis to alleviate edema.
Administration and dosage: 6~12 g.

LYCOPODII HERBA
伸筋草
Shen Jin Cao / Shen Jin Cao
Common Clubmoss Herb

Common clubmoss herb is the dried herb of Lycopodium japonicum Thunb. (Fam. Lycopodiaceae).

Description: Stolon slender cylindrical, slightly curved, up to 2 m in length, 3~5 mm in diameter, with numerous yellowish-white rootlets underneath. Erect stems bifurcated. Leaves densely growing on the stems, arranging spirally, crumpled and curved, linear-lanceolate, 3~5 mm in length, yellowish-green to pale yellowish-brown, glabrous, aristate at the apex, margin entire or serrate, veins indistinct. Sporangium rare, often broken. Texture soft, fracture pale yellow in bark and whitish in wood. Odour slight; taste weak.

Microscopic identification:
1. **Transverse section:**
   Stem of *Lycopodium japonicum*: Epidermis composed of 1 layer of cells covered with cuticle. Cortex relatively broad; sclerenchymatous tissue composed of 1~10 layers of cells, arranged in a ring below epidermis and stele, the walls gradually thickened and lignified from outer to inner, scattered with leaf-trace vascular bundles. Endodermis distinct. Pericycle composed of parenchymatous cells. Xylem divided into irregular stripes, arranging parallelly and alternately with phloem; phloem cells polygonal, the cells relatively small near xylem cells.
2. **Powder:** Yellowish-green. Epidermal cells subrounded or elliptical, the outer walls slightly thickened and lignified. Walls of parenchymatous cells thin, cells subrounded or oblong. Sclerenchymatous cells subrounded or elliptical, fibers relatively small and oblong, 15~50 μm in diameter. Endodermal cells long-polygonal. Tracheids extremely long, 10~50 μm in diameter, polygonal or elliptical, extremely lignified, mainly scalariform, spiral few. Simple starch granules elliptical, subrounded or polygonal.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 5.0 g of powdered sample to 30 mL of ethyl ether, immerse for 3 hours, filter, evaporate the filtrate to dryness, and dissolve the residue in 1 mL of absolute ethanol.
2. Reference drug solution: Take 5.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of petroleum ether (30~60℃) and ethyl acetate (5:3) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:
1. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
2. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
3. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
4. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
5. Lead (Pb): Not more than 10.0 ppm (General rule 2251, 6301).

Storage: Store in a ventilated and dry place.

Usage: Dampness-dispelling medicinal (Wind-dampness-dispelling medicinal).
Property and flavor: Warm; mild bitter and pungent.
Meridian tropism: Liver, spleen, and kidney meridians.
Effects: Dispel wind and dissipate cold, eliminate dampness and alleviate edema, relax sinews and activate blood.
Administration and dosage: 3~12 g.

LYGODII SPORA
海金沙
Hai Jin Sha / Hai Jin Sha
Lygodium Spore

Lygodium spore is the dried ripe spore of *Lygodium japonicum* (Thunb.) Sw. (Fam. Lygodiaceae).
It contains not less than 3.0% of dilute ethanol-soluble extractives.

Description: Powder, brownish-yellow or yellowish-brown. Externally smooth, texture light, float on the water, sank after heated. Crack and bright flame when burned. Odour slight; taste weak.

Microscopic identification:
1. **Transverse section:**
   Spore of *Lygodium japonicum*: Spores brownish-yellow or pale yellow, tetrahedral or triangular conical, tri-phase conical in top view, subtriangular in lateral view, subrounded in bottom view, 55~90 μm in diameter, with granular sculptures in outer walls.
2. **Powder:** Yellowish-brown. Spores with warty or smooth surface. Multicellular non-glandular hairs mostly broken, 120~600 μm in length and 20~50 μm in diameter. Wall cells of sporangium undulately curved, containing yellowish-brown contents. Girdle band cells of sporangium composed of several lignified cells, containing yellow contents.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 2.0 g of powdered sample to 20 mL of methanol, ultrasonicate for 30 minutes, evaporate to dryness, and dissolve the residue in 2 mL of methanol.
2. Reference drug solution: Take 2.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of petroleum ether (30~60℃), ethyl acetate, and methanol (15:3:1) as the developing solvent. Apply 10 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS, heat at 105℃ for 2 minutes. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:
1. Loss on drying: Not more than 7.0% dry at 105℃ for 5 hours (General rule 6015).
2. Acid-insoluble ash: Not more than 12.0% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).
Storage: Store in a cool and dry place, and protect from moisture.
Usage: Dampness-dispelling medicinal (Dampness-draining diuretic medicinal).
Property and flavor: Cold; sweet and salty.
Meridian tropism: Bladder and small intestine meridians.
Effects: Clear heat and induce diuresis, relieve strangury and remove urinary calculus.
Administration and dosage: 6~15 g.

LYSIMACHIAE HERBA
金錢草
Jin Cian Cao / Jin Qian Cao
Longhairy Antenoron Herb

Longhairy antenoron herb is the dried herb of *Lysimachia christinae* Hance (Fam. Primulaceae).
It contains not less than 7.0% of dilute ethanol-soluble extractives, not less than 5.0% of water extractive and not less than 0.1% of the total amount of quercetin and kaempferol.

Description: Frequently twisted into masses, glabrous or sparsely pubescent. Stems twisted, externally brown or dark brownish-red, with longitudinally wrinkles, the lower part of stem nodes occasionally with rootlets, fracture solid. Leaves opposite, mostly crumpled, broadly ovate or cordate as whole, 1~4 cm in length, 1~5 cm in width, base slightly concave, margin entire; the upper surface grayish-green or brown, the lower surface pale in color, midrib distinctly protuberant, after soaking in water, the black or brown stripes visible under the light; petioles 1~4 cm in length. Some with flowers, yellow, solitary in leaf axis, with long petioled. Capsules globose. Odour slight; taste weak.

Microscopic identification:

1. **Transverse section:**
   (1) Stem of *Lysimachia christinae*: Epidermis covered with cuticle, occasionally glandular hairs present, with head unicellular and 1~2 celled stalk. Cortex broad, cells occasionally containing reddish-brown contents, scattered with secretory canals, composed of 5~10 secretory cells, containing reddish-brown lumpy secretions. Endodermis distinct. Pericyclic fibers arranged in an interrupted ring, walls slightly lignified. Phloem narrow. Cambium indistinct. Xylem arranged in a ring. Pith usually hollow, parenchymatous cells contain starch granules.
   (2) Leaf of *Lysimachia christinae*: Glandular hairs reddish-brown, with head unicellular, subrounded, about 25 μm in diameter, stalk unicellular. Secretory canals scattered in mesophyllous tissue, about 45 μm in diameter, containing reddish-brown secretions. For sparsely pubescent ones, non-glandular hairs visible on the surface of stems and leaves, 1~17 celled, straight or curved, some cells shrunken, 59~1,070 μm in length, 13~53 μm in diameter at the base, finely striated on the surface, containing yellowish-brown contents.
2. **Powder:** Grayish-yellow. Starch granules abundant, simple granules subrounded, semicircular or helmet-shaped, 4~22 μm in diameter, hilum cleft-shaped, dotted rare; compound granules rare, composed of 2~3 components. Glandular hairs usually broken, with only 1 head cell or with broken stalk cells; head cells usually filled with reddish-yellow secretions, 18~42 μm in diameter, occasionally fragments of non-glandular hairs present. Epidermal cells with curved anticlinal walls, fine striations and round cicatrix from fallen off of glandular hairs, containing reddish-brown contents. Lower epidermis with anticlinal walls curved, stomata anisocytic or anomocytic. Fragments of parenchymatous cells occasionally contain reddish-brown masses or long strip-shaped contents. Fibers extremely long, with large and lignified lumen. Vessels mainly spiral, reticulate or pitted, 15~28 μm in diameter.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 50 mL of 80% methanol, heat under reflux for 1 hour, cool then filter, evaporate the filtrate to dryness, dissolve the residue in 10 mL of water, extract by shaking with two 10-mL quantities of ethyl ether, and discard the ethyl ether solutions. To the water solution add 10 mL of dilute hydrochloric acid, place in a water bath for 1 hour, cool immediately, extract shaking twice each with 20 mL of ethyl acetate, combine the ethyl acetate extracts, wash with 30 mL of water, discard the washing. Evaporate the ethyl acetate extract to dryness, dissolve the residue in 1 mL of methanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of quercetin and kaempferol and dissolve in methanol to produce a solution containing 0.5 mg per mL of each.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of toluene, ethyl acetate, and formic acid (10:8:1) as the developing solvent. Apply 5 μL of the sample solution and reference drug solution and 2 μL of each of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 3% $AlC1_3$/EtOH TS and heat at 105℃ for several minutes. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 11.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 13.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 5.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Quercetin and kaempferol:
   (1) Mobile phase: A solution of methanol and 0.4% phosphoric acid (50:50). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of quercetin and kaempferol and dissolve in 80% methanol to produce a solution containing 4 μg and 20 μg per mL of each.
   (3) Sample solution: Weigh accurately 1.5 g of powdered sample and place it in a conical flask with stopper, add accurately 50 mL of 80% methanol, stopper tightly and weigh, heat under reflux for 1 hour, cool, weigh again, replenish the loss of the weight with 80% methanol, and mix well. Filter and transfer 25 mL of successive filtrate, add accurately 5 mL of hydrochloric acid, place in a water bath at

90℃ for 1 hour, cool immediately, transfer to a 50-mL volumetric flask, make up to volume with 80% methanol, mix well, filter and use the successive filtrate.

(4) Chromatographic system: The liquid chromatography is equipped with an UV detector (360 nm) and a column packing L1. The number of theoretical plates of the peak of quercetin should not be less than 2,500.

(5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Quercetin or kaempferol (%)=0.01(r_U/r_S) (C_S) / (W)

r_U: peak area of quercetin or kaempferol of sample solution

r_S: peak area of quercetin or kaempferol of reference standard solution

C_S: concentration of quercetin or kaempferol of reference standard solution (μg/mL)

W: weight of test sample (g) calculated with dried sample

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place.
Usage: Dampness-dispelling medicinal (Dampness-draining diuretic medicinal).
Property and flavor: Mild cold; sweet and salty.
Meridian tropism: Liver, gallbladder, kidney, and bladder meridians.
Effects: Induce diuresis and relieve strangury, eliminate dampness and antiicteric, detoxicate and alleviate edema.
Administration and dosage: 15~60 g.

MAGNOLIAE CORTEX
厚朴
Hou Pu / Hou Pu
Magnolia Bark

Magnolia bark is the dried bark of trunk, root or branch of *Magnolia officinalis* Rehder & E.H.Wilson or *Magnolia officinalis* Rehder & E.H.Wilson var. *biloba* Rehder & E.H.Wilson (Fam. Magnoliaceae).
It contains not less than 4.5% of dilute ethanol-soluble extractives, not less than 4.0% of water extractive and not less than 0.8% of magnolol.

Description:

1. Bark of trunk of Magnoliae cortex: Singly or double quilled or slices, 30~35 cm in length, 2~7 mm thick, commonly known as “Tong Po”, near the root with one end spread out like a bell, 13~25 cm in length, 3~8 mm thick, commonly known as “Xue Tong Po”. Outer surface grayish-brown, rough, cork easily exfoliated to scaly, with distinct elliptical lenticels and longitudinal wrinkles, appearing yellowish-brown when the coarse bark peeled; inner surface relatively smooth, purplish-brown or dark purplish-brown, with fine and dense longitudinal striations, exhibiting oily trace on scratching. Texture hard, uneasily broken, outer fracture grayish-brown, granular, inner fracture purplish-brown or brown, oily, occasionally with numerous small bright spots (crystal of magnolol). Odour aromatic; taste bitter and pungent.
2. Bark of root (Gen Po) of Magnoliae cortex: Singly quilled or irregular slices, some broken after splitting, some curved like chicken intestines, commonly known as “Ji Chang Po”, 18~32 cm in length, 1~3 mm thick. Externally grayish-brown, with transverse striations and longitudinal wrinkles. Texture hard, uneasily broken, fracture fibrous. More residues after chewing. The other characters same as bark of trunk.
3. Bark of branch (Zhi Po) of Magnoliae cortex: Bark thin, quilled singly, 10~20 cm in length, 1~2 mm thick. Externally grayish-brown, with wrinkles. Texture fragile hard, easily broken, fracture fibrous. More residues after chewing. The other characters same as bark of trunk.

Microscopic identification:

1. **Transverse section:**
Magnoliae cortex: Cork composed of several layers of cells, with suberized and slightly lignified wall, rhytidome tissue present. The outer side of cortex showing a ring of stone cells composed of several layers of tangentially elongated stone cells, cells rectangular or elongated-rounded, 7~65 μm in diameter; the inner side scattered with numerous stone cell groups, stone cells mostly branched, fiber bundles rare; inside scattered with elongated tangentially oblong oil cells, with wall slightly thickened. Phloem occupied the most part of the cortex, rays broad, 1~3 rows of cells wide, gradually broad from inside to outside, phloem fiber bundles abundant, with walls extremely thickened, oil cells numerous, singly scattered or 2~5 linked. Parenchymatous cells contain yellowish-brown contents or filled with starch granules, after processing, starch granules mostly gelatinized, a few of prisms of calcium oxalate occasionally found.
2. **Powder:**
(1) Bark of trunk, root and branch of *Magnolia officinalis*: Brownish-yellow. Stone cells abundant, elongated-rounded or subsquare, 11~65 μm in diameter, some large one irregularly branched, branches short and obtuse-rounded or long and acute, occasionally lignified striations visible. Fibers 15~32 μm in diameter, wall extremely thickened and straight, lignified pit canals indistinct. Oil cells round or oblong, 50~85

μm in diameter, containing yellowish-brown oily contents, cell wall lignified. Cork cells polygonal, with thin and slightly curved walls. Compound sieve plate of sieve tubes with relatively large sieve area, sieve pits distinct. Prisms of calcium oxalate rarely present and gelatinized or ungelatinized fragments of starch granules.

(2) Bark of trunk, root and branch of *Magnolia officinalis* var. *biloba*: With fibers serrate at one side; oil cells 27~75 μm in diameter, wall unlignified or lignified; cork cells with wall extremely thin and straight, usually layers overlapped; starch granules round, 3~10 μm in diameter.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 10 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of magnolol and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of toluene and methanol (17:1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with vanillin/H_2SO_4 TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 12.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 7.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 4.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Magnolol:

(1) Mobile phase: A solution of water, acetonitrile, and glacial acetic acid (50:50:1). The ratio may be adjusted, if necessary.

(2) Reference standard solution: Weigh accurately a quantity of magnolol, and dissolve in 70% methanol to produce a solution containing 0.1 mg per mL.

(3) Sample solution: Weigh accurately 0.5 g of powdered sample, add accurately 40 mL of 70% methanol, ultrasonicate for 30 minutes, make up to volume with 70% methanol, mix well, filter and use the successive filtrate.

(4) Chromatographic system: The liquid chromatography is equipped with an UV detector (289 nm) and a column (4~6 mm × 15~25 cm) packing L1 (5~10 μm). The column temperature is maintained at room temperature. Inject reference standard solution into the liquid chromatography apparatus for 5 times, and record the peak areas. The relative standard deviation of the peak area of magnolol should not be more than 1.5%.

(5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Magnolol (%)=10(r_U/r_S) (C_S) / (W)

r_U: peak area of magnolol of sample solution

r_S: peak area of magnolol of reference standard solution

C_S: concentration of magnolol of reference standard solution (mg/mL)

W: weight of test sample (g) calculated with dried sample

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place.
Usage: Qi-regulating medicinal.
Property and flavor: Warm; bitter and pungent.
Meridian tropism: Spleen, stomach, lung, and large intestine meridians.
Effects: Dry dampness and resolve phlegm, direct qi downward and eliminate fullness.
Administration and dosage: 3~11.5 g.

MAGNOLIAE FLOS
辛夷
Sin Yi / Xin Yi
Magnolia Flower Bud

Magnolia flower bud is the dried flower bud of *Magnolia biondii* Pamp., *Magnolia denudata* Desr. or *Magnolia sprengeri* Pamp. (Fam. Magnoliaceae).

It contains not less than 10.0% of dilute ethanol-soluble extractives, not less than 11.0% of water extractives, not less than 1.0% (v/w) of volatile oil and not less than 2.5% of magnolin.

Description:

1. Flower bud of *Magnolia biondii*: Long ovate or like the tip of a writing brush, 1.2~2.6 cm in length, 0.7~1.5 cm in diameter. Mostly the base with a lignify and short pedicel, about 5 mm in length, externally yellowish-green or yellowish-brown, exhibiting whitish dotted lenticels. Bracts 2~3 layers, each layer 2 segments, bearing small scaly buds between 2 layers of bracts, outer surface of bract densely covered with grayish-yellow, grayish-white tomenta, inner surface brownish, glabrous, inner bract relatively thin. Perianth-segments 9, brownish-yellow, outer ones 3, stripe-shaped, about 1/4 in length of the inner ones, inner ones 6, arranged in 2 whorls of 3. Stamens and pistils numerous, spirally arranged. Texture light and fragile. Odour aromatic; taste pungent, with a cooling sensation, slightly bitter.
2. Flower bud of *Magnolia denudata*: 1.5~3.3 cm in length, 1~1.5 cm in diameter. Pedicels stout at the base, 4~8 mm in diameter, lenticels pale brown. Outer surface of bract densely covered with grayish-white or grayish-green tomenta. Perianth-segments 9, outer whorls and inner whorls homogeneous.
3. Flower bud of *Magnolia sprengeri*: 2~4.3 cm in length, 0.5~2 cm in diameter. Pedicels stout at the base, 0.6~1 cm in diameter, lenticels red-brown. Outer surface of bract densely covered with pale yellowish-brown or pale yellowish-green tomenta, occasionally the outer bracts appearing brown after the hairs fallen off. Perianth-segments 10~12, less differentiated between the outer and inner whorls.

Microscopic identification:

1. **Transverse section:**
   Dried flower bud of *Magnolia biondii*, *Magnolia denudata* or *Magnolia sprengeri*: Peduncle: Epidermal cells one row, resembling as stone cells, mostly differentiated to form non-glandular hairs. The non-glandular hairs composed of 1~3 cells. A few groups of oil cells and stone cells are found in the cortex. Stone cells subrounded, fusiform or irregular, 34~206 μm in length, 16~99 μm in diameter, occasionally with striations. Vascular bundles arranged in a ring. A few groups of oil cells and stone cells are also found in the pith.
2. **Powder:** Dried flower bud of *Magnolia denudata*: Grayish-green or pale yellowish-green. Non-glandular hairs numerous, with 2 types, first type is unicellular hairs, 14~19 μm in diameter, walls extremely thickened, the base occasionally lined with epidermal cells; second type is multicellular hairs, composed of 3~5 cells, up to about 4500 μm in length, 32~35 μm in diameter, the 1~2 basal cells extremely short, subsquare, 16~32 μm in length, slightly shrunken, occasionally surrounded by over 10 epidermal cells aggregated into spheroidal, the head cells extremely long, walls 10~14 μm thick; more hairs showing obvious spiral striations or overlapping double-helix. Branched stone cells extremely numerous, varying in size, terminal at branchlets tapering or blunt, walls 5~10 μm thick, some with distinct striations, pit canals fine. Oil cells extremely numerous, subrounded or oblong, walls thin and occasionally slightly shrunken, 48~115 μm in diameter.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, heat under reflux for 30 minutes, cool, filter and make up the filtrate to 10 mL.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of magnolin and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of dichloromethane and ethyl ether (5:1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105°C until the spots become visible. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 12.0% dry at 105°C for 5 hours (General rule 6015).
2. Total ash: Not more than 5.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.5% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Magnolin:
   (1) Mobile phase: A solution of acetonitrile and water (35:65). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of magnolin and

dissolve in methanol to produce a solution containing 0.1 mg per mL.

(3) Sample solution: Weigh accurately 0.25 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 25 mL of methanol, ultrasonicate for 90 minutes. Centrifuge for 5 minutes, transfer the supernatant to a 100-mL volumetric flask. Repeat the extraction of the residue three more times. Combine the supernatant and make up to volume with methanol, mix well, filter and use the successive filtrate.

(4) Chromatographic system: The liquid chromatography is equipped with an UV detector (278 nm) and a column packing L1. The column temperature is maintained at 25°C. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of magnolin should not be less than 5,000.

(5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Magnolin (%)=10(r_U/r_S) (C_S) / (W)

r_U: peak area of magnolin of sample solution

r_S: peak area of magnolin of reference standard solution

C_S: concentration of magnolin of reference standard solution (mg/mL)

W: weight of test sample (g) calculated

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).
4. Volatile oil: Carry out the method for determination of volatile oil (General rule 6013).

Storage: Refrigerate or store in a cool and dry place.
Usage: Exterior-releasing medicinal (Pungent-warm exterior-releasing medicinal).
Property and flavor: Warm; pungent.
Meridian tropism: Lung and stomach meridians.
Effects: Disperse wind, relieve stuffy nose.
Administration and dosage: 3~11.5 g, wrap-decocted.

MANTIDIS OŌ THECA
桑螵蛸
Sang Piao Siao / Sang Piao Xiao
Mantis Egg-case

Mantis egg-case is the dried egg capsule of *Tenodera sinensis* Saussure, *Statilia maculata* Thunberg or *Hierodula patellifera* Serville (Fam. Mantidae).
It contains not less than 4.0% of dilute ethanol-soluble extractives and not less than 4.0% of water extractives.

Description:

1. Capsule of Tuan Piao Xiao *(Tenodera sinensis)*: Subcylindrical or in masses, 2.5~4 cm in length, 2~3 cm in width, 1.5~2 cm thick, consisting of many layers of thin overlapping memberanous slices. Externally pale yellowish-brown or yellowish-brown, with indistinct protuberant, the bottom even or grooved. Texture light, tenacious, fracture yellowish-brown, the outer part spongy, the inner part with 15~20 radially arranged egg chambers, each side arranged 16~19 rows of ellipsoidal eggs, egg shell reddish-brown, consisting of yellowish-brown egg, lustrous. Odour slightly stinking; taste slightly salty.
2. Capsule of Chang Piao Xiao *(Statilia maculata)*: Slat-shaped, 2.5~5 cm in length, 1~1.5 cm in width, 1 cm thick. Externally grayish-yellow, with upward oblique striations, the upper part with ribbon-like ridge, each side of the ridge with one brown shallow groove, the bottom even or grooved. Texture hard and fragile, fracture with 13~14 radially arranged egg chambers, egg ellipsoidal, yellowish-brown, lustrous. Odour slightly stinking.
3. Capsule of Hei Piao Xiao *(Hierodula patellifera)*: Tetragonal, 2~3.5 cm in length, 1~1.5 cm in width, 1~1.5 cm thick. Externally blackish-brown, with upward oblique striations, the upper part with ribbon-like ridge, the bottom slightly curved. Texture hard and fragile, fracture with 14~20 radially arranged egg chambers, egg ellipsoidal, yellowish-brown, lustrous. Odour slightly stinking.

Microscopic identification:
Powder: Yellow. The outer layer spongy, both the outer and inner layer contain fiber-shaped structures and subrounded cavities, containing crystals. Egg cells contain fats and yolk grains.

Identification:
Check protein: Take 2.0 g of powdered sample, add 20 mL of water, boil for 10 minutes, and filter. Take 2 mL of the filtrate, add 3~4 drops of 0.2% ninhydrin solution, boil for 5 minutes, a purplish-blue color is produced.

Impurities and other requirements:

1. Loss on drying: Not more than 14.0% dry at 105°C for 5 hours (General rule 6015).
2. Total ash: Not more than 7.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 4.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place, and protect from moisture.
Usage: Astringent medicinal.
Property and flavor: Neutral; sweet and salty.
Meridian tropism: Liver, kidney and bladder meridians.
Effects: Tonify kidney and assist yang, secure essence and reduce urination, stop turbidity and stanch vaginal discharge.
Administration and dosage: 3~11.5 g.

MAYDIS STYLUS
玉米鬚
Yu Mi Syu / Yu Mi Syu
Corn Stylus

Corn stylus is the dried style and stigma of *Zea mays* L. (Fam. Gramineae).
It contains not less than 4.0% of dilute ethanol-soluble extractives and not less than 5.0% of water extractives.

Description: Linear or whisker-like, aggregates into loose clusters. 5~30 cm in length, about 0.05 cm in diameter. Pale yellow to brownish red, slightly shiny. Stigma 2 split and split 3 mm. Soft.

Microscopic identification:
Powder: Yellowish-brown. Style fragments reddish-brown, many non-glandular hairs on the surface, ducts on both sides of the style, non-glandular hairless, composed of several to more than 10 cells, multi-column branched hair, branch single cell, finger-like Non-glandular hair base 1~3 columns of cells, top 1 column, catheter mostly threaded and ring-shaped.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 1 mL of methanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of ergosterol and dissolve in methanol to produce a solution containing 0.2 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane and ethyl acetate (7:3) as the developing solvent. Apply 2 μL of each of the sample solution and reference drug solution and 5 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 14.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 8.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place.
Usage: Dampness-dispelling medicinal (Dampness-draining diuretic medicinal).
Property and flavor: Neutral; sweet.
Meridian tropism: Bladder and kidney meridians.
Effects: Induce diuresis to alleviate edema, cool the blood, clear heat, dispel dampness heat qi, pacify liver and drain bile.
Administration and dosage: 15~30 g.

MENTHAE HERBA
薄荷
Bo He / Bo He
Peppermint Herb

Peppermint herb is the dried aerial part of *Mentha canadensis* L. (*Mentha haplocalyx* Briq.) and the similar species (Fam. Labiatae).
It contains not less than 9.0% of dilute ethanol-soluble extractives, not less than 10.0% of water extractives and not less than 0.8% (v/w) of volatile oil.

Description: Stems square, with opposite branches, up to about 90 cm in length, 2~8 mm in diameter; externally

purplish-brown or pale green, with nodes, internodes 2~5 cm in length, the angular regions pubescent; texture fragile, fracture white, pith often hollowed. Leaves opposite, lamina rolled and crumpled, both surfaces pubescent and with dotted glandular scales. Verticillaster axillary, calyx mostly persistent. Odour characteristic and aromatic after rubbing the leaves; taste pungent and cool.

Microscopic identification:

1. **Transverse section:**
   (1) Leaf of *Mentha canadensis*: Upper epidermal cells rectangular; lower epidermal cells small and flat, with stomata; glandular scales (flat-globular glandular hairs) located at sunken spaces of both upper and lower epidermis. Palisade tissue composed of 1 layer of cells, occasionally 2-layered; spongy tissue composed of 4~7 layers of cells, mesophyll contains needle cluster shaped hesperidin crystals, mostly present in palisade tissue. Vascular bundles of main vein collateral, xylem vessels usually 2~4 arranged in rows, phloem cells small. Collenchymatous cells present inside upper and lower epidermis of main vein. Parenchymatous cells and vessels occasionally contain hesperidin crystals. Glandular scales with head 8-celled in surface view, up to about 90 μm in diameter, the stalk unicellular; small glandular hairs with head and stalk unicellular. Non-glandular hairs composed of 1~8 layers of cells, usually curved, wall thickened with warty protuberance. Stomata mostly present in lower epidermis, diacytic.
   (2) Stem of *Mentha canadensis*: Epidermal cells rectangular, with hairs and glandular scales. Cortex composed of 4~6 layers of parenchymatous cells, arranged sparsely; collenchyma tissue located at angular regions of stem; endodermis distinct. Phloem extremely thin, cells usually shrunken. Cambium in a ring. Xylem specially developed at angular regions of stem, vessels arranged radially, mainly bordered-pitted, and scattered with xylem fibers. Rays varying in width. Parenchymatous cells of pith large, usually hollowed in the center.
2. **Powder:** Pale yellowish-green. Epidermal cells of leaf with anticlinal walls curved; lower epidermis with diacytic stomata. Glandular scales with subrounded head, 8-celled, 61~99 μm in diameter; the stalk extremely short. Small glandular hairs with head unicellular, oblong, 15~26 μm in diameter, the stalk 1- to 2-celled. Non-glandular hairs 1- to 8-celled, slightly curved, some nodular-shaped, 10~43 μm in diameter, wall 2~7 μm thick, up to about 792 μm in length, warty protuberance slightly fine. Epidermal cells of stem subrectangular or subpolygonal, with longitudinal cutinized striations. Hesperidin crystals present in epidermal cells of stem and leaf, and parenchymatous cells, pale yellow, slightly fan-shaped or irregular, radial striations faintly visible. Vessels and xylem fibers also visible.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and the upper layer of toluene, acetone, and water (4:1:1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray *p*-anisaldehyde/H_2SO_4 TS and heat at 105℃ until the spots become visible. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:

1. Total ash: Not more than 11.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 3.0% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 15.0 ppm (General rule 2251, 6301).
   ※ Note: "When this TCM herb is sold commercially, the limit of heavy metals, sulfur dioxide and aflatoxins should follow the food standard."

Assay:

1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).
3. Volatile oil: Carry out the method for determination of volatile oil (General rule 6013).

Storage: Refrigerate or store in a cool and dry place, and not store too long.

Usage: Exterior-releasing medicinal (Pungent-cold exterior-releasing medicinal).

Property and flavor: Cool, pungent.

Meridian tropism: Lung and liver meridians.
Effects: Disperse wind-heat, clear head and eyes, soothe the throat, outthrust rashes.
Administration and dosage: 3~10 g, decocted later.

MERETRICIS SEU CYCLINAE CONCHA
蛤殼
Ge Ke / Ge Ke
Clam Shell

Clam shell is the dried shell of *Meretrix meretrix* (Linnaeus) or *Cyclina sinensis* (Gmelin) (Fam. Veneridae).

Description:
1. Shell of *Meretrix meretrix*: Fan-like or triangular; the dorsal margin somewhat triangular; the ventral margin arch-like, 3~10 cm in length, 2~8 cm in height, 1.5~2.5 mm thick. Externally yellowish-brown or grayish-white, umbo protuberant near the front of the dorsal side, with distinct brown or silver-gray undulated growth lines nearly umbo or all. The inner surface whitish or slightly greenish-purple, lustrous, ventral margin smooth, without tooth-like stripes. The hinge rather wide. The right shell with three cardinal teeth and two front lateral teeth; the left shell with three cardinal teeth and one front lateral tooth. Texture hard and heavy, fracture with laminated stripes. Odourless; taste weak.
2. Shell of *Cyclina sinensis*: Subrounded, 3~5 cm in length and height, 1~1.5 mm thick. Externally yellowish-white or greenish-white, umbo protuberant near the center of the dorsal side, the concentric growth lines projected from the shell, somewhat like circular ribs, arranged densely, margin slight purple. The inner surface white or pale pink, smooth, the margin with neat small teeth, ventral margin one smaller and dorsal margin gradually thick. Both the right and left shells with three cardinal teeth, but no lateral tooth at the hinge. Texture hard and slightly fragile, fracture with laminated stripes indistinct. Odourless; taste weak.

Microscopic identification:
1. **Transverse section:**
   (1) Shell of *Meretrix meretrix*: The shell striations slightly curved, 5~10 μm in width, between each striation 20~90 μm; criss-cross striations fine and small.
   (2) Shell of *Cyclina sinensis*: The shell striations 15~30 μm in width, between each striation 15~100 μm. Striation margins composed of two striations arranged neatly are found under microscope of high magnification.
2. **Powder:** Calcium carbonate white, containing gravel-like yellow fluorescence. Porcelain white and fine particles scattered with a few of brownish-yellow or purplish-black particles.

Identification:
Take a quantity of powdered sample, add dilute hydrochloric acid, a lot of bubbles is produced; filter and the filtrate show the result consistent with the reaction of calcium salt.

Impurities and other requirements:
1. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
2. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
3. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
4. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
5. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Storage: Store in a ventilated and dry place.
Usage: Phlegm-dispelling medicinal (Heat-phlegm clearing and resolving medicinal).
Property and flavor: Cold; bitter and saltyt.
Meridian tropism: Lung, kidney, and stomach meridians.
Effects: Clear lung and resolve phlegm, soften hardness and disperse bind, promote urination to alleviate edema.
Administration and dosage: 6~15 g, wrap-decocted.

MOMORDICAE SEMEN
木鼈子
Mu Bieh Zih / Mu Bieh Zih
Cochinchina Momordica Seed

Cochinchina momordica seed is the dried seed of *Momordica cochinchinensis* (Lour.) Spreng. (Fam. Cucurbitaceae).
It contains not less than 6.0% of dilute ethanol-soluble extractives and not less than 6.0% of water extractives.

Description: Flat round plate, slightly asymmetrical, with a slight bulge or slight depression in the middle, 2~4 cm in length, about 0.5 cm width, externally grayish brown to brownish black, rough, with a stenciled pattern or only fine wrinkles. Two irregularly arranged coarse teeth in the periphery, light yellow umbilicus on the larger gingival projections. Testa hard and fragile,endotesta film-like, cotyledon 2 leaves, rich oil quality. special oily smell and bitter taste.

Microscopic identification:
Transverse section:
Seed of *Momordica cochinchinensis*: Epidermis composed of 1 layer of subrectangle cells, outer layer cuticle. Under the epidermis composed of 3~4 layers of subsquare parenchymatous cells, and the inner side is several layers of subcircular or irregularly shaped sclerenchyma cells. Cotyledon parenchymatous cells containing fatty oil droplets and aleurone grain, fatty oil droplets subcircular , with reticular striations on the surface.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add accurately 1.5 g of powdered sample to 50 mL of a solution of petroleum ether (30~60℃) and dichloromethane (1:1), heat under reflux for 2 hour, cool then filter, discard the filtrate. Evaporate the residue to dryness, dissolve in 100 mL of 60% methanol, heat under reflux for 4 hour, cool then filter, evaporate the filtrate to dryness, and dissolve the residue in 10 mL of water and 0.6 mL of concentrated sulfuric acid, heat in a boiling water bath for 2 hour, cool then filter, discard the filtrate. Dissolving the residue in 8 mL of methanol, add a few of concentrated sulfuric acid and adjust pH value to 2, macerate with 50℃ warm water for 4 hours, cool, and make up the filtrate to 10 mL.
2. Reference drug solution: Take 1.5 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of gypsogenin-3-*O*-*β*-D-glucuronide and dissolve in methanol to produce a solution containing 0.2 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate and methanol (10:1) as the developing solvent. Apply 8 μL of each of the sample solution and reference drug solution and 2 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 8.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 4.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Storage: Store in a ventilated and dry place.
Usage: Carbuncle-sore medicinal.
Property and flavor: Cool, bitter and mild sweet.
Meridian tropism: Liver, spleen, and stomach meridians.
Effects: Remove swelling and disperse stagnation, attack toxin to treat sore.
Administration and dosage: 0.9~12 g; used an appropriate amount for external use.
Precaution and warning: Use cautiously during pregnancy.

MORI CORTEX
桑白皮
Sang Bai Pi / Sang Bai Pi
Mulberry Root bark

Mulberry root bark is the dried bark of root without cork of *Morus alba* L. (Fam. Moraceae).
It contains not less than 5.0% of dilute ethanol-soluble extractives and not less than 5.0% of water extractives.

Description: Twisted quilled or flat pieced, l.5~4 mm thick. Outer surface milky-white, even, occasionally remained with reddish-brown cork, inner surface yellowish-white or pale yellowish-brown, with fine longitudinal striations. Texture hard, fracture milky-white, strongly fibrous, easily stripped longitudinally. Taste slightly sweet.

Microscopic identification:

1. **Transverse section:**
   Bark of root without cork of *Morus alba*: Phloem rays distinct, 3~6 rows of cells wide; phloem scattered with laticiferous tubes; fibers abundant, singly scattered or in bundles, wall thick, unlignified or slightly lignified; stone cells usually grouped with crystal-containing sclerenchymatous cells. Parenchymatous cells contain starch granules, some containing prisms of calcium oxalate.
2. **Powder:** Pale grayish-yellow. Fibers numerous, colorless, extremely long, straight or slightly curved, with wavy edge, 13~31 μm in diameter, with wall extremely thickened, unlignified or slightly lignified. Laticiferous tubes up to about 57 μm in diameter, containing extremely fine granular secretions. Stone cells pale yellow or yellowish-brown, subrounded, subsquare, subpolygonal or short-fusiform, 24~52 μm in diameter, with walls relatively thickened or extremely thickened, pits mostly distinct, pit canals with branches. Crystal-containing sclerenchymatous cells subrounded or rounded-triangular, up to about 48 μm in diameter, wall lignified and thickened unevenly, containing prisms of calcium oxalate, 11~32 μm in diameter. Simple starch granules subspheroidal or oblong, 2~16 μm in diameter; compound granules composed of 2~8 components.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 1 mL of methanol.

2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of morusin and dissolve in methanol to produce a solution containing 0.1 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of dichloromethane and ethanol as the developing solvent. Apply 8 μL of each of the sample solution and reference drug solution and 2 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 254 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 14.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 12.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 5.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place, and protect from moisture and insects.
Usage: Phlegm-dispelling medicinal (Cough-suppressing and panting-calming medicinal).
Property and flavor: Cold; sweet.
Meridian tropism: Lung meridians.
Effects: Drain lung to calm panting, induce diuresis to alleviate edema.
Administration and dosage: 6~12 g.

MORI FOLIUM
桑葉
Sang Ye / Sang Ye
Mulberry Leaf

Mulberry leaf is the dried leaf of *Morus alba* L. (Fam. Moraceae).
It contains not less than 15.0% of dilute ethanol-soluble extractives, not less than 15.0% of water extractives and not less than 0.1% of rutin.

Description: Mostly crumpled and broken, oval as whole, 8~15 cm in length, 6~12 cm in width, margin serrate, base rounded or cordate, apex acuminate. Upper surface yellowish-green or yellowish-brown, slightly lustrous, occasionally with protuberance, sparsely pubescent on the veins. Lower surface relatively light in color, pale yellow, lateral veins reticulate and protuberant, pubescent. Texture fragile, easily broken. Odour slight; taste weak, slightly bitter and astringent.
Mori folium

Microscopic identification:
1. **Transverse section:**
   Leaf of *Morus alba*: Upper epidermis with 1 row of cells, covered with cuticle, cells large, polygonal, 15~30 μm in diameter, large cells with cystoliths, and the outer wall slightly protruded. Unicellular glandular hairs and non-glandular hairs visible. Lower epidermis with 1 row of flat and relatively small cells, with numerous stomata. Main vein protuberant downwards, containing collateral vascular bundles; collenchymatous tissue scattered in the outer part of vascular bundles, cells relatively small, phloem narrow, xylem crescent-shaped, spiral vessels present, 5~12 μm in diameter. Parenchymatous cells filled with abundant prisms and clusters of calcium oxalate. Palisade tissue 1~2 rows, arranged densely, cells square or subrounded, 25~35 μm in length and 2~6 μm in width. Spongy tissue with cells subrounded or polygonal, 5~10 μm in diameter.
2. **Powder:** Yellowish-green or yellowish-brown. Upper epidermal cells polygonal, 50 μm in diameter, anticlinal walls straight, containing crystals of calcium oxalate. Lower epidermal cells relatively small, stomata numerous, with 4~6 subsidiary cells. Epidermal cells containing cystoliths subrounded, 30~60 μm in diameter, surrounded by epidermal cells arranging radially. Non-glandular hairs mostly unicellular, usually broken. Glandular hairs rare, composed of multicellular head and unicellular stalk. Clusters of calcium oxalate scattered in mesophyll; prisms of calcium oxalate scattered in parenchymatous cells. Laticiferous tubes also present, 7~15 μm in diameter, containing yellow secretions.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of ethanol, ultrasonicate for 30 minutes, cool, filter and make up the filtrate to 10 mL.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane, ethyl acetate, and acetone (5:2:1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:

1. Loss on drying: Not more than 14.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 13.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 5.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Rutin:
   (1) Mobile phase: Methanol as the mobile phase A, and 0.5% phosphoric acid as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of rutin and dissolve in methanol to produce a solution containing 0.1 mg per mL.
   (3) Sample solution: Weigh accurately 1.0 g of powdered sample and place it in a round bottom flask, add 50 mL of methanol, heat under reflux for 30 minutes, filter, Repeat the extraction of the residue three more times. Combine the filtrates, evaporate to dryness, dissolve the residue in a quantity of methanol, transfer to a 25-mL volumetric flask, make up to volume with methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (358 nm) and a column packing L1. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of rutin should not be less than 5,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~5	30	70
5~10	30→35	70→65
10~15	35→40	65→60
15~18	40→50	60→50

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Rutin (%)=2.5(r_U/r_S) (C_S) / (W)
   r_U: peak area of rutin of sample solution
   r_S: peak area of rutin of reference standard solution
   C_S: concentration of rutin of reference standard solution (mg/mL)
   W: weight of test sample (g) calculated with dried sample
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place, and protect from moisture.
Usage: Exterior-releasing medicinal (Pungent-cold exterior-releasing medicinal).
Property and flavor: Cold; sweet and bitter.
Meridian tropism: Lung and liver meridians.
Effects: Disperse wind-heat, clear lung and moisten dryness, clear liver to improve vision.
Administration and dosage: 3~12 g.

MORI RAMULUS
桑枝
Sang Jhih / Sang Zhi
Mulberry Twig

Mulberry twig is the dried twig of *Morus alba* L. (Fam. Moraceae).
It contains not less than 2.0% of dilute ethanol-soluble extractives and not less than 0.12% of oxyresveratrol.

Description: Long cylindrical, branched less, varying in length, 0.5~1.5 cm in diameter. Externally grayish-yellow to grayish-brown, with numerous pale brown dotted lenticels and fine longitudinal striations, with grayish-white and slightly semicircular leaf scars and brownish-yellow budlets. Texture tenacious, uneasily broken,

fracture yellowish-white, fibrous. Slices 2~5 mm thick, bark relatively thin, wood with radial striations, pith white, spongy. Odour slight; taste weak.

Microscopic identification:

1. **Transverse section:**
   Twig of *Morus alba*: Cork brownish-yellow. Cortex contains lignified fibers and crystal fibers. Pericycle contains unlignified fiber bundles. Phloem scattered with unlignified fibers and mucilage cells, phloem rays distinct. Cambium in a ring. Xylem developed, vessels scattered singly or 2 parallelly scattered, with distinct annual ring. Pith distinct.
2. **Powder:** Grayish-yellow. Fibers mostly tangled, pale yellow or colorless, extremely long and slightly curved, 8~33 μm in diameter, with walls thickened and unlignified, lumen linear. Stone cells pale yellow or yellow, subrounded, oblong or square, 13~39 μm in diameter, wall 6~20 μm thick, pit canals relatively distinct or branched. Crystal-containing sclerenchymatous cells with shape and size similar to stone cells, walls mostly vary in thickness, 2~6 μm thick, lumen containing 1~2 prisms of calcium oxalate. Prisms of calcium oxalate polyhedral, square, rhombic or subdouble-conical, 5~20 μm in diameter; clusters of calcium oxalate rare. Xylem rays heterocellular, 4~80 cells high and 1~3 cells wide in sectional view, 1~3 upright cells at both ends. Laticiferous tubes, xylem fibers, vessels, cork cells and prisms of calcium oxalate also present.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 15 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of oxyresveratrol and dissolve in methanol to produce a solution containing 0.1 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of dichloromethane and methanol (5:1) as the developing solvent. Apply 2 μL of each of the sample solution and reference drug solution and 1 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 12.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 6.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 3.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Oxyresveratrol:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and water as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of oxyresveratrol, and dissolve in methanol to produce a solution containing 10 μg per mL.
   (3) Sample solution: Weigh accurately 0.2 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 20 mL of 50% ethanol, ultrasonicate for 30 minutes, filter to 40-mL volumetric flask with filter paper. Repeat the extraction of the residue one more time. Combine the filtrate and make up to volume with 50% ethanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (326 nm) and a column packing L1. The column temperature is maintained at room temperature. The flow rate is about 1 mL/min.Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of oxyresveratrol should not be less than 20,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~15	10→30	90→70
15~22	30→100	70→0

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Oxyresveratrol (%)=0.004(r_U/r_S) (C_S) / (W)
   r_U: peak area of oxyresveratrol of sample solution
   r_S: peak area of oxyresveratrol of reference standard solution
   C_S: concentration of oxyresveratrol of reference standard solution (μg/mL)
   W: weight of test sample (g) calculated with dried sample

2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place.
Usage: Dampness-dispelling medicinal (Wind-dampness-dispelling medicinal).
Property and flavor: Neutral; mild bitter.
Meridian tropism: Liver meridians.
Effects: Dispel wind dampness, promote joint.
Administration and dosage: 9~15 g.

MORINDAE OFFICINALIS RADIX
巴戟天
Ba Ji Tian / Ba Ji Tian
Morinda Root

Morinda root is the dried root of *Morinda officinalis* F.C.How (Fam. Rubiaceae).
It contains not less than 50.0% of dilute ethanol-soluble extractives, not less than 55.0% of water extractives and not less than 2.0% of nystose.

Description: Compressed-cylindrical, slightly curved, varying in length, 0.5~2 cm in diameter. Externally grayish-yellow or dark gray, with longitudinal wrinkles and transverse furrows, some bark transversely broken and wood exposed. Texture tenacious, fracture bark thick, purple or pale purple, easily exfoliated from wood, wood hard, yellowish-brown or yellowish-white, 1~5 mm in diameter. Odourless; taste sweetish and slightly astringent.

Microscopic identification:
1. **Transverse section:**
   Root of *Morinda officinalis*: Cork composed of several layers of cells. Stone cells present individually or in groups in the outer part of cortex, arranged in an interrupted ring; parenchymatous cells contain raphides of calcium oxalate, tangentially elongated. Phloem broad; parenchymatous cells in the inner part contains raphides of calcium oxalate, radially elongated. Cambium distinct. Xylem vessels scattered individually or 2~3 in groups, arranged radially, up to 105 μm in diameter; xylem fibers relatively developed; xylem rays 1~3 layers of cells wide; some with existence of unlignified xylem parenchymatous cell groups.
2. **Powder:** Pale purple or purplish-brown. Stone cells pale yellow, subrounded, subsquare, subrectangular, strip-shaped or irregular, with acute end, 21~96 μm in diameter, cell wall up to 39 μm thick, occasionally with distinct striations, pits and pit canals; some stone cells large, wall thick. Raphides of calcium oxalate scattered in parenchymatous cells, up to 184 μm long. Bordered-pitted vessels pale yellow, up to 105 μm in diameter, pits very fine and dense. Fibers long-fusiform, with relatively large bordered pits, pit apertures obliquely slit-shaped, V-shaped or cruciate.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 0.5 g of powdered sample to 20 mL of methanol, ultrasonicate for 15 minutes, filter and use the filtrate.
2. Reference drug solution: Take 0.5 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of nystose and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, glacial acetic acid, formic acid, and water (6:2:2:3) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Total ash: Not more than 6.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 1.5% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 10.0 ppm (General rule 2251, 6301).

Assay:
1. Nystose:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and water as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of nystose, and dissolve in 60% ethanol to produce a solution containing 0.2 mg per mL.
   (3) Sample solution: Weigh accurately 0.2 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 25 mL of 60% ethanol, ultrasonicate for 30 minutes. Centrifuge for 10 minutes, filter, transfer successive filtrate to a 25-mL volumetric flask, make up to volume with 60% ethanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: It is equipped with an evaporative light-scattering detector (ELSD) and a column packing L3. The column temperature is maintained at 35°C. The flow

rate is about 0.7 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of nystose should not be less than 8,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~25	90→65	10→35

(5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from mold and insects.
Usage: Tonifying and replenishing medicinal (Yang-tonifying medicinal).
Property and flavor: Mild warm; sweet and pungent.
Meridian tropism: Kidney and liver meridians.
Effects: Tonify kidney and assist yang, strengthen sinew and bone, dispel wind and eliminate dampness.
Administration and dosage: 3~15 g.

MOSLAE HERBA
香薷
Siang Ru / Xiang Ru
Chinese Mosla Herb

Chinese mosla herb is the dried aerial part of *Mosla chinensis* Maxim. or *Mosla chinensis* 'Jiangxiangru' (Fam. Labiatae). The former is called "Qingxiangru" and the latter is called"Jiangxiangru".
It contains not less than 10.0% of dilute ethanol-soluble extractives and not less than 9.0% of water extractives.

Description: Stem 30~50 cm in length, the basal part purplish-red, the upper part yellowish-green or pale yellow, whole plant covered densely with white pubescences. Stems quadrangular, base subrounded, nodes distinct, internodes 4~7 cm in length. Leaves opposite, mostly crumpled or fallen off, grayish-green or green, lamina lanceolate as whole, margin with 3~5 sparsely lobed, both surfaces pubescent and with glandular dots. Spike terminal and axillary; bracts board ovate; calyx persistent, campanulate, pale purplish-red or grayish-green, apex 5-lobed, densely pubescent. Nutlets 4, subspheroidal, with reticulations. Odour intensely aromatic; taste slightly pungent and cool.

Microscopic identification:
Transverse section:
Moslae herba: Upper epidermal cells with walls relatively straight, polygonal, with relatively numerous non-glandular hairs, glandular scales with an 8-celled head and an unicellular stalk, about 36~80 μm in diameter; lower epidermal cells with walls not thickened, glandular scales 70~80 μm in diameter. Stomata diacytic, more frequently observed on the lower surface. Non-glandular hairs on the upper and lower epidermis mostly 2-celled, the upper cells frequently hook-like, warty protruding distinct.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, cool, filter and make up the filtrate to 10 mL.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of dichloromethane and acetone (5:1) as the developing solvent. Apply 10 μL of each of the above solutions to the plate. Once the top of solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible, examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:
1. Loss on drying: Not more than 12.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 10.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place, and protect from insects.
Usage: Exterior-releasing medicinal (Pungent-warm exterior-releasing medicinal).
Property and flavor: Mild warm; pungent.
Meridian tropism: Lung and stomach meridians.

Effects: Release exterior to dispel summerheat, resolve dampness and harmonize middle.
Administration and dosage: 3~11.5 g.

MOUTAN RADICIS CORTEX
牡丹皮
Mu Dan Pi / Mu Dan Pi
Tree Peony Bark

Tree peony bark is the dried bark of root of *Paeonia suffruticosa* Andrews (Fam. Ranunculaceae).
It contains not less than 23.0% of dilute ethanol-soluble extractives, not less than 20.0% of water extractives, not less than 1.2% of paeonol and not less than 0.5% of paeoniflorin.

Description: Quilled or semiquilled, with in longitudinal cut fissures, curved inward or opened, varying in length, 5~25 cm in length, 0.5~1.4 cm in diameter, 2~4 mm thick. Outer surface grayish-brown or yellowish-brown, the exposed surface where cork fallen off appearing pale grayish-yellow, pink or pale reddish-brown, with numerous transverse and slightly dented lenticels and rootlet scars, inner surface pale grayish-yellow or brown, with obvious fine longitudinal striations, showing white needle, flake or crystalline crystals. Texture hard and fragile, fracture relatively even, starchy, and grayish-white to pink. Odour aromatic; taste slightly bitter and astringent, with numb and pungent sensation.

Microscopic identification:
1. **Transverse section:**
   Bark of root of *Paeonia suffruticosa*: Cork composed of several layers of cells, walls pale red. Cortex extremely thin, composed of several rows of prolonged tangentially parenchymatous cells. Phloem occupied the most part of the transverse section. Rays broad, 1~3 rows of cells wide. Phloem, parenchymatous cells of cortex and intercellular spaces all contain clusters of calcium oxalate; parenchymatous cells also contain starch granules.
2. **Powder:** Pale reddish-brown. Starch granules abundant, simple granules subspheroidal, spheroidal or polygonal, 3~16 μm in diameter, hilum dotted, clef-shaped, Y-shaped or stellate; compound granules composed of 2~6 components. Clusters of calcium oxalate extremely abundant, 9~45 μm in diameter, crystal-containing parenchymatous cells arranged in rows, occasionally one parenchymatous cell containing several clusters or intercellular spaces filled with clusters. Cork cells rectangular, walls slightly thickened, pale red. Raphides or flaky crystals of paeonol occasionally present.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of ethyl acetate, ultrasonicate for 30 minutes, filter, evaporate the filtrate to dryness, dissolve the residue in 2 mL of methanol and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of paeonol and dissolve in methanol to produce a solution containing 2.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane, ethyl acetate, and glacial acetic acid (4:1:0.1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 13.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 5.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 5.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).
9. Pesticide residues:
   (1) The total DDT content: Not more than 0.2 ppm (General rule 6305).
   (2) The total BHC content: Not more than 0.2 ppm (General rule 6305).

Assay:
1. Paeonol and paeoniflorin:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and water as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of paeonol and paeoniflorin, dissolve in methanol to produce a solution containing 50 μg and 25 μg per mL.
   (3) Sample solution: Weigh accurately 0.2 g of the powdered sample, add accurately 25 mL of methanol, heat under reflux for 30 minutes, cool and filter, transfer the filtrate to a 50-mL volumetric flask, and repeat the extraction of the residue one more time and transfer the second filtrate into same flask. Combine the filtrate and make up to volume with methanol, mix well, filter and use the successive filtrate.

(4) Chromatographic system: The liquid chromatography is equipped with an UV detector (274 nm for paeonol and 230 nm for paeoniflorin) and a column packing L1. The column temperature is maintained at 35℃. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of paeonol and paeoniflorin should not be less than 8,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~15	10→18	90→82
15~30	18→60	82→40
30~35	60→100	40→0

(5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, calculate the content.

Paeonol or paeoniflorin (%)=0.005 (r_U/r_S) (C_S) / (W)

r_U: peak area of paeonol or paeoniflorin of sample solution

r_S: peak area of paeonol or paeoniflorin of reference standard solution

C_S: concentration of paeonol or paeoniflorin of reference standard solution (μg/mL)

W: weight of test sample (g) calculated with dried sample

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place.
Usage: Heat-clearing medicinal (Heat-clearing and blood-cooling medicinal).
Property and flavor: Mild cold; bitter and pungent.
Meridian tropism: Heart, liver and kidney meridians.
Effects: Clear heat to cool the blood, activate blood dissipate stasis.
Administration and dosage: 6~12 g.

【Decoction pieces】

MOUTAN RADICIS CORTEX

It contains not less than 23.0% of dilute ethanol-soluble extractives, not less than 20.0% of water extractives, not less than 1.2% of paeonol and not less than 0.5% of paeoniflorin.

Raw medicinal materials are processed to remove impurities, clean selection, soften thoroughly, cut into thin slices, and dry, mostly rounded or curled thin slices. Externally greyish-brown or yellowish-brown, fine rootlet scars and lenticels can be seen, the exposed surface where cork fallen off appearing pink. Inner surface pale greyish-yellow, sometimes showing bright crystals. Texture hard and fragile, easily broken, cut surface even, pale pink, starchy. Odour aromatic; taste slightly bitter and astringent.

Thin layer chromatographic identification test: The method is the same as that for crude herb.
Impurities and other requirements: Methods and specifications are the same as those for crude herb.
Assay: The method is the same as that for crude herb.
Storage: The method is the same as that for crude herb.
Usage: Heat-clearing medicinal (Heat-clearing and blood-cooling medicinal).
Property and flavor: Mild cold; bitter and pungent.
Meridian tropism: Heart, liver and kidney meridians.
Effects: Clear heat to cool the blood, activate blood dissipate stasis.
Administration and dosage: 6~12 g.

MUME FRUCTUS
烏梅
Wu Mei / Wu Mei
Dark Plum Fruit

Dark plum fruit is the smoked and baked prearation obtained from the dried and almost ripe fruit of *Prunus mume* (Siebold) Siebold & Zucc. (Fam. Rosaceae).
It contains not less than 18.0% of dilute ethanol-soluble extractives, not less than 18.0% of water extractives and not less than 12.0% of citric acid.

Description: Subspheroidal or flattened-spheroidal, 1.5~3 cm in diameter. Externally brownish-black to black, shrunken and uneven, pubescent, base with a rounded fruit stalk scar. Pulp soft or slightly hard. Kern hard, ellipsoidal, brownish-yellow, with dented spots on surface; seed 1, flattened-ovate, pale yellow. Odour burnt and sour; taste extremely sour and astringent.

Microscopic identification:
Powder: Brownish-black. Non-glandular hairs mostly unicellular, few with 2~5 cells, straight or sickle-shaped curved, pale yellowish-brown, 32~720 μm in length and 16~49 μm in diameter, with walls thickened, unlignified or slightly lignified, spiral overlapped striations occasionally visible on the surface, the base slightly rounded or straight, lumen usually containing brown contents. Parenchymatous cells of mesocarp shrunken, occasionally containing clusters of calcium oxalate, 26~35 μm in diameter. Fibers singly scattered or several in bundles, scattered in parenchyma tissue, long-fusiform, 6~29 μm in diameter, wall 3~9 μm thick, unlignified or slightly lignified. Epidermal cells subpolygonal in surface view, lumen containing blackish-brown contents, scars after non-glandular hairs fallen off frequently present. Stone cells few, rectangular, subrounded or subpolygonal, 20~36 μm in diameter, lumen containing reddish-brown contents.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, cool, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of ursolic acid and dissolve in methanol to produce a solution containing 0.5 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane, dichloromethane, ethyl acetate, and formic acid (15:5:8:0.1) as the developing solvent. Apply 10 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Total ash: Not more than 6.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
3. Sulfur dioxide: Not more than 400 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).
   ※Note: "When this TCM herb is sold commercially, the limit of heavy metals, sulfur dioxide and aflatoxins should follow the food standard."

Assay:

1. Citric acid:
   (1) Mobile phase: A solution of 0.5% ammonium dihydrogen phosphate and water solution (50:50). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of citric acid and dissolve in water to produce a solution containing 0.5 mg per mL.
   (3) Sample solution: Weigh accurately 0.2 g of powdered sample and place it in a conical flask with a stopper, add accurately 50 mL of water then weigh, heat under reflux for 1 hour, cool, weigh again, replenish the loss of the weight with water, mix well, centrifuge, filter the supernatant and use the filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (210 nm) and a column packing L1. The column temperature is maintained at 35℃. The flow rate is about 0.5 mL/min. The number of theoretical plates of the peak of citric acid should not be less than 7,000
   (5) Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Citric acid (%)=5(r_U/r_S) (C_S) / (W)
   r_U: peak area of citric acid of sample solution
   r_S: peak area of citric acid of reference standard solution
   C_S: concentration of citric acid of reference standard solution (mg/mL)
   W: weight of test sample (g) calculated with dried sample
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place, and protect from moisture.
Usage: Astringent medicinal.
Property and flavor: Neutral; sour and astringent.
Meridian tropism: Liver, spleen, lung, and large intestine meridians.
Effects: Costrain the lung, astringent intestines, engender fluid to stop thirsting, quiet ascaris.
Administration and dosage: 6~12 g.

MYRISTICAE SEMEN
肉豆蔻
Rou Dou Kou / Rou Dou Kou
Nutmeg Seed

Nutmeg seed is the dried ripe kernel of *Myristica fragrans* Houtt. (Fam. Myristicaceae).
It contains not less than 8.0% of dilute ethanol-soluble extractives, not less than 4.0% of water extractives, not less than 5.0% (v/w) of mace oil and not less than 0.1% of dehydrodiisoeugenol.

Description: Ovate or ellipsoidal, 2~3.5 cm in length, 1.5~2.5 cm in diameter. Externally grayish-brown or blackish-brown, with pale longitudinal furrows and irregular reticulated wrinkles. A hilum occurring at the broad end, chalaza dark and dented at the other end, raphe longitudinally furrowed, connecting with two ends. Texture hard, fracture showing marble-like striations, made by outer layer of blackish-brown perisperm inserting into pale yellowish-orange endosperm; the broad

longitudinal section with small cavity gap, within a dried and shrunken embryo. Odour strongly aromatic; taste pungent.

Microscopic identification:

1. **Transverse section:**
   Kernel of *Myristica fragrans*: Outer layers of perisperm tissue composed of more than 10 layers of flattened and shriveled cells, containing brown contents, occasionally small prisms present. Crisscross tissue contains small vascular bundles. Inner layers of perisperm tissue dark brown, inserting to the pale yellow endosperm, formed crisscross tissue with marble striations, containing numerous oil cells. Endosperm with thin wall, subrounded, filled with starch granules, fatty oil droplets and aleurone granules, scattered with sparse pale yellow cells. Starch granules mostly individual, 10~20 μm in diameter; less compound granules composed of 2~6 components, 25~30 μm in diameter, hilum distinct. Treated with iodine solution and then mounting with glycerin, showing large aleurone granules among many bluish-black starch granules; while mounting with chloral hydrate, the fatty oil often shaped in clumpy or lamellar, it alters into oil droplets when heated.
2. **Powder:** Reddish-brown. Starch granules numerous, spheroidal, up to 20 μm in diameter; hilum stellated or cleft-shaped, compound granules also present. Perisperm cells polygonal, brown or brownish-black. Oil cells occasionally present. Endosperm cells colorless, polygonal, sparsely scattered with brown pigment cells. Vessels spiral. While mounting with chloral hydrate, numerous fatty oil droplets separated out, the oil droplets occasionally solidified gradually to form needle-clustered crystals.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 2.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter the supernatant and use filtrate.
2. Reference drug solution: Take 2.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of petroleum ether (30~60℃) and ethyl acetate (9:1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with a solution of 5% vanillin/EtOH TS and heat at 105℃ until the spots become visible. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:

1. Loss on drying: Not more than 13.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 3.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).
   ※ Note: "When this TCM herb is sold commercially, the limit of heavy metals and sulfur dioxide should follow the food standard."

Assay:

1. Dehydrodiisoeugenol:
   (1) Mobile phase: water as the mobile phase A, and methanol as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of dehydrodiisoeugenol, and dissolve in methanol to produce a solution containing 10 μg per mL.
   (3) Sample solution: Weigh accurately 0.5 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 20 mL of ethanol, ultrasonicate for 30 minutes. Centrifuge for 10 minutes, transfer the supernatant to a 50-mL volumetric flask. Repeat the extraction of the residue one more time. Combine the supernatant and make up to volume with ethanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (275 nm) and a column packing L1. The column temperature is maintained at 25℃. The flow rate is about 1 mL/min.. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of dehydrodiisoeugenol should not be less than 4,500.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~15	30	70
15~25	30→25	70→75
25~30	25→20	75→80

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Dehydrodiisoeugenol: (%)=0.005(r_U/r_S) (C_S) / (W)

r_U: peak area of dehydrodiisoeugenol of sample solution

r_S: peak area of dehydrodiisoeugenol of reference standard solution

C_S: concentration of dehydrodiisoeugenol of reference standard solution (μg/mL)

W: weight of test sample (g) calculated with dried sample

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).
4. Volatile oil: Carry out the method for determination of volatile oil (General rule 6013).

Storage: Refrigerate or store in a cool and dry place, and protect from insects.
Usage: Astringent medicinal.
Property and flavor: Warm; pungent.
Meridian tropism: Spleen, stomach, and large intestine meridians.
Effects: Warm the middle and move qi, astringe the intestines and antidiarrheal.
Administration and dosage: 1.5~10 g.

MYRRHA
沒藥
Mei Yao / Mei Yao
Myrrh

Myrrh is the dried resin collected from the bark of trunk of *Commiphora myrrha* (T.Nees) Engl.or *Commiphora molmol* (Engl.) Engl. ex Tschirch and similar species (Fam. Burseraceae). The drug is divided into "natural myrrh" and "colloidal myrrh".
It contains not less than 10.0% of dilute ethanol-soluble extractives and not less than 21.0% of water extractives.

Description:
1. Natural myrrh: Irregular granular agglomerates, varying in size, the large one up to or more than 6 cm in diameter. Externally yellowish-brown or reddish-brown, the translucent part in brownish-black color, covered with yellow dust-like powder. Texture hard and fragile, broken surface uneven, lusterless. Odour characteristic; taste bitter and slightly pungent.
2. Colloidal myrrh: Irregular pieces and grains, mostly agglutinated into lumps, varying in size, the large one up to or more than 6 cm in diameter. Externally brownish-yellow to brown, opaque. Texture compact or loose. Odour characteristic; taste bitter and viscous.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 2.0 g of powdered sample to 5 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 2.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane and ethyl acetate (4:1) as the developing solvent. Apply 10 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with *p*-anisaldehyde/H_2SO_4 TS and heat at 105°C until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:
1. Total ash: Not more than 15.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 10.0% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Total heavy metals: Not more than 20 ppm (General rule 6301).

Assay:
1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place.
Usage: Blood-regulating medicinal (Blood-activating and stasis-dispelling medicinal).
Property and flavor: Neutral; pungent and bitter.
Meridian tropism: Heart, liver and spleen meridians.
Effects: Activate blood to relieve pain, disperse swelling and promote tissue regeneration.
Administration and dosage: 3~5 g.
Precaution and warning: Contraindicated in pregnancy and bleeding.

NATRII SULFAS
芒硝
Mang Siao / Mang Xiao
Mirabilitum

Mirabilitum is a crystalline substance purified from a mineral of sulfates of Glauber's salts group, containing mainly hydrated sodium sulfate ($Na_2SO_4 \cdot 10H_2O$).

Description: Prismatic, irregular masses or granules. Colorless and transparent, or a whitish and translucent. Texture fragile and easily broken, fracture with glassy luster. Soluble in water and insoluble in ethanol. Odourless; taste salty.

Identification:

1. Check sodium salt: Take a platinum wire moistened with hydrochloric acid, dampen with a little powdered sample, burn in a colorless flame, a yellow colored flame is produced. Take a neutral sample solution, add a solution of uranyl zinc acetate, and a yellow precipitate is produced (General rule 2191).
2. Check sulfate salt: Take a sample solution, add barium chloride solution, a white precipitate is produced and insoluble in hydrochloric acid or nitric acid (General rule 2191).
3. Check iron and zinc: Dissolve 5.0 g of powdered sample in 20 mL of water, add 2 drops of nitric acid, boil for 5 minutes, neutralize with sodium hydroxide, add 1 mL of dilute hydrochloric acid, 1 mL of potassium ferrocyanide and a quantity of water to 50 mL, mix well, stand for 10 minutes, no turbidity or a blue color is produced (General rule 2191).

Impurities and other requirements:

1. Loss on drying: Not more than 53.0%~59.0% dry at 105℃ for 5 hours (General rule 6015).
2. Acid-insoluble ash: Not more than 9.0% (General rule 6007).
3. Total heavy metals: Not more than 30 ppm (General rule 6301).

Storage: Preserve in a cool, dry and well-closed container, and protect from efflorescence.
Usage: Purgative medicinal (Offensive purgative medicinal).
Property and flavor: Cold; salty and bitter.
Meridian tropism: Stomach and large intestine meridians.
Effects: Drain heat and frees stool, moisten dryness with soften hardness, clear fire to disperse swelling.
Administration and dosage: 3~15 g.
Precaution and warning: Use cautiously during pregnancy.

NELUMBINIS FOLIUM
荷葉
He Ye / He Ye
Lotus Leaf

Lotus leaf is the dried leaf of *Nelumbo nucifera* Gaertn. (Fam. Nymphaeaceae).
It contains not less than 13.0% of dilute ethanol-soluble extractives, not less than 8.0% of water extractives and not less than 0.06% of nuciferine.

Description: Semicircular or plicate, peltate or subrounded when spread, 30~60 cm in diameter. Upper surface brownish-green, relatively rough, with white and short glandular hairs; lower surface grayish-brown, smooth and lustrous, center remained with petiole. Veins radiating from the center to the border, wrinkles arranged parallelly to the veins. Texture fragile, easily broken. Odour slight; taste weak and slightly astringent.

Microscopic identification:

1. **Transverse section:**
   Leaf of *Nelumbo nucifera*: Upper epidermis composed of square or irregular flatten cells, anticlinal walls straight or curved, periclinal walls with papillary protuberances and cutinized. Lower epidermis composed of polygonal or subrounded cells, anticlinal walls undulated, periclinal walls with thick cuticle, without protuberance. Main vein with numerous vascular bundles, the middle two relatively large, arranged vertically in closed collateral type, surrounded by 1~4 rows of fibers, fibers relatively numerous near upper and lower epidermis, triangular or polygonal. Mesophyll composed of collenchyma tissue, palisade tissue and spongy tissue, main vein scattered with collenchyma tissue near upper and lower epidermis; palisade tissue square or subrounded; spongy tissue subrounded or polygonal, containing clusters of calcium oxalate.
2. **Powder:** Grayish-green. Upper epidermal cells polygonal, with papillary protuberances, stomata usually visible, 15~20 μm in diameter, palisade tissue obviously visible. Lower epidermal cells irregular in shape, stomata occasionally found. Vessels mainly spiral, annular vessels occasionally found, 10~80 μm in diameter. Fibers slender, 10~30 μm in diameter. Mesophyll cells contain abundant clusters of calcium oxalate, 10~40 μm in diameter.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 2.0 g of powdered sample to 30 mL of 50% methanol, heat under reflux for 1 hour, filter, evaporate the filtrate to 10 mL, add 5 mL water, add 0.5 mL dilute sulfuric acid; heat under reflux for 1 hour, extract by shaking with two 15 mL quantities of ethyl acetate, combine the ethyl acetate extracts, add a few quantity of anhydrous sodium sulfate, mix well, filter and use the filtrate.
2. Reference drug solution: Take 2.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of quercetin and dissolve in ethyl acetate to produce a solution containing 0.2 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of toluene, ethyl acetate, and formic acid (5:4:1) as the developing solvent. Apply 3 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10

cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained with the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 14.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 12.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Nuciferine:
   (1) Mobile phase: A solution of acetonitrile and water (contain 2.2% trimethylamine and 1.1% glacial acetic acid) (32:68). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of nuciferine, and dissolve in methanol to produce a solution containing 10 μg per mL.
   (3) Sample solution: Weigh accurately 0.5 g of the powdered sample and place it in a 50-mL conical flask, then add accurately 25 mL of methanol, ultrasonicate for 30 minutes, filter to 50 mL volumetric flask with filter paper. Repeat the extraction of the residue one more time. Combine the filtrate and make up to volume with methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (270 nm) and a column packing L1. The column temperature is maintained at room temperature. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of nuciferine should not be less than 6,000.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Nuciferine (%)=0.005(r_U/r_S) (C_S) / (W)
   r_U: peak area of nuciferine of sample solution
   r_S: peak area of nuciferine of reference standard solution
   C_S: concentration of nuciferine of reference standard solution (μg/mL)
   W: weight of test sample (g) calculated with dried sample
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place, and protect from moisture.
Usage: Blood-regulating medicinal (Hemostatic medicinal).
Property and flavor: Neutral; bitter.
Meridian tropism: Liver, spleen, and stomach meridians.
Effects: Clear summerheat and drain dampness, upraise yang and hemostatic.
Administration and dosage: 3~12 g.

NELUMBINIS PLUMULA
蓮子心
Lian Zih Sin / Lian Zih Sin
Lotus Plumule

Lotus plumule is the dried young leaves and radicle of *Nelumbo nucifera* Gaertn. (Fam. Nymphaeaceae).
It contains not less than 22.0% of dilute ethanol-soluble extractives and not less than 25.0% of water extractives and not less than 0.2% of liensinine

Description: It has a thin cylindrical shape, 1~1.4 cm in length, 0.2 cm in diameter. The young leaves are green, one long and one short, rolled into an arrow shape, and the apex is folded back downward, and small germs are seen between the young leaves. The radicle is cylindrical, about 3 mm in length, yellowish white. It is brittle and easy to break. There are several small holes in the section. Odor sligh, bitter taste.

Microscopic identification:

1. **Transverse section:**
   Radicle of *Nelumbo nucifera*: The epidermal cells are composed of 10 layers of oval, round, and amorphous soft cells (thin parenchyma cells) with large intercellular spaces containing a large amount of starch and elliptical colorless inclusions. The gas chambers are arranged in a ring shape between the two layers of transporting tissue, 150~200 μm in diameter. The transport organization consists of 2 layers, which are radially present in the germ layer, elliptical shape, 100~200 μm in diameter. It consists of oval, amorphous cells and is not lignified. The transverse section of the young leaves, the epidermis is a small layer of subsquare parenchyma cells; it consists of 10 layers of oval, round, amorphous soft cells (parenchyma cells). The cell gap is large and contains many starches and green

pigments. The gas chamber is interspersed in the germ layer and is between the transporting tissues, 150~400 μm in diameter. The conducting tissue is present in the germ layer, radial, elliptical, 100~200 μm in diameter, composed of elliptical, amorphous cells, without lignification.

2. **Powder:** Grayish-green. Filled with a lot of oil drops. The epidermal cells are slightly rectangular and have thin walls. The radicle cells are rectangular in shape, neatly arranged, with thin walls and some fat-containing oil droplets. The mesophyll cell wall is thin, round, and contains many starch granules and green pigment. Pigment cells are subround or elliptical in shape, yellowish-brown material inside. A large number of starch granules, single-granular oblong, round, ovoid or trigonoid, slightly flat, not obvious.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 2.0 g of powdered sample to 30 mL of ethanol, ultrasonicate for 30 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 1 mL of ethanol.
2. Reference drug solution: Take 2.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of liensinine and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of dichloromethane, acetone, and diethylamine (1:6:1) as the developing solvent. Apply 5 μL of each of the sample solution and reference drug solution and 2 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Expose to iodine vapor for 3~5 minutes. Examine under the ultraviolet light at 254 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 13.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 4.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 0.7% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Liensinine:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and 0.05% diethylamine as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of liensinine and dissolve in 75% ethanol to produce a solution containing 20 μg per mL.
   (3) Sample solution: Weigh accurately 0.2 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 7 mL of 75% ethanol, ultrasonicate for 30 minutes, centrifuge for 15 minutes. Transfer the supernatant to a 25-mL volumetric flask. Repeat the extraction of the residue two more times, combine the supernatant, and make up to volume with 75% ethanol, mix well, filter and use the filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (282 nm) and a column packing L1. The column temperature is maintained at 25℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of liensinine should not be less than 1,500.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~15	35→50	65→50
15~25	50→95	50→5

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Liensinine (%)=0.0025(r_U/r_S) (C_S) / (W)

r_U: peak area of liensinine of sample solution

r_S: peak area of liensinine of reference standard solution

C_S: concentration of liensinine of reference standard solution (μg /mL)

W: weight of test sample (g) calculated with dried sample

Storage: Store in a ventilated and dry place, and protect from moisture and insects.

Usage: Heat-clearing medicinal (Heat-clearing and fire-purging medicinal).

Property and flavor: Cold; bitter.

Meridian tropism: Heart and kidney meridians.

Effects: Clear heart, remove heat, hemostatic, astringe essence.

Administration and dosage: 1.5~5 g.

NELUMBINIS RHIZOMATIS NODUS
藕節
Ou Jie / Ou Jie
Lotus Rhizome Node

Lotus rhizome node is the dried node of rhizome of *Nelumbo nucifera* Gaertn. (Fam. Nymphaeaceae).
It contains not less than 8.0% of dilute ethanol-soluble extractives and not less than 10.0% of water extractives.

Description: Shortly cylindrical, 2~4 cm in length, 2~3 cm in diameter. Externally grayish-yellow or grayish-brown, with remains of round rootlets scars and lax rootlets. Both ends with residual lotus rhizomes, wrinkled and longitudinal-striated externally. Texture light and hard, uneasily broken, fracture with numerous subrounded pores, the pore in the center relatively small. Odour slight; taste slightly sweet and astringent.

Microscopic identification:
Powder: Grayish-brown. Simple starch granules subrounded, elongated-ovate or elongated-oblong, few gourd-shaped, reniform or rhombic, some with margins protuberant, 5~49 μm in diameter, up to 81 μm in length, large granules with distinct hilum, mostly located at one side, striations distinct; compound granules composed of 2~6 components. Clusters of calcium oxalate 16~60 μm in diameter. Vessels mainly scalariform, reticulate and spiral vessels few, double-spiral vessels occasionally found, 10~144 μm in diameter. Xylem fibers long-fusiform, 7~29 μm in diameter, wall slightly thickened and lignified, pits oblique slit-shaped or V-shaped, pit canals distinct. Epidermal cells long strip-shaped in surface view, wall straight.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 20 mL of dilute ethanol, ultrasonicate for 20 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of alanine and dissolve in dilute ethanol to produce a solution containing 0.5 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-butanol, glacial acetic acid, and water (4:1:1) as the developing solvent. Apply 10 μL of each of the sample solution and reference drug solution and 2 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with ninhydrin TS and heat at 105°C to the spots become visible clear. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Total ash: Not more than 8.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 3.0% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a dry place, and protect from insects.
Usage: Blood-regulating medicinal (Hemostatic medicinal).
Property and flavor: Neutral; sweet and astringent.
Meridian tropism: Liver, lung and stomach meridians.
Effects: Astringes and hemostatic.
Administration and dosage: 9~15 g.

NELUMBINIS SEMEN
蓮子
Lian Zih / Lian Zi
Lotus Seed

Lotus seed is the dried ripe seed of *Nelumbo nucifera* Gaertn. (Fam. Nymphaeaceae).
It contains not less than 8.0% of dilute ethanol-soluble extractives and not less than 10.0% of water extractives.

Description: A protruding cap object at one end, endosperm has two petals, is pale yellowish-white, powdery, and has a green lotus seed heart in the middle. The seeds are Odourless, taste sweet and light, slightly astringent. Lotus flesh, remove the seeds from the shell, ellipsoidal or subrounded, 1.3~1.7 cm in length, 1.0~1.3 cm in diameter. Externally pale yellowish-brown to reddish-brown, with longitudinal brown striations. The center of one end papillate, dark brown, mostly with cracks, occasionally dented around the edge. Texture hard, testa thin, uneasily peeled off. Cotyledons 2, yellowish-white, fleshy, with green plumule at the space between two cotyledons. Odourless, slight; taste testa astringent; cotyledons slightly sweet; lotus plumule extreme bitter. Usually use after removing teste and lotus plumule.

Microscopic identification:

1. **Transverse section:**
   Seed of *Nelumbo nucifera*: Testa composed of several layers of rectangular or polygonal parenchymatous cells, arranged tangentially, containing reddish-brown contents, slightly lignified; inside showing pigment layer, several layers of polygonal parenchymatous cells surrounding embryo, containing yellowish-brown contents. Embryo composed of several dozens layers of oblong, round or irregular parenchymatous cells, containing abundant starch granules and oblong colorless contents; procambium filaments present in embryo layer, oblong, 100~200 μm in diameter, composed of oblong or irregular cells, unlignified. Endotesta composed of 1 layer of square or rectangular parenchymatous cells, containing pale yellow contents.
2. **Powder:** Off-white (removed germ). Starch granules occupied the major portion of the powder, simple granules elongated-rounded, subrounded, ovate, triangular or reniform, 5~25 μm in diameter, 20~30 μm in length, hilum few, cleft-shaped or dotted, striations indistinct; compound granules few, composed of 2~3 components. Fragments of testa pale brown or nearly colorless, epidermal cells subpolygonal or irregular in surface view, wall thin. Stomata rounded or elongated-rounded. Cells of pigment layers yellowish-brown, subrectangular or polygonal. Clusters of calcium oxalate occasionally found. Vessels occasionally found, mainly spiral, annular vessels few, 8~36 μm in diameter.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 15 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane and acetone (7:2) as the developing solvent. Apply 10 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with vanillin/H_2SO_4 TS and heat at 105℃. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:

1. Loss on drying: Not more than 15.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 5.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 3.0% (General rule 6007).
4. Sulfur dioxide: Not more than 400 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).
9. Aflatoxins
   (1) Aflatoxins (sum of B_1, B_2, G_1 and G_2): Not more than 10.0 ppb (General rule 6307).
   (2) Aflatoxin B_1: Not more than 5.0 ppb (General rule 6307).

※Note: "When this TCM herb is sold commercially, the limits of heavy metals, sulfur dioxide and aflatoxins should follow the food standard."

Assay:

1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from insects.
Usage: Astringent medicinal.
Property and flavor: Neutral; sweet and astringent.
Meridian tropism: Spleen, kidney, and heart meridians.
Effects: Tonify spleen and antidiarrheal, tonify kidney and secure essence, nourish heart to tranquilize.
Administration and dosage: 6~15 g.

NELUMBINIS STAMEN
蓮鬚
Lian Syu / Lian Xu
Lotus Stamen

Lotus stamen is the dried stamen *Nelumbo nucifera* Gaertn. (Fam. Nymphaeaceae).
It contains not less than 16.0% of dilute ethanol-soluble extractives and not less than 9.0% of water extractives and not less than 0.01% of kaemperol.

Description: Linear, anther twisted, longitudinally split, 1.2~1.5 cm long, 0.1 cm in diameter, yellowish or brownish yellow. The filaments are slender, slightly curved, 1.5~1.8 cm in length, and lavender. Odor slightly fragrant, astringent taste.

Microscopic identification:

1. **Transverse section:**
   Stamen of *Nelumbo nucifera*: There is one vascular bundle in the middle, there are no secretory cells and stone cells in the septum, the inner wall cells and pollen grains of the pollen sac are only present in the anther chamber.

2. **Powder:** Yellowish-brown. Pollen grains are spherical or oblong, 45~86 μm in diameter, with 3 holes, surface granules reticulate. Epidermal cells are rectangular, polygonal or irregular. The vertical wall is microscopically curved; the lateral view of the outer wall is papillary. The inner wall of the pollen sac is long strip, the wall is slightly thick, slightly rim-like, with obvious sulcus, and some cells contain yellowish-brown inclusions. The spiral conduit is approximately 20 μm in diameter. Some clusters containing calcium oxalate, 15~45μm in diameter, exist in parenchyma cells.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 1 mL of methanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of kaempferol and dissolve in methanol to produce a solution containing 0.5 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane, ethyl acetate, formic acid, and water (7:12:2:1) as the developing solvent. Apply 2 μL of each of the sample solution and reference drug solution and 1 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 5% $AlC1_3$/EtOH TS. Examine immediately under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 14.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 5.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 0.5% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Kaempferol:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and 0.2% phosphoric acid as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of kaempferol and dissolve in methanol to produce a solution containing 5 μg per mL.
   (3) Sample solution: Weigh accurately 2.0 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 20 mL of methanol, ultrasonicate for 30 minutes, centrifuge for 15 minutes. Transfer the supernatant to a 50-mL volumetric flask. Repeat the extraction of the residue one more time, combine the supernatant, and make up to volume with methanol, mix well, filter and use the filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (365 nm) and a column packing L1. The column temperature is maintained at 25℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of kaempferol should not be less than 10,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~5	30	70
5~10	30→60	70→40
10~25	60	40

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Kaempferol (%)=0.005(r_U/r_S) (C_S) / (W)

r_U: peak area of kaempferol of sample solution

r_S: peak area of kaempferol of reference standard solution

C_S: concentration of kaempferol of reference standard solution (mg /mL)

W: weight of test sample (g) calculated with dried sample

Storage: Store in a ventilated and dry place, and protect from mold.

Usage: Astringent medicinal.

Property and flavor: Neutral; sweet and astringent.

Meridian tropism: Heart and kidney meridians.

Effects: Clear heart and secure kidney, astringe essence to hemostatic.

Administration and dosage: 1.5~15 g.

NEOPICRORHIZAE RHIZOMA
胡黃連
Hu Huang Lian / Hu Huang Lian
Figwortflower Neopicrorhiza Rhizome

Figwortflower neopicrorhiza rhizome is the dried rhizome of *Neopicrorhiza scrophulariiflora* (Pennell) D.Y.Hong (Fam. Scrophulariaceae).
It contains not less than 28.0% of dilute ethanol-soluble extractives and not less than 28.0% of water extractives and not less than 2.43% of the total amount of picroside I and picroside II.

Description: Cylindrical, slightly curved, occasionally branched, 3~12 cm in length, 0.3~1cm in diameter. Epidermis grayish brown to dark brown, rough, dense ring segments, slightly raised buds or root marks, upper end is densely covered with dark brown scale-like petiole residues. Light body, hard and brittle, easy break, slightly flat section, pale brown to dark brown, 4~10 white-like vascular bundles in the xylem arranged in a ring. Odor slight, taste extremely bitter.

Microscopic identification:

1. **Transverse section:**
   Rhizome of *Neopicrorhiza scrophulariiflora*: 1 column of epidermal cells, epidermis of coarser rhizomes often absent. Cork layer consists of several to 10 columns of cells. Cortical cells oblong, rectangular or tangentially elongated. Endothelial cells rectangular. Phloem angular or oblong-shaped cell of 9~13 layers. Medullary cell consists of several to 9 columns of cells. Xylem vessels more in groups. Pith subcircular or polygonal cell.
2. **Powder:** Brown. Cork cells yellowish brown, polygonal to irregular surface, side rectangular. Parenchyma cells long ovate or irregular, thin walls or thickened beaded areas, distinct intercellular spaces, clearly visible Pitted. vessel multi reticulate vessel, 8~28 μm in diameter.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of ethanol, ultrasonicate for 10 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of picroside I and picroside II in methanol to produce a solution containing 1.0 mg per mL of each.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, ethanol, and glacial acetic acid (6:3:0.2) as the developing solvent. Apply 2 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 254 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 11.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 4.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Picroside I and picroside II:
   (1) Mobile phase: A solution of acetonitrile and 0.1% phosphoric acid (19:81). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of picroside I and picroside II and dissolve in methanol to produce a solution containing 25 μg per mL of each.
   (3) Sample solution: Weigh accurately 0.1 g of the powdered sample and place it in a 50-mL conical flask, then add accurately 25 mL of methanol, ultrasonicate for 30 minutes, filter, transfer the filtrate to a 50-mL volumetric flask. Repeat the extraction of the residue one more time. Combine the filtrate and make up to volume with methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (275 nm) and a column packing L1. The column temperature is maintained at 25℃. The flow rate is about 0.9 mL/min. The number of theoretical plates of the peak of picroside I and picroside II should not be less than 4,000 and 3,000 of each.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Picroside I or picroside II (%)= 0.005 (r_U/r_S) (C_S) / (W)
   r_U: peak area of picroside I or picroside II of sample solution
   r_S: peak area of picroside I or picroside II of reference standard solution

Cs: concentration of picroside I or picroside II of reference standard solution (μg/mL)
W: weight of test sample (g) calculated with dried sample

Storage: Store in a ventilated and dry place.
Usage: Heat-clearing medicinal (Deficiency heat-clearing medicinal).
Property and flavor: Cold; bitter.
Meridian tropism: Liver, stomach, and large intestine meridians.
Effects: Relieve deficiency heat, relieve malnutrition fever, clear dampness heat, detoxicate and alleviate edema.
Administration and dosage: 3~15 g.

NEPETAE HERBA
荊芥
Jing Jie / Jing Jie
Fineleaf Nepeta Herb

Fineleaf nepeta herb is the dried aerial part of *Nepeta tenuifolia* Benth. (Fam. Labiatae).
It contains not less than 7.0% of dilute ethanol-soluble extractives, not less than 7.0% of water extractives, not less than 0.3% (v/w) of volatile oil and not less than 0.02% of pulegone.

Description: Up to 100 cm in length. Stems branched at the upper part, quadrangular, 2~4 mm in diameter; externally pale yellowish-green or pale purplish-red, pubescent; texture light and fragile, fracture whitish. Leaves opposite, mostly fallen off, lamina 3~5 pinnatipartite as whole, lobes strip or lanceolate, pubescent. Pseudo-spike verticillaster terminal, 2~9 cm in length. Calyx persistent, campanulate, apex 5-toothed, pale brown or yellowish-green, pubescent. Corolla mostly fallen off. Nutlets brownish-black. Odour aromatic; taste slightly astringent, pungent, with a cooling sensation.

Microscopic identification:
1. **Powder:** Yellowish-brown. Glandular scales with a 8~13 celled subrounded head, 22~108 μm in diameter, and an unicellular stalk, extremely short, containing light yellow or brown contents. Small glandular hairs with a 1~2 celled head, 16~27 μm in diameter, and a unicellular short stalk. Non-glandular hairs 1~6 celled, 67~810 μm in length, the middle part slightly narrow, 22~45 μm in diameter at the base, wall slightly thickened, the upper cells with fine warty, the 1~2 lower cells with lateral cuticle striations. Epidermal cells of stem with thin and straight anticlinal walls; stomata anomocytic. Epidermal cells of leaf with anticlinal walls wavy and curved in surface view, containing stomata and trichomes. Pollen grains subspheroidal, 27~31 μm in diameter, with 6 pit canals, with reticular sculptures on the outer wall. Epidermal cells of pericarp (mucilage layer) subsquare or subrectangular in sectional view, walls mucilaginous, lumen small, irregularly branched, containing pale brown contents; inside showing pigment layer, the cells occasionally accompanied by epidermal cells upward; subpolygonal or rounded-polygonal in surface view, walls mucilaginous, with remains of lumen containing brown contents, small pigment cell groups scattered in epidermal tissue. Stone cells of pericarp 1 layered in sectional view, subrectangular or subsquare, with indistinct borders, walls thickened with clefts, lumen stellate, cells with numerous uneven branches after dissociation; subpolygonal in surface view, anticlinal walls deeply and undulately curved, pits sparse. Pigment cells of pericarp, testa cells, vessels and fibers present.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 15 minutes, centrifuge for 10 minutes, filter, evaporate the supernatant to dryness, and dissolve the residue in 1 mL of methanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of pulegone and dissolve in petroleum ether (30~60℃) to produce a solution containing 1 μL mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane and ethyl acetate (17:3) as the developing solvent. Apply 2 μL of each of the sample solution and reference drug solution and 1 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with *p*-anisaldehyde/H_2SO_4 TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 15.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 13.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 5.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).

8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:

1. Pulegone:
   (1) Mobile phase: A solution of methanol and water (75:25). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of pulegone, and dissolve in methanol to produce a solution containing 10 μg per mL.
   (3) Sample solution: Weigh accurately 0.5 g of the powdered sample and place it in a 50-mL conical flask, then add accurately 12.5 mL of methanol, ultrasonicate for 30 minutes, filter to 25-mL volumetric flask with filter paper. Repeat the extraction of the residue one more time. Combine the filtrate and make up to volume with methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (254 nm) and a column packing L1. The column temperature is maintained at room temperature. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of pulegone should not be less than 8,000.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Pulegone (%)=0.0025(r_U/r_S) (C_S) / (W)
   r_U: peak area of pulegone of sample solution
   r_S: peak area of pulegone of reference standard solution
   C_S: concentration of pulegone of reference standard solution (μg/mL)
   W: weight of test sample (g) calculated with dried sample
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).
4. Volatile oil: Carry out the method for determination of volatile oil (General rule 6013).

Storage: Refrigerate or store in a cool and dry place.
Usage: Exterior-releasing medicinal (Pungent-warm exterior-releasing medicinal).
Property and flavor: Mild warm; pungent.
Meridian tropism: Lung and liver meridians.
Effects: Dispel wind to release exterior, outthrust rashes, eliminates sore.
Administration and dosage: 3~11.5 g.

NEPETAE SPICA
荊芥穗
Jing Jieh Suei / Jing Jie Sui
Fineleaf Nepeta Spike

Fineleaf nepeta spike is the dried spica of *Nepeta tenuifolia* Benth. (Fam. Labiatae).
It contains not less than 9.0% of dilute ethanol-soluble extractives and not less than 8.0% of water extractives and not less than 0.74% of pulegone.

Description: Cylindrical, 3~15 cm in length, 7 mm in diameter. Corolla mostly shedding, calyx tubular yellowish green, bell-shaped, crisp and fragile, brownish black nutlets. Odor fragrant, taste slight astringent pungent and cool.

Microscopic identification:
Transverse section:
Spica of *Nepeta tenuifolia*: Yellowish brown. Vertical wall of the calyx tubular epidermal cells deeply wavy. 8 cells in the head of the glandular squamous head. Top surface is circular, 95~110 μm diameter. Stalk is a single cell with yellow to yellowish brown secretions. Small glandular hairs are spherical, 1~2 cells, and stalk single cells. Non-glandular hair is often broken, intact one is 1~6 cells, wall verrucose. Outer pericarp cells have a polygonal surface, mucoid wall, a small cell, and a yellowish brown substance. Fibers bundled, walls straight or microwave-shaped, bright yellowish white under a polarizing microscope. Endocarp cells are colorless, yellow to pale brown, Vertical wall of the pericarp epidermal cells deeply wavy. densely grained, yellowish white under a polarizing microscope. Vessel is primarily a spiral vessel.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 15 minutes, centrifuge, filter, evaporate the filtrate to dryness, and dissolve the residue in 1 mL of methanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of pulegone and dissolve in petroleum ether (30~60℃) to produce a solution containing 1 μL per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane and ethyl acetate (17:3) as the developing solvent. Apply 2 μL of each of the sample solution and reference drug solution and 1 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with *p*-anisaldehyde/H_2SO_4 TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained

from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 13.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 11.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 5.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Pulegone:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and water as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of pulegone and dissolve in methanol to produce a solution containing 0.1 mg per mL.
   (3) Sample solution: Weigh accurately 1.0 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 25 mL of methanol, ultrasonicate for 1 hour. Centrifuge for 15 minutes, transfer the supernatant to a 100-mL volumetric flask. Repeat the extraction of the residue one more time and wash the residue with a small quantity of methanol, centrifuge for 15 minutes. Combine the supernatant and make up to volume with methanol, mix well, filter and use the filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (254 nm) and a column packing L1. The column temperature is maintained at 25℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of pulegone should not be less than 3,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~12	30→40	70→60
12~30	40→95	60→5

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Pulegone (%)=10(r_U/r_S) (C_S) / (W)
   r_U: peak area of pulegone of sample solution
   r_S: peak area of pulegone of reference standard solution
   C_S: concentration of pulegone of reference standard solution (mg/mL)
   W: weight of test sample (g) calculated with dried sample

Storage: Store in a cool and dry place.
Usage: Exterior-releasing medicinal (Pungent-warm exterior-releasing medicinal).
Property and flavor: Mild warm; pungent.
Meridian tropism: Lung and liver meridians.
Effects: Resolve the exterior to scatters wind, vents rash and eliminates sore, hemostatic.
Administration and dosage: 3~10 g.

NOTOGINSENG RADIX ET RHIZOMA
三七
San Ci / San Qi
Notoginseng Root

Notoginseng root is the dried root and rhizome of *Panax notoginseng* (Burkill) F.H.Chen (Fam. Araliaceae).
It contains not less than 18.0% of dilute ethanol-soluble extractives, not less than 20.0% of water extractives and not less than 5.0% of the total amount of ginsenoside Rg_1, ginsenoside Rb_1, and notoginsenoside R_1.

Description: Subconical, fusiform or irregular masses, with a few branches, 1~6 cm in length, 1~4 cm in diameter. Externality grayish-yellow or grayish-brown, with a wax-like luster, irregular longitudinal fine striations and a few transverse lenticels, the upper with several tumor-like scars of rootlet, apex remained with roots base. Texture heavy and compact. Bark and xylem often separated when crushed. Fracture grayish-green, yellowish-green or grayish-white, bark with small brown spots (resin canals). Odour slight; taste bitter and slightly sweet.

Microscopic identification:

1. **Transverse section:**
   Root and rhizome of *Panax notoginseng*: Outermost layer composed of 1 layer of epidermal cells covered with cuticle, mostly broken, cells rectangular or subsquare. Phelloderm composed of 7~10 layers of rectangular, subrectangular or subsquare cells. Cortex narrow, cells rectangular or flattened-rectangular. Phloem occupied about 1/3 portion of the root, mainly composed of parenchymatous cells filled with starch granules; cells rectangular, subrectangular, subsquare, subpolygonal or subrounded, with distinct intercellular spaces, clusters of calcium oxalate occasionally found; resin canals containing yellow secretions scattered, composed of 5~8 flat and small cells, rounded or elongated-rounded, 60~120 μm in diameter; phloem showing irregular clefts in the outer part, cells arranged densely in the inner part, relatively numerous resin canals arranged in a ring near

cambium. Cambium distinct, composed of 3~4 rows of cells, arranged in an interrupted ring. Xylem composed of vessels, xylem parenchymatous cells and ray cells; vessels 16~56 μm in diameter, mainly reticulate or scalariform, a few spiral, cells subrounded, subpolygonal, subovate or subsquare. Pith broad, composed of subrectangular, subsquare, subpolygonal or subrounded parenchymatous cells, filled with starch granules, clusters of calcium oxalate occasionally found. Primary xylem existed in the center, scattered with few vessels, mainly composed of small parenchymatous cells.

2. **Powder:** Yellowish-white. Simple starch granules subrounded, 3~28 μm in diameter, hilum dotted, short slit-shaped or V-shaped; compound granules composed of 2~10 components. Reticulate and scalariform vessels 16~55 μm in diameter. Resin canals 60~128 μm in diameter, secretory cells and canals contain brownish-yellow droplets-like or mass-like secretions. Cork cells rectangular or polygonal, walls thin. Clusters of calcium oxalate rare, 48~80 μm in diameter, angles broad and blunt.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 0.2 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 2.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of ginsenoside Rb_1 and ginsenoside Rg_1 and dissolve in methanol to produce a solution containing 1.0 mg per mL of each.
4. Procedure: Use silica gel F_{254} as the coating substance and the lower layer of a solution of ethyl acetate, formic acid, acetic acid, and water (19:3:3:2) as the developing solvent. Apply 2 μL of the sample solution and reference drug solution and 1 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air, spray with 10% H_2SO_4/EtOH TS and heat at 105℃until the spots become visible. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.
   (According to the chromatogram obtained from the assay, the retention time of the main peak of the test solution and the standard solution of noto-ginsenoside R1 is consistent.)

Impurities and other requirements:

1. Loss on drying: Not more than 14.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 7.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 5.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Ginsenoside Rg_1, ginsenoside Rb_1, notoginsenoside R_1:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and water as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of ginsenoside Rg_1, Rb_1, and notoginsenoside R_1 and dissolve in methanol to produce a solution containing 0.4 mg, 0.4 mg and 0.1 mg per mL of each.
   (3) Sample solution: Weigh accurately 0.3 g of powdered sample and place it in a 50-mL round bottom flask, then add accurately 25 mL of 75% methanol, heat under reflux for 2 hours, cool, filter with filter paper, transfer the filtrate to a 10-mL volumetric flask, make up to volume with 75% methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (203 nm) and a column packing L1. The column temperature is maintained at 35 ℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of ginsenoside Rg_1, ginsenoside Rb_1 and notoginsenoside R_1 should not be less than 8,000 of each.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~20	19	81
20~30	19→20	81→80
30~75	20→42	80→58

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus and calculate the content.
   Ginsenoside Rg_1, ginsenoside Rb_1, or noto-ginsenoside R_1 (%)=2.5 (r_U/r_S) (C_S) / (W)
   r_U: peak area of ginsenoside Rg_1, ginsenoside Rb_1, or notoginsenoside R_1 of sample solution

rs: peak area of ginsenoside Rg_1, ginsenoside Rb_1, or notoginsenoside R_1 of reference standard solution

Cs: concentration of ginsenoside Rg_1, ginsenoside Rb_1, or notoginsenoside R_1 of reference standard solution (mg/mL)

W: weight of test sample (g) calculated with dried sample

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from insects.
Usage: Blood-regulating medicinal (Hemostatic medicinal).
Property and flavor: Mild warm; sweet and mild bitter.
Effects: Stasis-dispelling and hemostatic, activate blood to relieve pain.
Administration and dosage: 3~11.5 g, 1~4 g for powdering; used an appropriate amount for external use.

【Decoction pieces】

NOTOGINSENG RADIX ET RHIZOMA

It contains not less than 18.0% of dilute ethanol-soluble extractives, not less than 20.0% of water extractives and not less than 5.0% of the total amount of ginsenoside Rg_1, ginsenoside Rb_1, and notoginsenoside R_1.
Raw medicinal materials are processed to remove impurities, clean selection, soften thoroughly, cut into thin slices, and dry, mostly irregular thin slices, fracture greyish-green, yellowish-green or greyish-white, surface with tiny brown spots(resin canals). Odour slight, taste bitter and slight sweet.

Thin layer chromatographic identification test: The method is the same as that for crude herb.
Impurities and other requirements: Methods and specifications are the same as those for crude herb.
Assay: The method is the same as that for crude herb.
Storage: The method is the same as that for crude herb.
Usage: Blood-regulating medicinal (Hemostatic medicinal).
Property and flavor: Mild warm; sweet and mild bitter.
Meridian tropism: Liver, stomach, and large intestine meridians.
Effects: Stasis-dispelling and hemostatic, activate blood to relieve pain.
Administration and dosage: 3~11.5 g, 1~4 g for powder; used an appropriate amount for external use.

NOTOPTERYGII RHIZOMA ET RADIX
羌活
Ciang Huo / Qiang Huo
Notopterygium Rhizome and Root

Notopterygium rhizome and root is the dried rhizome and root of *Notopterygium incisum* K.C.Ting ex H.T.Chang or *Notopterygium franchetii* H.Boissieu (Fam. Umbelliferae). It contains not less than 18.0% of dilute ethanol-soluble extractives, not less than 15.0% of water extractives, not less than 0.8% (v/w) of volatile oil and not less than 0.21% of isoimperatorin.

Description:
1. Rhizome of *Notopterygium incisum*: Cylindrical, branched less, 4~13 cm in length, 0.6~2.5 cm in diameter. Externally dark brown or blackish-brown, with dense protuberant annulations, like a silkworm, commonly known as “Can Qiang”, or internodes elongated like the nodes of a bamboo, commonly known as ” Zhu Jie Qiang”, nodes with dotted protuberant root scars, apex with round stem scars. Texture light and loose, fracture uneven, bark and pith yellowish-brown, with numerous clefts, scattered with oil dots (secretory cavities), wood pale yellow, with cleft rays. Odour aromatic; taste slightly bitter and pungent.
2. Rhizome of *Notopterygium franchetii*: Rhizome subcylindrical, apex remained with stems and leaf sheaths, externally brown, with dense annulations, remained with protuberant rootlet or its scars, with dense transverse lenticels; root subconical, 8~15 cm in length, 0.6~3 cm in diameter, with longitudinally wrinkles and transverse lenticels, commonly known as “Tiao Qiang”. Some rhizome large and stout, irregularly nodiform, apex with several stem bases, roots relatively thin, commonly known as “Datou Qiang”. Texture loose and fragile, fracture slightly even, bark brown, xylem pale yellow, scattered with indistinct oil dots.

Microscopic identification:
1. **Transverse section:**
   (1) Rhizome of *Notopterygium incisum*: Cork composed of over 10 layers of cork cells. Cortex narrow. Phloem with many clefts. Cambium in a ring. Xylem with many vessels present. Pith broad. Phloem, pith and rays all contain numerous secretory canals. Secretory canals rounded or irregularly long-rounded, up to about 200 μm in diameter, containing yellowish-brown oil contents.
   (2) Rhizome of *Notopterygium forbesii*: Vessels rare, vessel bundles and flaky xylem fiber bundles arranged alternately. Pith relatively broad. Secretory canals up to about 180 μm in diameter.
2. **Powder:**
   (1) Rhizome and root of *Notopterygium incisum*: Brownish-yellow. Secretory cells of secretory

canals mostly slender in lateral view, walls thin or slightly thickened, containing pale yellow secretions and starch gelatinous contents, and usually containing golden or yellowish-brown linear secretions. Parenchymatous cells mainly elongated, mostly containing pale yellow secretions and oil droplets, and filled with starch granules. Reticulate and bordered-pitted vessels 13~52 μm in diameter; spiral vessels 7~23 μm in diameter, some reticulate vessels up to about 32 μm in diameter. Cork cells in lateral view multiseriate, occasionally with a rhytidome outside, filled with yellowish-brown or brown contents; anticlinal walls thin in surface view, slightly curved. Simple starch granules subrounded or oblong, hilum and striations indistinct; compound granules composed of 2~3 components; mass-like secretions yellowish-brown, varying in size.

(2) Rhizome and root of *Notopterygium forbesii*: Grayish-yellow. Parenchymatous cells fusiform or slender, fusiform ones 20~38 μm in diameter, walls slightly thickened with oblique crisscross striations distinctly, some cells with very thin transverse septa; slender ones 10~27 μm in diameter, walls thin and with some cell boundaries indistinct. Secretory cells of secretory canals slender in lateral view, containing pale yellow secretions and starch gelatinous contents; linear secretions rare.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of isoimperatorin and dissolve in methanol to produce a solution containing 0.5 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane and ethyl acetate (2:1) as the developing solvent. Apply 2 μL of each of the sample solution and reference drug solution and 1 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 254 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 14.0% dry at 105°C for 5 hours (General rule 6015).
2. Total ash: Not more than 6.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 3.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 5.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Isoimperatorin:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and water as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of isoimperatorin, and dissolve in methanol to produce a solution containing 50 μg per mL.
   (3) Sample solution: Weigh accurately 1.0 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 25 mL of methanol, ultrasonicate for 30 minutes. Centrifuge for 10 minutes, transfer the supernatant to a 50-mL volumetric flask. Repeat the extraction of the residue one more time. Combine the supernatant and make up to volume with methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (249 nm) and a column packing L1. The column temperature is maintained at 25°C. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of isoimperatorin should not be less than 10,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~10	40→50	60→50
10~25	50	50
25~30	50→95	50→5
30~40	95	5

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Isoimperatorin (%)=0.005(r_U/r_S) (C_S) / (W)

r_U: peak area of isoimperatorin of sample solution

r_S: peak area of isoimperatorin of reference standard solution

Cs: concentration of isoimperatorin of reference standard solution (μg/mL)
W: weight of test sample (g) calculated with dried sample

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).
4. Volatile oil: Carry out the method for determination of volatile oil (General rule 6013).

Storage: Refrigerate or store in a cool and dry place, and protect from mold and insects.
Usage: Exterior-releasing medicinal (Pungent-warm exterior-releasing medicinal).
Property and flavor: Warm; pungent and bitter.
Meridian tropism: Bladder and kidney meridians.
Effects: Resolve exterior to disperse cold, dispel wind and eliminate dampness, relieve pain.
Administration and dosage: 3~10 g.

OLDENLANDIAE DIFFUSAE HERBA
白花蛇舌草
Bai Hua She She Cao / Bai Hua She She Cao
Spreading Oldenlandia Herb

Spreading oldenlandia herb is the dried herb of *Oldenlandia diffusa* (Willd.) Roxb. (Fam. Rubiaceae).
It contains not less than 0.09% of asperuloside.

Description: Usually winded into masses, varying in length, grayish-green or grayish-brown, main root curved, 1~3 mm in diameter, numerous fibrous roots. Stem slender, slightly compressed, branched at the base. Leaves opposite, sessile, mostly crumpled; slat-shaped or slat-shaped lanceolate as whole, 1~3 cm in length, 1~3 mm in width, apex acute, margin slightly curved inwards, stipules with 1~4 toothed at the apex. Capsule solitary or opposite in leaf axis, compressed-globose, 2~2.5 mm in diameter, loculicidal dehiscence. Calyx persistent, 4-lobed at the upper part, margin with short and setose hairs. Odour slight; taste weak.

Microscopic identification:
Transverse section:
Stem of *Oldenlandia diffusa*: Epidermis composed of 1 layer of subsquare or ovate cells, individual cell usually intensely protuberant to outward, covered with cuticle, occasionally slightly sunken stomata present. Cortex relatively narrow, the cells generally smaller than epidermal cells, containing few small oil droplets, individual cell contains raphides of calcium oxalate, the crystals usually arranged along axis; usually densely dotted in sectional view. Endodermis composed of 1 layer of cells, the cells larger than cortex cells, tangentially prolate, 17~25 μm in width, 17~30 μm in length. Phloem narrow, about 2~5 layers of cells. Xylem in a ring, vessels usually 2~6 arranged radially in single rows or individual scattered, the large vessels 30~41 μm in diameter; xylem fibers arranged radially, walls thickened and lignified; rays composed of 1 layer of cells, walls relatively thinned and slightly lignified. Pith broad, the cells relatively large, raphides of calcium oxalate and few starch granules also exist.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of asperuloside and dissolve in methanol to produce a solution containing 0.5 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, methanol, and water (8:2:1) as the developing solvent. Apply 5 μL of each of the sample solution and reference drug solution and 2 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
2. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
3. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
4. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
5. Lead (Pb): Not more than 10.0 ppm (General rule 2251, 6301).

Assay:
1. Asperuloside:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and 0.2% acetic acid as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of asperuloside, and dissolve in 70% methanol to produce a solution containing 0.1 mg per mL.
   (3) Sample solution: Weigh accurately 0.5 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 20 mL of 70% methanol, ultrasonicate for 30 minutes. Centrifuge for 10 minutes, filter the

supernatant. Repeat the extraction of the residue one more time. Combine the extracts, transfer to a 50-mL volumetric flask and make up to volume with 70% methanol, mix well, filter and use the successive filtrate.

(4) Chromatographic system: The liquid chromatography is equipped with an UV detector (240 nm) and a column packing L1. The column temperature is maintained at 35℃. The flow rate is about 0.8 mL/min. Program the chromatographic gradient system as follows. The ratio may be adjusted if necessary. The number of theoretical plates of the peak of asperuloside should not be less than 60,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~10	5	95
10~20	5→10	95→90
20~45	10→15	90→85
45~60	15→18	85→82

(5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Asperuloside (%)=5(r_U/r_S) (C_S) / (W)

r_U: peak area of asperuloside of sample solution

r_S: peak area of asperuloside of reference standard solution

C_S: concentration of asperuloside of reference standard solution (mg /mL)

W: weight of test sample (g) calculated with dried sample

Storage: Refrigerate or store in a cool and dry place.
Usage: Heat-clearing medicinal (Heat-clearing and detoxcating medicinal).
Property and flavor: Cold; mild bitter and sweet.
Meridian tropism: Stomach, large intestine, and small intestine meridians.
Effects: Clear heat and detoxicate, drain dampness, relieve strangury, disperse abscesses.
Administration and dosage: 15~60 g.

OLIBANUM
乳香
Ru Siang / Ru Xiang
Frankincense

Frankincense is the dried resin exuding from the bark of *Boswellia carterii* Birdw. and similar species (Fam. Burseraceae).
It contains not less than 6.0% of dilute ethanol-soluble extractives and not less than 12.0% of water extractives.

Description: Drop-like or irregular pieces, about 0.5~3 cm in length, occasionally agglutinated into masses. Externally pale yellow or with slightly green, blue or reddish-brown, translucent, covered with yellow dust-like powder, dull after removing the powder. Texture hard and fragile, fracture waxy, dull, some with slightly glass-like luster. Odour slightly aromatic; taste weak, slightly bitter. Softened when heating, with a slight aroma, smoke and black residues after burned.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 5.0 g of powdered sample to 5 mL of ethyl ether, ultrasonicate for 5 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 2 mL of ethyl ether.
2. Reference drug solution: Take 5.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane and ethyl acetate (4:1) as the developing solvent. Apply 1 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with vanillin/H_2SO_4 TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:

1. Loss on drying: Not more than 8.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 3.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 0.5% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Total heavy metals: Not more than 20 ppm (General rule 6301).

Assay:

1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place.
Usage: Blood-regulating medicinal (Blood-activating and stasis-dispelling medicinal).
Property and flavor: Warm; pungent and bitter.
Meridian tropism: Heart, liver and spleen meridians.
Effects: Activate blood and move qi and relieve pain, disperse swelling and promote tissue regeneration.
Administration and dosage: 3~6 g.
Precaution and warning: Forbit to use during pregnancy.

OPHIOPOGONIS RADIX
麥門冬
Mai Men Dong / Mai Men Dong
Dwarf Lilyturf Root

Dwarf lilyturf root tuber is the dried root tuber of *Ophiopogon japonicus* (Thunb.) Ker Gawl. (Fam. Liliaceae), commonly known as "Mai Dong".
It contains not less than 50.0% of dilute ethanol-soluble extractives and not less than 55.0% of water extractives.

Description: Fusiform, flattened or cylindrical, 1.5~3.5 cm in length, 3~7 mm in diameter in the middle part. Externally yellowish-white or pale yellow, translucent, with deeply and finely longitudinally wrinkles, sometimes one end exposed with a fine and small stele. Texture tough and viscosity when moistened, fracture whitish, horny, center with a fine and small stele. Odour slightly aromatic; taste sweetish and slightly bitterish, viscous on chewing.

Microscopic identification:

1. **Transverse section:**
   Root tuber of *Ophiopogon japonicus*: Velamen composed of 3~5 rows of lignified cells of subsquare, subrectangular or polygonal shape. Exodermal cells wall slightly thickened. Cortex broad, scattered with mucilage cells containing raphides of calcium oxalate of 2 types: one type is thin and short, the other type is thicker and longer. Stone cell layer composed of 1~2 rows of cells located outside of the endodermis, the shape of the cells long polygonal to subpolygonal, with the inner and lateral wall thickened, and containing dense pits. Endodermis composed of cells with evenly thickened and lignified wall, as well as passage cells. Pericycle relatively small, composed of 1~2 rows of parenchymatous cells. Phloem bundles 16~22, located between two star-angles of the xylem bundles. Xylem composed of vessels, tracheids, xylem fibers and lignified cells in the inner side, linking up to a ring. Pith small, with subrounded parenchymatous cells.
2. **Powder:** Pale yellowish-brown. Raphides of calcium oxalate relatively numerous, scattered or in bundles located in subrounded to elliptical mucilage cells; the thin type 12~65 μm in length, some are thicker and longer, up to 129 μm in length. Stone cells subsquare or rectangular, up to 180 μm in length, 22~64 μm in diameter, wall up to 16 μm thick, occasionally with one side extremely thin, pits dense, flatten-elliptical or short slit-shaped, with relatively thick pit canals. Endodermal cells rectangular or long strip-shaped, 54~216 μm in length, 20~37 μm in diameter, wall up to 7 μm thick, evenly thickened or one side slightly thin, lignified, pits dotted and relatively sparse, pit canals distinct. Xylem fibers slender, the end oblique, 16~36 μm in diameter, walls slightly thickened and lignified, pits obliquely cleft-shaped, mostly criss-cross or into V-shaped. Pitted and reticulate tracheids 14~24 μm in diameter.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, cool, filter, evaporate the filtrate to dryness, and dissolve the residue in 1 mL of methanol..
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of toluene, methanol, and glacial acetic acid (15:1:0.05) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:

1. Total ash: Not more than 4.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 5.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from insects.
Usage: Tonifying and replenishing medicinal (Yin-tonifying medicinal).
Property and flavor: Mild cold; sweet and mild bitter.
Meridian tropism: Heart, lung and stomach meridians.
Effects: Nourishe yin and moisten lung, calm cough and eliminate phlegm, supplement stomach and engender fluid, clear heart to eliminate vexation.
Administration and dosage: 6~15 g.

ORIGANI VULGARIS HERBA
牛至
Niou Jhih / Niou Jhih
Oregano

Oregano is the dried herb of *Origanum vulgare* L. (Fam. Labiatae), commonly known as "Bei Yin Chen".
It contains not less than 12.0% of dilute ethanol-soluble extractives and not less than 11.0% of water extractives and not less than 0.08% of protocatechuic acid.

Description: 23~50cm in length, stem square column shape (quadrangular shape), purplish brown to pale brown, densely covered with fine hair, fine branches on the upper part; section distinct, internode length is 2~5 cm. Single leaf opposite, wrinkled or detached, dark green or yellowish green, intact when expanded, ovate to broadly ovate, 1.5~3 cm in length, 0.7~1.7 cm in width. Apex acute, calyx campanulate with 5 terminal lobes, edges densely white and velvety. Small nut flat oval, reddish brown. Texture crisp, odor slightly fragrant, taste slightly bitter.

Microscopic identification:

1. **Transverse section:**
   (1) Stem of *Origanum vulgare*: 1 column of epidermal cells, square or slightly tangentially elongated, sometimes visible glandular hairs and non-glandular hairs. Collenchyma consists of 6~ 10 rows of parenchyma cells located in the stalks. Cortex consists of 4~5 tangentially elongated parenchyma cells. Phloem narrow, cell small. Formation layer not very obvious. Xylem developed, ducts scattered, wood fibers, xylem of parenchyma cells walls thick, lignified. Pith developed, parenchyma cells large, old stems hollow.
   (2) Leaf of *Origanum vulgare*: upper epidermis composed of a row of tangentially elongated cells, outer wall serrated, sometimes non-glandular hairs., glandular hairs or large glandular scales visible. Grid cells oblong, 1 column, containing chloroplasts; sponge cells irregular in shape, loosely arranged. Vascular bundle vertical; phloem narrow; xylem semilunar, catheter multi-column, often 3~5 per column. 3~4 columns of collenchyma on the inner side of the main vein. Glandular scale consists of 6~10 cells, which are present in the depression of the grid-like cells. Glandular scale is orange-yellow and transparent. Head is composed of four cells.
2. **Powder:** Pale yellowish brown. Non-glandular hair composed of 1 to 6 cells, 270-1000 μm in length. Glandular hairs pear-shaped, with single cells in the head, oblong; stem single-celled, shorter. Epidermal cells of the stem are rectangular in shape, perivascular wall is curved, cells closely arranged. Epidermal wall of the leaf epidermal cells slightly curved, stomata mostly straight-axis. Wood fibers bundled or single scattered, slender, about 70~105 μm length, walls thick. Glandular head composed of 6~10 secretory cells ,contains orange-yellow volatile oil, transparent. Main conduit threaded conduit.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of ethanol, ultrasonicate for 30 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 1 mL of ethanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of protocatechuic acid and dissolve in ethanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of dichloromethane, acetone, and formic acid (15:3:2) as the developing solvent. Apply 5 μL of each of the sample solution and reference drug solution and 1 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 10.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 11.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 5.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Protocatechuic acid:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and 0.1% phosphoric acid as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of protocatechuic acid and dissolve in 50% methanol to produce a solution containing 20 μg per mL.

(3) Sample solution: Weigh accurately 1.0 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 15 mL of 50% methanol, ultrasonicate for 30 minutes. Centrifuge for 15 minutes, transfer the supernatant to a 50-mL volumetric flask. Repeat the extraction of the residue two more times. Combine the supernatant and make up to volume with 50% methanol, mix well, filter and use the filtrate.

(4) Chromatographic system: The liquid chromatography is equipped with an UV detector (260 nm) and a column packing L1. The column temperature is maintained at 30℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of protocatechuic acid A should not be less than 5,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~15	5→16	95→84
15~25	16→95	84→5

(5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Protocatechuic acid: (%)= 0.005(r_U/r_S) (C_S) / (W)

r_U: peak area of protocatechuic acid of sample solution

r_S: peak area of protocatechuic acid of reference standard solution

C_S: concentration of protocatechuic acid of reference standard solution (μg/mL)

W: weight of test sample (g) calculated with dried sample

Storage: Store in a cool and dry place, and protect from insects.

Usage: Dampness-dispelling medicinal (Dampness-draining diuretic medicinal).

Property and flavor: Mild cold; bitter.

Effects: Release exterior and clear summerheat and drain dampness.

Administration and dosage: 6~15 g.

OROXYLI SEMEN
木蝴蝶
Mu Hu Dieh / Mu Hu Dieh
Indian Trum et Flower Seed

Indian trum et flower seed is the dried seed of *Oroxylum indicum* (L.) Benth. ex Kurz (Fam. Bignoniaceae). Commonly known as " Gu Jhih Hua".

It contains not less than 15.0% of dilute ethanol-soluble extractives and not less than 7.0% of water extractives and not less than 0.06% of oroxin B, not less than 1.98% of baicalin.

Description: Butterfly-shaped thin slices, seed coat is extended into three large and thin wings except the base, 5~8 cm in length,3.5~4.5 cm indiameter, externally pale yellowish white, silky lustrous, wing-shaped translucent, radial striations, margins mostly broken. Light body, after peeling off the seed coat, found that the film-like endosperm was tightly wrapped around the cotyledons. Cotyledon 2 leaves, butterfly-shaped, pale yellow to yellowish green, 1~1.5 cm indiameter. Odor slight, taste slightly bitter.

Microscopic identification:

1. **Transverse section:**
   Seed of *Oroxylum indicum*: Cotyledon cross section, endosperm composed of 2~4 layers of cells. Upper epidermal cells square or rectangular, arranged densely, lower epidermal cells small.Palisade tissue cells rectangular, contain oil droplets and chloroplast. Sponge tissue cells oval or irregular in shape, containing the oil droplets and starch granules. Primary vascular bundle is distributed in the sponge tissue.
2. **Powder:** yellow to yellowish-green. Wing cells fibrous,20~40 μm indiameter, walls thickened , multicolor under polarized light. Endosperm cells polygonal or sub-square, wall moniliform thickened. Seeds and endosperm cells contain many calcium oxalate crystals, 2~19 μm indiameter, multicolor under polarized light.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of 80% methanol, ultrasonicate for 30 minutes, filter and transfer the filtrate to 20-mL volumetric flask, wash the container and residue with a small quantity of 80% methanol, combine the washings to the same volumetric flask, and make up to volume with 80% methanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of baicalein and chrysin in methanol to produce a solution containing 1.0 mg per mL of each.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of toluene, acetone, and formic acid (4:2:1) as the developing solvent. Apply 2 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 254 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 8.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 5.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 0.6% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Oroxin B and baicalin:
   (1) Mobile phase: Methanol as the mobile phase A, and 0.5% formic acid as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of oroxin B and baicalin and dissolve in methanol to produce a solution containing 4 μg and 8 μg per mL of each.
   (3) Sample solution: Weigh accurately 20 mg of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 20 mL of methanol, ultrasonicate for 15 minutes. Centrifuge for 10 minutes, transfer the supernatant to a 50-mL volumetric flask. Repeat the extraction of the residue one more time. Combine the supernatant and make up to volume with methanol, mix well, filter and use the filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with a column packing L1. The column temperature is maintained at 23 ± 4℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The ratio may be adjusted if necessary. The number of theoretical plates of the peak of oroxin B and baicalin should not be less than 2,000 and 6,000 of each.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~20	40	60
20~45	40→100	60→0

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Oroxin B or baicalin: (%)= 5(r_U/r_S) (C_S) / (W)
   r_U: peak area of oroxin B or baicalin of sample solution
   r_S: peak area of oroxin B or baicalin of reference standard solution
   C_S: concentration of oroxin B or baicalin of reference standard solution (μg/mL)
   W: weight of test sample (g) calculated with dried sample

Storage: Store in a ventilated and dry place.
Usage: Heat-clearing medicinal (Heat-clearing and detoxicating medicinal).
Property and flavor: Cool, bitter and sweet.
Meridian tropism: Lung liver and stomach meridians.
Effects: Clear heat and detoxicate, clear lung and promote throat, soothe liver and harmonize stomach.
Administration and dosage: 1~4 g.

ORTHOSIPHONIS HERBA
貓鬚草
Mao Syu Tsao / Mao Xu Cao
Cat's Mustache Herb

Cat's mustache herb is the dried aerial part of *Orthosiphon aristatus* (Blume) Miq. (Fam. Labiatae).
It contains not less than 14.0% of dilute ethanol-soluble extractives and not less than 15.0% of water extractives and not less than 0.5% of rosmarinic acid.

Description: Stem square, purplish-brown. Leaflets chartaceous, shrunken, broken, sparse serrated edges. Both surface pubescent and dotted glandular scales present in the back part of the leave, dark green. Flowers pale purple. Nutlets spheroidal, surface reticular. Odour slight; taste slight.

Microscopic identification:

1. **Transverse section:**
   (1) Stem of *Orthosiphon aristatus*: Quadrangular, epidermis composed of 1 row of cells. 3~6 rows of collenchymatous cells present in the angular regions. Pericyclic fibre lignified, 3~10 in groups, arranged in an interrupted ring. Cortex composed of 5~10 rows of parenchymatous cells. Phloem composed of small and slightly shrunken parenchymatous cells. Cambium distinct. Xylem vessels single or 2~3 in boundles, radially scattered. Xylem parenchymatous cells and fibers square and polygonal, rays 1~2 cell wide. Pith parenchymatous cells with pits.
   (2) Leaf of *Orthosiphon aristatus*: Both surface pubescent, Stomata mostly present in lower epidermis. Palisade tissue composed of 1 row of cells. Spongy tissue composed of 4~6 row of cells, arranged sparsely. Collenchyma tissue present inside the epidermis of midrib, vessels bundles collateral.
2. **Powder:** Brown. Phloem fibers 100 μm in length, 26~42 μm in diameter, with walls lignified, containing pits. Glandular scales with head 4~8

cells, 82~96 μm in diameter, the stalk unicellular. Xylem fibers 1000 μm in length, 31~46 μm in diameter, with walls slightly lignified, containing pits. Lower epidermis of leaf with anticlinal walls curved, stomata diacytic. Unicellular non-glandular with base 81~108 μm in length, 31~38 μm in diameter. Multicellular non-glandular composed of 2~5 rows of cells, with base 62~80 μm in diameter, walls thickened with walls warty. Glandular hair with head unicellular, 41~63μm in diameter, the stalk unicellular. Vessels mainly spiral.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of 70% ethanol, ultrasonicate for 30 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 1 mL of ethanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of ursolic acid and rosmarinic acid in ethanol to produce a solution containing 0.2 mg for ursolic acid and 0.1 mg for rosmarinic acid per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane, ethyl acetate, isopropanol, and formic acid (12:3:4:1) as the developing solvent. Apply 2 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 12.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 10.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.4% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Rosmarinic acid:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and 0.1% phosphoric acid as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of rosmarinic acid and dissolve in 75% methanol to produce a solution containing 0.3 mg per mL.
   (3) Sample solution: Weigh accurately 0.2 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 20 mL of 75% methanol, ultrasonicate for 30 minutes, centrifuge for 15 minutes. Transfer the supernatant to a 50-mL volumetric flask. Repeat the extraction of the residue one more time, combine the supernatant, and make up to volume with 75% methanol, mix well, filter and use the filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (330 nm) and a column packing L1. The column temperature is maintained at 35℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of rosmarinic acid should not be less than 2,500.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~20	20→26	80→74
20~35	26→95	74→5

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   Rosmarinic acid (%)=0.005(r_U/r_S) (C_S) / (W)

   r_U: peak area of rosmarinic acid of sample solution

   r_S: peak area of rosmarinic acid of reference standard solution

   C_S: concentration of rosmarinic acid of reference standard solution (μg /mL)

   W: weight of test sample (g) calculated with dried sample

Storage: Store in a cool and dry place.
Usage: Dampness-dispelling medicinal (Dampness-draining diuretic medicinal).
Property and flavor: Mild Cool, sweet and mild bitter.
Effects: Clear heat and dispel dampness, remove urinary calculus and induce diuresis.
Administration and dosage: 3~30 g.

ORYZAE FRUCTUS GERMINATUS
穀芽
Gu Ya / Gu Ya
Rice-grain Sprout

Rice-grain sprout is the dried and germinated ripe caryopsis of *Oryza sativa* L. (Fam. Gramineae).

It contains not less than 4.0% of dilute ethanol-soluble extractives and not less than 4.0% of water extractives.

Description: Oblong, slightly flattened, both ends slightly protuberant, 6~10 mm in length, 3~4 mm in width. Shell (palea) hard, yellow, with 5 distinctly ribs, ribs covered with flossy pubescences; base with 2 liner lodicules, pale yellowish-white, memberanous, fibrous roots (primary root) pale yellow derived from one side lodicule. Lemma thinly memberanous, smooth, pale yellowish-white, containing 1 seed. Texture hard, fracture white, starchy. Odour slight; taste slightly sweet.

Microscopic identification:
Powder: Yellowish-white. Simple starch granules irregularly polyhedral, with acute edge, 2~10 μm in diameter, pits occasionally found, without striations; compound granules ovate or round.

Impurities and other requirements:
1. Total ash: Not more than 8.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 5.0% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from mold and insects.
Usage: Disgestant medicinal.
Property and flavor: Warm; sweet.
Meridian tropism: Spleen and stomach meridians.
Effects: Disperse food and harmonize middle, fortify spleen and increase appetite.
Administration and dosage: 9~30 g.

PAEONIAE RADIX ALBA
白芍
Bai Shao / Bai Shao
Peony Root

Peony root is the peeled and dried root of *Paeonia lactiflora* Pall. (Fam. Ranunculaceae).

It contains not less than 10.0% of dilute ethanol-soluble extractives, not less than 15.0% of water extractives and not less than 1.6% of paeoniflorin.

Description: Cylindrical, 5~8 cm in length, 1~3 cm in diameter. Externally pale brown or whitish, glossy, with indistinct long transverse lenticels, longitudinal wrinkles and rootlet scars, occasionally remained with brown cork. Texture compact, uneasily broken, fracture whitish or pale red, horny, cambium ring distinct and rays radial. Odour slight; taste slightly bitter and sour.

Microscopic identification:
1. **Transverse section:**
   Root of *Paeonia lactiflora*: Cork composed of several layers of brown cells. Cortex and phloem relatively narrow. Cambium presents in a ring. Xylem rays composed of about 30 rows of cells, vessels usually arranged tangentially with xylem fibers and xylem parenchymatous cells. Parenchymatous cells contain clusters of calcium oxalate and starch granules.
2. **Powder:** Off-white. Parenchymatous cells contain gelatinized starch granules, clusters of calcium oxalate relatively abundant, 11~35 μm in diameter, often contain 2 to several cluster crystals in one cell, crystal cells present as longitudinal rows. Xylem fibers long-fusiform, 15~40 μm in diameter, walls thickened. Vessels bordered-pitted or reticulate, 20~65 μm in diameter.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 5 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of paeoniflorin and dissolve in methanol to produce a solution containing 2.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and the lower layer of a solution of ethyl acetate, methanol, and water (12:2:1) as the developing solvent. Apply 5 μL of the sample solution and reference drug solution and 2 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS, heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 13.0% dry at 105℃ for 5 hours (General rule 6015).

2. Total ash: Not more than 4.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 400 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 5.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 0.3 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Paeoniflorin:
   (1) Mobile phase: A solution of acetonitrile and water (14:86). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of paeoniflorin, and dissolve in methanol to produce a solution containing 30 μg per mL.
   (3) Sample solution: Weigh accurately 0.1g of powdered sample, accurately add 20 mL of 50% methanol, ultrasonicate for 30 minutes, filter and use the filtrate, transfer to 50-mL volumetric flask. Repeat the extraction of the residue one more time. Combine the filtrate, make up to volume with 50% ethanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (230 nm) and a column packing L1. The column temperature is maintained at 35℃. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of paeoniflorin should not be less than 5,000.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Paeoniflorin (%)= 0.005(r_U/r_S) (C_S) / (W)
   r_U: peak area of paeoniflorin of sample solution
   r_S: peak area of paeoniflorin of reference standard solution
   C_S: concentration of paeoniflorin of reference standard solution (μg/mL)
   W: weight of test sample (g) calculated with dried sample.
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place, and protect from insects.

Usage: Tonifying and replenishing medicinal (Blood-tonifying medicinal).
Property and flavor: Mild cold; bitter and sour.
Meridian tropism: Liver and spleen meridians.
Effects: Nourish blood astringent yin, emolliate liver to relieve pain, pacify and repress the liver yang.
Administration and dosage: 6~15 g.

【Decoction pieces】

PAEONIAE RADIX ALBA

It contains not less than 10.0% of dilute ethanol-soluble extractives, not less than 15.0% of water extractives and not less than 1.6% of paeoniflorin.
Raw medicinal materials are processed to remove impurities, clean selection, soften thoroughly, cut into thin slices, and dry, mostly sub-rounded thin slices. Externally sub-white or slightly with pink, the centre marked with chrysanthemum-flower-like, cambium ring distinct, dotted vascular bundles slightly raised and radially arranged. Odour slightly; taste slightly bitter and acid.

Thin layer chromatographic identification test: The method is the same as that for crude herb.
Impurities and other requirements: Methods and specifications are the same as those for crude herb.
Assay: The method is the same as that for crude herb.
Storage: The method is the same as that for crude herb.
Usage: Tonifying and replenishing medicinal (Blood-tonifying medicinal).
Property and flavor: Mild cold; bitter and sour.
Meridian tropism: Liver and spleen meridians.
Effects: Nourish blood astringent yin, emolliate liver to relieve pain, pacify and repress the liver yang.
Administration and dosage: 6~15 g.

PAEONIAE RADIX RUBRA
赤芍
Chih Shao / Chi Shao
Red Peony Root

Red peony root is the dried root of *Paeonia lactiflora* Pall. or *Paeonia veitchii* Lynch (Fam. Ranunculaceae).
It contains not less than 27.0% of dilute ethanol-soluble extractives, not less than 26.0% of water extractives and not less than 2.0% of paeoniflorin.

Description:

1. Root of *Paeonia lactiflora*: Cylindrical, occasionally thick at the middle, 10~40 cm in length, 0.6~3 cm in diameter. Externally dark brown or purplish-brown, with rough and slightly twined longitudinally wrinkles and transverse lenticels, older root relatively rough, cork easily exfoliated to scaly. Texture hard and fragile, easily broken, fracture chalk-white, yellowish-white or purplish-white, bark narrow, color dark, wood with distinct

radial pith ray, occasionally with clefts. Odour slight; taste slightly bitter and astringent.

2. Root of *Paeonia veitchii*: 5~20 cm in length. Externally with the scars of cork, brownish-red or dark brown occasionally. Texture loose, fracture blackish-brown in bark, wood yellowish-white. Peeled one externally pale purplish-red or chalk-white, fracture yellowish-white.

Microscopic identification:

1. **Transverse section:**
   (1) Root of *Paeonia lactiflora*: Cork composed of 5~10 layers of cork cells, rhytidome occasionally remained. Parenchymatous cells in the cortex elongated tangentially. Phloem narrow. Cambium in an undulating ring. Xylem rays broad; vessels singly scattered or in groups, arranged alternately with xylem fibers; vessels and xylem fibers aggregated in two groups in the center. Cortex, phloem and parenchymatous cells of rays occasionally with large pits. Parenchymatous cells contain starch granules, occasionally containing clusters of calcium oxalate.
   (2) Root of *Paeonia veitchii*: Cork composed of several layers of brown cells, rhytidome occasionally remained. Cortex and phloem narrow. Cambium in an undulating ring. Xylem vessels mainly occurring near cambium, individually scattered or in groups; xylem fibers arranged alternately with vessels; some vessels and xylem fibers scattered in the center. Parenchymatous cells contain starch granules, occasionally containing clusters of calcium oxalate.
2. **Powder:**
   (1) Root of *Paeonia lactiflora*: Pale brownish-red. Clusters of calcium oxalate usually arrange in several to dozens rows longitudinally, 7~41 μm in diameter; crystal cells relatively small, walls curved, occasionally one cell containing two to several crystals. Xylem fibers long-fusiform, 14~38 μm in diameter, walls 5~13 μm thick, bordered pits large, pit apertures oblique slit-shaped, some relatively wide and occasionally crossed in cruciate shape, few phloem fibers containing oblique simple pits. Cork cells long strip-shaped, rectangular or long-polygonal in surface view, up to 225 μm in length; some cells filled with brown or reddish-brown masses. Bordered-pitted vessels oval, 25~78 μm in diameter, some elongated laterally forming reticulate or scalariform, perforations 1~4 in end or lateral walls. Starch granules up to about 15 μm in diameter.
   (2) Root of *Paeonia veitchii*: Brown. Xylem fibers 25~30 μm in diameter; phloem fibers 14~36 μm in diameter. Starch granules up to about 21 μm in diameter.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of paeoniflorin and dissolve in 1 mL of methanol to produce a solution containing 2.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, methanol, and water (12∶2∶1) as the developing solvent. Apply 2 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with a solution of 10% H_2SO_4/EtOH TS, heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 13.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 10.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.5% (General rule 6007).
4. Sulfur dioxide: Not more than 400 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 5.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 0.3 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Paeoniflorin:
   (1) Mobile phase: A solution of acetonitrile and water (14∶86). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of paeoniflorin, and dissolve in methanol to produce a solution containing 0.2 mg per mL.
   (3) Sample solution: Weigh accurately 0.5g of the powdered sample, add accurately 20 mL of 50% methanol, ultrasonicate for 30 minutes, filter. Repeat the extraction of the residue one more time. Combine the filtrate, transfer to

50-mL volumetric flask, make up to volume with 50% methanol, mix well, filter and use the successive filtrate.

(4) Chromatographic system: The liquid chromatography is equipped with an UV detector (230 nm) and a column packing L1. The column temperature is maintained at 35℃. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of paeoniflorin should not be less than 5,000.

(5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Paeoniflorin (%)=5(r_U/r_S) (C_S) / (W)

r_U: peak area of paeoniflorin of sample solution

r_S: peak area of paeoniflorin of reference standard solution

C_S: concentration of paeoniflorin of reference standard solution (mg/mL)

W: weight of test sample (g) calculated with dried sample.

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from insects.
Usage: Heat-clearing medicinal (Heat-clearing and blood-cooling medicinal).
Property and flavor: Mild cold; bitter.
Meridian tropism: Liver and spleent meridians.
Effects: Clear heat to cool the blood, dissipate stasis to relieve pain.
Administration and dosage: 3~12 g.

PANACIS QUINQUEFOLII RADIX
西洋參
Si Yang Shen / Xi Yang Shen
American Ginseng

American ginseng is the dried root of *Panax quinquefolius* L. (Fam. Araliaceae). Commonly known as“hua qi san”or“fen guang san”.
It contains not less than 25.0% of dilute ethanol-soluble extractives, not less than 25.0% of water extractives and not less than 1.0% of ginsenoside Rb_1.

Description:

1. Long conical, long fusiform or cylindrical, 3~12 cm in length, 0.5~2 cm in diameter. Externally pale yellowish-brown or yellowish-white, with fine ring transverse striations and irregular in shallow longitudinal wrinkles. Rhizome (lutou) removed or remained, with fine transverse wrinkles densely arranging into annulations at the upper part, main roots often with 1~several forked branch of lateral or residual root scar at the lower part. Texture full and hard, fracture even, pale yellow or whitish, slightly powdery, brown cambium rings can be seen, scattered with yellowish-brown or reddish-brown dots (resin canals) at inner or outer ring. Odor slightly characteristic; taste slightly bitter.

Microscopic identification:

1. **Transverse section:**
   Root of *Panax quinquefolius*: Cork composed of several layers of upright-type cells, yellowish-brown. Cortex narrow, some cells contain clusters of calcium oxalate. Clefts existed in the outer part of phloem; parenchymatous cells arranged densely in the inner part of phloem, scattered with resin canals containing yellowish-brown secretions. Cambium composed of 3~5 layers of rectangular cells. Xylem vessels singly scattered or several in groups, with interrupted radial arrangement, occasionally unlignified fibers present adjacent vessels. Parenchymatous cells filled with starch granules.
2. **Powder:** Pale yellow or pale yellowish-white. Resin canal longitudinal fragment present, containing golden-yellow oil droplets and some orange-red strip-shaped or mass-shaped secretions. Secretory cells contain oil droplets or granules. Clusters of calcium oxalate 17~78 μm in diameter, angles mostly acute. Individual starch granules subrounded or suboblong, 7~22 μm in diameter, hilum mostly dotted, cleft-shaped or V-shaped; compound granules few, composed of 2~8 components. Vessels mainly reticulated and scalariform, up to 45 μm in diameter. Cork cells subpolygonal, subrectangular or subsquare in surface view, walls thin and undulately curved. In longitudinal view, phelloderm cells contain pits arranged radically. Parenchymatous cells subrounded or long-subrounded, containing fine particles.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 0.2 g of powdered sample to 5 mL of methanol in a centrifuge tube, ultrasonicate for 30 minutes, centrifuge for 10 minutes, filter, and use the filtrate.
2. Reference drug solution: Take 0.2 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of ginsenoside Rb_1, ginsenoside Re, and ginsenoside Rg_1 and dissolve in methanol to produce a solution containing 1.0 mg per mL of each.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-butanol, glacial acetic acid, and water (7:1:2) as the developing solvent. Apply 2 μL of the sample solution and reference drug solution and 1 μL of the reference standard

solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 13.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 7.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).
9. Pesticide residues:
   (1) The total DDT content: Not more than 1.0 ppm (General rule 6305).
   (2) The total BHC content: Not more than 0.9 ppm (General rule 6305).
   (3) The total PCNB content: Not more than 1.0 ppm (General rule 6305).

Assay:

1. Ginsenoside Rb_1:
   (1) Mobile phase: A solution of acetonitrile and water (32:68). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of ginsenoside Rb_1, and dissolve in methanol to produce a solution containing 0.3 mg per mL.
   (3) Sample solution: Weigh accurately 0.5 g of powdered sample and place it in a 100-mL round bottom flask, then add accurately 50 mL of 75% methanol, heat under reflux for 4 hours, cool, filter with filter paper, use the filtrate. Repeat the extraction of the residue one more time, combine the filtrate, transfer the filtrate to a 200-mL round bottom flask, evaporate the filtrate to a small amount and transfer to 10-mL volumetric flask, make up to volume with 75% methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (203 nm) and a column packing L1. The column temperature is maintained at 35℃. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of ginsenoside Rb_1 should not be less than 2,000.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   Ginsenoside Rb_1 (%)=(r_U/r_S) (C_S) / (W)

   r_U: peak area of ginsenoside Rb_1 of sample solution

   r_S: peak area of ginsenoside $Rb_1$of reference standard solution

   C_S: concentration of ginsenoside Rb_1 of reference standard solution (mg/mL)

   W: weight of test sample (g) calculated with dried sample.
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, preserve in a well-closed container, and protect from light, dust, insects and oil seeping.
Usage: Tonifying and replenishing medicinal (Qi-tonifying medicinal).
Property and flavor: Cool, sweet and mild bitter.
Meridian tropism: Heart, lung, and kidney meridians.
Effects: Tonify qi, tonify yin, Clear heat to engender fluid.
Administration and dosage: 3~12 g.
Precaution and warning: Incompatible with Veratri Nigri Radix et Rhizoma.

【Decoction pieces】

PANACIS QUINQUEFOLII RADIX

It contains not less than 25.0% of dilute ethanol-soluble extractives, not less than 25.0% of water extractives and not less than 1.0% of ginsenoside Rb_1.
Raw medicinal materials are processed to remove impurities, clean selection, soften thoroughly, cut into thin slices, and dry, or break to pieces before use, mostly elliptical or oblong oblique piece, externally pale yellowish-brown or yellowish-white, with longitudinal wrinkles; cut surface pale yellow or pinkish-white; with brown ring in the cambium, xylem with radial striations, yellowish-brown or reddish-brown dots in the cortex. Odour slight and characteristic; taste slightly bitter and sweet.

Thin layer chromatographic identification test: The method is the same as that for crude herb.
Impurities and other requirements: Methods and specifications are the same as those for crude herb.
Assay: The method is the same as that for crude herb.
Storage: The method is the same as that for crude herb.
Usage: Tonifying and replenishing medicinal (Qi-tonifying medicinal).
Property and flavor: Cool, sweet and mild bitter.

Meridian tropism: Heart, lung, and kidney meridians.
Effects: Tonify qi, tonify yin, Clear heat to engender fluid.
Administration and dosage: 3~12 g.
Precaution and warning: Incompatible with Veratri Nigri Radix et Rhizoma.

PATRINIAE HERBA
敗醬
Bai Jiang/Bai Jiang
Patrinia Herb

Patrinia Herb is the dried herb of *Patrinia villosa* Juss. (Fam. Valerianaceae).
It contains not less than 16.0% of dilute ethanol-soluble extractives and not less than 18.0% of water extractives and not less than 0.1% of chlorogenic acid.

Description: Rhizome is cylindrical, the appearance is dark brown, with fine vertical lines, the center of the section is mostly hollow, quality is hard and easy to break. Leaves are dry shrunk and broken, appearance is brownish green. The whole plant is gas-specific, tastes bitter.

Microscopic identification:
Transverse section:
Herb of *Patrinia villosa*: Round, outer epidermal cells 1 row are rectangular in shape, outer wall thickened, and non-glandular hair is visible. The skin is narrower, the endothelial cells are subsquare. Phloem is narrow, formation layer is not obvious. Xylem vessels are hashed, the xylem fibers are well developed, and the central pith is broad.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of 50% ethanol, ultrasonicate for 30 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 1 mL of 50% ethanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of chlorogenic acid and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, formic acid, and water (4:1: 1) as the developing solvent. Apply 1 μL of each of the sample solution and reference drug solution and 2 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 9.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 7.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
1. Chlorogenic acid:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and 1.0% phosphoric acid as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of chlorogenic acid and dissolve in methanol to produce a solution containing 25 μg per mL.
   (3) Sample solution: Weigh accurately 0.5 g of the powdered sample and place it in a 50-mL conical flask with a stopper, then add accurately 20 mL of 50% methanol, ultrasonicate for 30 minutes, filter, transfer the filtrate to 40-mL volumetric flask. Repeat the extraction of the residue one more time, combine the filtrate and make up to volume with 50% methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (327 nm) and a column packing L1. The column temperature is maintained at 25℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of chlorogenic acid should not be less than 10,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~3	5	95
3~5	5→10	95→90
5~20	10	90

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Chlorogenic acid (%)=0.004(r_U/r_S) (*Cs*) / (*W*)
   r_U: peak area of chlorogenic acid of sample solution

rs: peak area of chlorogenic acid of reference standard solution
Cs: concentration of chlorogenic acid of reference standard solution (μg/mL)
W: weight of test sample (g) calculated with dried sample.

Storage: Store in a cool and dry place, and protect from mold and insects.
Usage: Heat-clearing medicinal (Heat-clearing and detoxicating medicinal).
Property and flavor: Neutral; bitter.
Meridian tropism: Liver, stomach, and large intestine meridians.
Effects: Clear heat and detoxicate, disperse abscesses and expel pus, dissipate stasis to relieve pain.
Administration and dosage: 3~15.

PELODISCCI CARAPAX
鱉甲
Bie Jia / Bie Jia
Turtle Shell

Turtle shell is the dried shell of *Pelodiscus sinensis* (Wiegmann) (Fam. Trionychidae).

Description: Ellipsoidal or oval, dorsal surface convex, 10~15 cm in length, 9~14 cm in width. The outer surface blackish-brown or blackish-green, slightly lustrous, with fine reticular wrinkles and grayish-yellow or grayish-white spots, a longitudinal ridge in the middle, vertebral plates 7~8, 8 transverse concave strips arranged symmetrically on each side of the ridge. Serrated sutures observable when the outer skin peeled off. Inner surface whitish, protuberant vertebrae in the middle, the cervical vertebrae curved inward and alar, 8 ribs arranged on each side of the vertebrae, stretched out of the margin. Texture hard. Odour slightly stinking; taste weak.

Microscopic identification:
Transverse section:
Shell of *Pelodiscus sinensis*: Fragments of carapace irregular in shape, varying in size, grayish-white or grayish-yellow, with longitudinal or crisscross fine-reticular striations and fine-dotted pores on the surface; bone lacunae irregular, long-prismatic or slender slit-shaped; bone canaliculus faintly visible.

Impurities and other requirements:
1. Loss on drying: Not more than 11.0% dry at 105℃ for 5 hours (General rule 6015).
2. Acid-insoluble ash: Not more than 12.0% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Storage: Store in a ventilated and dry place, and protect from insects.
Usage: Tonifying and replenishing medicinal (Yin-tonifying medicinal).
Property and flavor: Mild cold; salty.
Meridian tropism: Liver, spleen, and kidney meridians.
Effects: Enriche yin and subdue yang, soften hardness and disperse bind, abate heat and relieve steaming.
Administration and dosage: 9~24 g.

PERILLAE CAULIS
紫蘇梗
Zih Su Geng / Zi Su Geng
Perilla Stem

Perilla stem is the dried stem of *Perilla frutescens* (L.) Britton (Fam. Labiatae).
It contains not less than 2.0% of dilute ethanol-soluble extractives, not less than 3.0% of water extractives and not less than 0.1% of rosmarinic acid.

Description: Square, four angles obtuse, 30~90 cm in length, 0.5~1.5 cm in diameter in the middle part, up to 2 cm in diameter in the base. Externally purplish-brown or dark purple, with a longitudinal furrow of each sides, and with fine longitudinal striations, nodes slightly swollen, with opposite branch scars and leaf scars. Texture fragile and hard, fracture lobed, center with white and lax pith. Odour slightly aromatic; taste weak.

Microscopic identification:
1. **Transverse section:**
Stem of *Perilla frutescens*: Epidermis composed of 1 layer of tangentially elongated cells, young stems contain glandular hairs, glandular scales and non-glandular hairs. Above cortex showing several dozens layers of polygonal or oblong collenchymatous cells present at angular regions, inner layer showing several layers of rectangular or polygonal parenchymatous cells, containing yellowish-brown contents, scattered with pericyclic fiber bundles arranging in an interrupted ring, lignified to strongly lignified, stone cells occasionally visible at the inner side, slightly lignified to lignified. Phloem contains numerous yellowish-brown contents. Xylem well developed, vessels arranged radially, mainly bordered-pitted and pitted, scattered with xylem fibers, lignified to strongly lignified. Pith cells oblong, subrounded or polygonal, containing raphides crystals, prism crystals and yellowish-green contents.
2. **Powder:** Grayish-white. Parenchymatous cells of cortex polygonal, containing yellowish-brown contents, fibers singly scattered or in bundles, pale

yellow to yellowish-brown, 12~40 μm in diameter. Xylem fibers mostly in bundles, usually linked with outer xylem cells, 12~56 μm in diameter, slightly lignified to lignified. Stone cells 20~60 μm in length, 10~40 μm in diameter, slightly lignified to lignified. Vessels bordered-pitted, pitted, spiral, reticulate and annular, 22~68 μm in diameter. Parenchymatous cells of xylem rectangular, 48~150 μm in length, 12~62 μm in diameter, slightly lignified to lignified. Pith cells extremely large, subrounded or oblong, wall thickened, containing raphides crystals, prism crystals and yellowish-green contents.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of rosmarinic acid and dissolve in methanol to produce a solution containing 0.1 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of toluene, ethyl acetate and, formic acid (6:3:1) as the developing solvent. Apply 5 μL of the sample solution and reference drug solution and 1 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 10.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 6.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Rosmarinic acid:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and 0.1% formic acid as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of rosmarinic acid and dissolve in methanol to produce a solution containing 10 μg per mL.
   (3) Sample solution: Weigh accurately 0.5 g of the powdered sample, add accurately25 mL of 50% ethanol, ultrasonicate for 30 minutes, use the supernatant, transfer to 50-mL volumetric flask. Repeat the extraction of the residue one more time. Combine the supernatant, make up to volume with 50% ethanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (330 nm) and a column packing L1. The column temperature is maintained at room temperature. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of rosmarinic acid should not be less than 8,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~18	15→40	85→60
18~20	40→100	60→0
20~25	100	0

   (5) Procedure: Inject accurately 10 μL of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   Rosmarinic acid (%)=0.005(r_U/r_S) (C_S) / (W)

   r_U: peak area of rosmarinic acid of sample solution

   r_S: peak area of rosmarinic acid of reference standard solution

   C_S: concentration of rosmarinic acid of reference standard solution (μg/mL)

   W: weight of test sample (g) calculated with dried sample.
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place.
Usage: Qi-regulating medicinal.
Property and flavor: Warm; pungent.
Meridian tropism: Lung and spleen meridians.
Effects: Regulate qi and harmonize middle, release depression to relieve pain.
Administration and dosage: 5~11.5 g.

PERILLAE FOLIUM
紫蘇葉
Zih Su Ye / Zi Su Ye
Perilla Leaf

Perilla leaf is the dried leaf of *Perilla frutescens* (L.) Britton (Fam. Labiatae).
It contains not less than 14.0% of dilute ethanol-soluble extractives, not less than 14.0% of water extractives and not less than 0.5% of rosmarinic acid.

Description: Mostly crumpled, rolled and broken, oval as whole, 4~11 cm in length, 2.5~9 cm in width. Apex acuminate or acute, base rounded or broadly cuneate, margin crenate. Both surfaces purple or the upper green and the lower purple, scattered with grayish-white hairs, and occurring numerous dented and dotted glandular scales on the lower surface. Petioles 2~7 cm in length, purple or purplish-green. Texture fragile. Odour delicately aromatic; taste slightly pungent.

Microscopic identification:

1. **Transverse section:**
   Leaf of *Perilla frutescens*: Epidermis composed of 1 row of fine and flat cells, with stomata, mostly distributed in lower epidermis. Glandular scales hemispheroidal, located at sunken spaces, non-glandular hairs mostly present in main vein. Palisade tissue of mesophyll composed of 1 layer of cells, containing clusters of calcium oxalate, spongy tissue several rows, arranging sparsely. Vascular bundles of main vein crescent-shaped, xylem vessels arranged radially, inside showing phloem, scattered with a few of fibers.
2. **Powder:** Dark green to brownish-green. Walls of upper epidermal cells sinuous, with distinct cutinized striations, scattered with a few of stomata, mostly diacytic, occasionally anomocytic; walls of lower epidermal cells sinuous, with relatively numerous stomata. Glandular hairs of 2 types: one type is glandular scales, the other type is small glandular hairs; glandular scales with head flatten-rounded, composed of 6~8 cells, containing yellow oil droplets, irregularly triangular in shape after broken, the stalk unicellular and short; small glandular hairs with head 1~2 cells, the stalk unicellular; non-glandular hairs composed of 2~8 cells, slightly sickle-shaped curved, occasionally with shrunken middle cells. Clusters of calcium oxalate extremely small, 4~8 μm in diameter, scattering in mesophyll cells.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 0.5 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 0.5 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of rosmarinic acid and dissolve in methanol to produce a solution containing 0.1 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of toluene, ethyl acetate, and formic acid (6:3:1) as the developing solvent. Apply 5 μL of each of the sample solution and reference drug solution and 2 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 13.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 13.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.3% (General rule 6007)
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).
9. Pesticide residues:
   (1) The total DDT content: Not more than 0.2 ppm (General rule 6305).
   (2) The total BHC content: Not more than 0.2 ppm (General rule 6305).

Assay:

1. Rosmarinic acid:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and 0.1% formic acid as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of rosmarinic acid and dissolve in methanol to produce a solution containing 50 μg per mL.
   (3) Sample solution: Weigh accurately 0.5 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 25 mL of 50% methanol, vortex oscillation for 30 seconds, ultrasonicate for 30 minutes. Centrifuge for 15 minutes, filter the supernatant. Repeat the extraction of the residue one more time. Combine the filtrate, transfer to 50-mL volumetric flask and make up to volume with 50% methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid

chromatography is equipped with an UV detector (330 nm) and a column packing L1. The column temperature is maintained at room temperature. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of rosmarinic acid should not be less than 10,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~18	15→40	85→60
18~20	40→100	60→0
20~25	100	0

(5) Procedure: Inject accurately 10 μL of the reference standard solution and 5~20 μL of the sample solution into the liquid chromatography apparatus, and calculate the content.

Rosmarinic acid (%)=0.005(r_U/r_S) (C_S) / (W)

r_U: peak area of rosmarinic acid of sample solution

r_S: peak area of rosmarinic acid of reference standard solution

C_S: concentration of rosmarinic acid of reference standard solution (μg/mL)

W: weight of test sample (g) calculated with dried sample.

Storage: Store in a cool and dry place.
Usage: Exterior-releasing medicinal (Pungent-warm exterior-releasing medicinal).
Property and flavor: Warm; pungent.
Meridian tropism: Lung and spleen meridians.
Effects: Release exterior to dissipate cold, move qi and harmonize the stomach.
Administration and dosage: 5~11.5 g.

PERILLAE FRUCTUS
紫蘇子
Zih Su Zih / Zi Su Zi
Perilla Fruit

Perilla fruit is the dried ripe fruit of *Perilla frutescens* (L.) Britton (Fam. Labiatae).
It contains not less than 2.0% of dilute ethanol-soluble extractives, not less than 2.0% of water extractives and not less than 0.25% of rosmarinic acid.

Description: Ovate or subspheroidal, 1.5~2.2 mm in diameter. Externally grayish-brown and brown, with slightly protuberant and dark brown reticulate striations, one acute side with pale and round scar, within a pointed fruit stalk scar. Pericarp thin and fragile, easily broken. Seed yellowish-white, testa membranous, cotyledons 2, whitish and oily. Odour aromatic by pressing; taste slightly pungent.

Microscopic identification:

1. **Transverse section:**
Fruit of *Perilla frutescens*: Epidermis suberized, yellowish-brown, cell striations faintly visible, subfusiform; inside showing 1 layer of palisade cells, composed of stone cells, about 33 μm in length, cell boundaries indistinct and lignified; inside showing several layers of obliterated cells, yellowish-brown, scattered with slightly lignified vessels. Beneath obliterated cells showing 1 to several layers of heteromorphic stone cells, subpolygonal or fusiform, cell boundaries indistinct, walls varying in thickness, pits relatively dense, some lumens indistinct and slightly lignified, this layer separated from cotyledon cells and forming clefts. Cotyledon cells with the outermost layer cells smaller, subrectangular or flatten-oblong, inner cells larger, subpolygonal or subrectangular, wall thin, filled with starch granules and fatty oil droplets.
2. **Powder:** Grayish-brown. Epidermal cells of testa extremely flattened in sectional view, with hooked thickened walls; elliptical in surface view, walls with dense carving and hook-patterned thickened. Exocarp cells yellowish-brown, flattened in sectional view, outer walls with papillary protuberance; subrounded in surface view, with slightly curved and fine cuticle striations. Endocarp tissue composed of irregular heteromorphic stone cells in sectional view; subpolygonal in top view, cell borders indistinct, lumina stellate. Endosperm cells varying in size, containing oil droplets; some containing fine prisms of calcium oxalate. Cotyledon cells subrectangular, filled with oil droplets.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter, evaporate to dryness, and dissolve the residue in 1 mL of methanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of rosmarinic acid and dissolve in methanol to produce a solution containing 0.1 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of toluene, ethyl acetate, and formic acid (6:3:1) as the developing solvent. Apply 5 μL of the sample solution and reference drug solution and 1 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 8.0% dry at 105°C for 5 hours (General rule 6015).
2. Total ash: Not more than 12.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 5.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Rosmarinic acid:
   (1) Mobile phase: A solution of methanol and 0.1% formic acid (40:60). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of rosmarinic acid and dissolve in methanol to produce a solution containing 25 μg per mL.
   (3) Sample solution: Weigh accurately 0.5 g of the powdered sample and place it in a conical flask with stopper, accurately add 50 mL of 80% methanol, stopper tightly and weigh, heat under reflux for 2 hours, cool, weigh again, replenish the loss of the weight with 80% methanol, mix well, filter, and use the filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (330 nm) and a column packing L1. The number of theoretical plates of the peak of rosmarinic acid should not be less than 3,000.
   (5) Procedure: Inject accurately 20 μL of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Rosmarinic acid (%)=0.005(r_U/r_S) (C_S) / (W)
   r_U: peak area of rosmarinic acid of sample solution
   r_S: peak area of rosmarinic acid of reference standard solution
   C_S: concentration of rosmarinic acid of reference standard solution (μg/mL)
   W: weight of test sample (g) calculated with dried sample.
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place and preserve in a well-closed container, and protect from insects.
Usage: Phlegm-dispelling medicinal (Cough-suppressing and panting-calming medicinal).
Property and flavor: Warm; pungent.
Meridian tropism: Lung meridians.
Effects: Suppress cough and to calm panting, downbear qi and disperse phlegm, moisten the intestine and relax the bowel.
Administration and dosage: 3~11.5 g.

PERSICAE SEMEN
桃仁
Tao Ren / Tao Ren
Peach Kernel

Peach kernel is the dried ripe seed of *Prunus persica* (L.) Batsch or *Prunus davidiana* (Carrière) Franch. (Fam. Rosaceae).
It contains not less than 4.0% of dilute ethanol-soluble extractives, not less than 8.0% of water extractives and not less than 2.0% of amygdalin.

Description:

1. Seed of *Prunus persica*: Flattened-elliptical, apex acute, middle swollen, base obtuse-rounded and slightly oblique, 1.2~1.8 cm in length, 0.8~1.2 cm in width, 2~4 mm thick. Externally yellowish-brown or reddish-brown, with numerous granular protuberances. A linear hilum occurring at the acute end, chalaza at the other end, with numerous brown longitudinal vascular bundles radiated from the chalaza, testa scattered with longitudinal vascular bundles. Testa thin, cotyledons 2, whitish, hypertrophy and oily. Odour slight; taste slightly bitter.
2. Seed of *Prunus davidiana*: Suboval, slightly flattened, relatively small but thicker, 0.9~1.5 cm in length, about 7 mm in width, about 5 mm thick. Testa reddish-brown or yellowish-red. Externally with granular protuberances, relatively rougher and denser. Odour slight; taste slightly bitter.

Microscopic identification:

1. **Transverse section:**
   (1) Seed of *Prunus persica*: Surface view of testa, stone cells are single or 2~4 connected and scattered in the epidermal tissue, oval or polygonal-like subrounded, 20~160 μm in diameter, sometimes can see concentric circles due to squashing (the outer circle is the wall of the base of the stone cell, the inner circle is the top wall of the stone cell).
   (2) Seed of *Prunus davidiana*: Surface view of testa, subrounded pits in stone cells are obvious, 42~300 μm in diameter, it is often seen that the stone cells are in concentric circles due to squashing or protruding top on one side.
2. **Powder:**

(1) Seed of *Prunus persica*:: Stone cells yellow, oval, narrow oblong, conchoidal or trapezoid due to flat top, 20~90 μm in diameter, height 40~140 μm, no holes in the upper part, wall thickness is about 8-20 μm, lower wall is thin, with holes, contain yellowish-brown contents, the pits are not obvious; prismatic unicellular hairs with thick walls, length 63~250 μm

(2) Seed of *Prunus davidiana*: Stone cells yellow, mostly form a triangle with enlarged base, slightly pointed or rounded on the top, few truncated, also have subrounded, narrow oblong, 42~150 μm in diameter, height 70~300 μm, the wall of one end without holes thickness is 6~10 μm, the one end of thin wall has obvious pits; single cell hair spindle, hair rare, length 100~570 μm.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, heat under reflux for 10 minutes, cool, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of amygdalin and dissolve in methanol to produce a solution containing 2.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, methanol, and water (7:3:1) as the developing solvent. Apply 10 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 10.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 5.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).
9. Aflatoxins
   (1) Aflatoxins (sum of B_1, B_2, G_1 and G_2): Not more than 10.0 ppb (General rule 6307).
   (2) Aflatoxin B_1: Not more than 5.0 ppb (General rule 6307).

Assay:

1. Amygdalin:
   (1) Mobile phase: A solution of acetonitrile, methanol and water (5:20:75). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of amygdalin and dissolve in 70% methanol to produce a solution containing 80 μg per mL.
   (3) Sample solution: Weigh accurately 0.3 g of powdered sample and place it in a conical flask with a stopper, add 50 mL of petroleum ether (30~60℃), heat under reflux for 1 hour, cool, filter, discard the petroleum ether extract. Evaporate the residue and filter paper to dryness, transfer to an initial conical flask, add accurately 50 mL of 70% methanol, and weigh, heat under reflux for 1 hour, cool, weigh again, replenish the loss of weight with 70% methanol, mix well, filter. Transfer 5 mL of the successive filtrate to a 10-mL volumetric flask, make up to volume with 50% methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (210 nm) and a column packing L1. The number of theoretical plates of the peak of amygdalin should not be less than 3,000.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   Amygdalin (%)=0.01(r_U/r_S) (C_S) / (W)

   r_U: peak area of amygdalin of sample solution

   r_S: peak area of amygdalin of reference standard solution

   C_S: concentration of amygdalin of reference standard solution (μg/mL)

   W: weight of test sample (g) calculated with dried sample.
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from insects.

Usage: Blood-regulating medicinal (Blood-activating and stasis-dispelling medicinal).

Property and flavor: Neutral; bitter and sweet.

Meridian tropism: Heart, liver, and large intestine meridians.

Effects: Activate blood and dissipate stasis , moisten the intestine and relax the bowel, suppress cough and to calm panting.
Administration and dosage: 4.5~10 g.

PEUCEDANI RADIX
前胡
Cian Hu / Qian Hu
Hogfennel Root

Hogfennel root is the dried root of *Peucedanum praeruptorum* Dunn (Fam. Umbelliferae).
It contains not less than 16.0% of dilute ethanol-soluble extractives, not less than 16.0% of water extractives and not less than 0.8% of praeruptorin A.

Description: Root stock and main root stout, cylindrical or conical, frequently curved or oblique, 2~4 cm in length, 1~1.5 cm in diameter, with scars of rootlets or 1~2 rootlets at the lower part, rootlets 3~5 cm in length. Externally brown, with densely annul striations and remains of leaf base at the root stock, commonly known as "Chiou Yin Tou (earthworm-like)", rootlets with irregular longitudinal furrows and transverse lenticels. Texture of main root, hard and fragile, fracture yellowish-white, bark broad, relatively loose, with numerous yellow oil dots (secretory cavities) in bark and xylem. Cambium ring slightly square at the transverse section of root stock, with pith. Odour aromatic; taste slightly sweet, and then bitter and pungent.

Microscopic identification:
1. **Transverse section:**
   Root of *Peucedanum praeruptorum*: Cork composed of over 10 layers of cells. Cortex extremely narrow, with some oil cavities. Phloem relatively broad, outer cells frequently with clefts, numerous subrounded oil cavities scattered, with 5~11 secretory cells, containing pale yellow oil secretions; phloem rays mostly curved at the outside. Cambium in a ring. Xylem relatively small, primary rays relatively broad and distinct, divided xylem into two parts; vessels arranged radially; a few oil cavities scattered. Parenchymatous cells contain starch granules.
2. **Powder:**
   Pale yellow. Stone cells subsquare, subrectangular, ovate, subtriangular or long strip-shaped, 66~206 μm in length, 22~97 μm in diameter, wall 3~40 μm thick, striations mostly distinct, some lumen contains orange contents. Cork cells mostly over 10 layers, overlapped; cells extremely flat in lateral view, arranged in order, 3~13 μm in diameter, 25~216 μm in length, wall slightly lignified or lignified; rectangular, subtriangular or slender in surface view, wall slightly curved, fragments of cork tissue with edge mostly arranged in order. Fragments of oil cavities surrounded by cells with indistinct cell boundaries, some lumen filled with pale yellow secretions. Xylem fibers fusiform, 83~312 μm in length, 15~26 μm in diameter, wall 3~8 μm thick, pits sparse, fine and dotted, with pit canals faintly present, some lumen contains yellowish-brown contents. Simple starch granules subrounded, broadly ovoid or oblong, hilum dotted or cleft-shaped, with striations indistinct; compound granules composed of 2~4 components. Vessels also present.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 15 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of praeruptorin A and dissolve in methanol to produce a solution containing 0.5 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane and ethyl acetate (2:1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 15.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 8.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 3.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
1. Praeruptorin A:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and water as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of praeruptorin A, and dissolve in methanol to produce a solution containing 40 μg per mL.
   (3) Sample solution: Weigh accurately 0.1 g of the powdered sample and place it in a 50-mL

centrifuge tube, then add accurately 25 mL of 75% methanol, ultrasonicate for 30 minutes. Centrifuge for 15 minutes, filter, transfer the filtrate to a 25-mL volumetric flask, make up to volume with 75% methanol, mix well, filter and use the successive filtrate.

(4) Chromatographic system: The liquid chromatography is equipped with an UV detector (325 nm) and a column packing L1. The column temperature is maintained at room temperature. The flow rate is about 1 mL/min.Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of praeruptorin A should not be less than 10,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~10	70→80	30→20
10~25	80→95	20→5

(5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Praeruptorin A (%)=0.0025(r_U/r_S) (C_S) / (W)

r_U: peak area of praeruptorin A of sample solution

r_S: peak area of praeruptorin A of reference standard solution

C_S: concentration of praeruptorin A of reference standard solution (μg/mL)

W: weight of test sample (g) calculated with dried sample.

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from mold and insects.
Usage: Phlegm-dispelling medicinal (Heat-phlegm clearing and resolving medicinal).
Property and flavor: Mild cold; bitter and pungent.
Meridian tropism: Lung meridians.
Effects: Dispel phlegm and downbear qi, disperse wind-heat.
Administration and dosage: 3~10 g.

PHARBITIDIS SEMEN
牽牛子
Cian Niou Zih / Qian Niu Zi
Pharbitis Seed

Pharbitis seed is the dried ripe seed of *Pharbitis nil* (L.) Choisy or *Pharbitis purpurea* (L.) Voigt (Fam. Convolvulaceae).

It contains not less than 12.0% of dilute ethanol-soluble extractives and not less than 18.0% of water extractives.

Description: Orange segment-shaped or ovate, with 3-ridged, 4~8 mm in length, 3~5 mm in width, both sides slightly flattened, dorsal side arcuate with a longitudinal furrow, ventral side with a rib, the lower end with a pointed and white hilum. Externally grayish-black (commonly known as “Hei Chou”) or pale yellow (commonly known as “Bai Chou”). Testa hard and shrunken. In transverse section, pale yellowish-green, with 2 shrunken and folded cotyledons. Odour slight; taste slightly pungent and bitter.

Microscopic identification:

1. **Transverse section:**
Pharbitidis semen Epidermis composed of 1~2 rows of subsquare cells, some parts differentiated into unicellular non-glandular hairs, 30~250 μm in length. Inside the epidermis showing 2~3 rows of subsquare or elongated-elliptical palisade tissue, elongated radially, with a light line near outside. Nutritive layer composed of several rows of cells and yellowish-brown decadent cells, subsquare, elongated radially, with small vascular bundles. The outermost layer of endosperm was 1~2 rows of subsquare sclerenchymatous cells. Cotyledon composed of subrounded parenchymatous cells, containing starch granules, fatty oil and clusters of calcium oxalate, 5~30 μm in diameter.
2. **Powder:** Pale yellowish-brown. Epidermal cells of testa irregular in shape, anticlinal walls thin and undulating. Unicellular non-glandular hairs 30~250 μm in length, about 30 μm in diameter, wall slightly thickened. Palisade cells subsquare, with thickened and lignified walls, some lumens containing yellowish-brown contents, light line visible. Cotyledon cells subrounded, containing starch granules, fatty oil and clusters of calcium oxalate, prism crystals occasionally found. Secretory canals subrounded, containing oil droplets.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, cool, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of caffeic acid and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of dichloromethane, methanol, and formic acid (23:4:1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The

spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 12.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 6.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:

1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place, and protect from moisture.
Usage: Purgative medicinal (Offensive purgative and water-expelling medicinal).
Property and flavor: Cold; bitter.
Meridian tropism: Lung, kidney and large intestine meridians.
Effects: Expel water, purgation, remove accumulation, kill worms.
Administration and dosage: 3~6 g.
Precaution and warning: Unprocessed one toxic, should be used cautiously for oral admininistration. Forbit to use during pregnancy.

PHELLODENDRI CORTEX
黃蘗
Huang Bo / Huang Bo
Phellodendron Bark

Phellodendron bark is the dried bark of trunk of *Phellodendron chinense* C.K.Schneid. or *Phellodendron amurense* Rupr. (Fam. Rutaceae). The former is commonly known as “Chuan Huang Bo”, and the latter is commonly known as “Guan Huang Bo”, also known as “Huang Bo”.
It contains not less than 14.0% of dilute ethanol-soluble extractives, not less than 6.0% of water extractives and not less than 1.2% of berberine, calculated with berberine chloride.

Description:

1. Bark of *Phellodendron chinense*: Tabular or shallowly channelled, varying in length and width, 3~7 mm thick. Outer surface yellowish-brown, relatively even, with transverse lenticels distinct on young bark and irregular longitudinally fissures, occasionally remained with grayish-brown cork cortex. Inner surface dark yellow or yellowish-brown, with fine longitudinally ribs. Texture light and relatively hard, fracture dark yellow, laminated and fibrous. Odour slight; taste bitter, viscous and saliva dyed yellow on chewing.
2. Bark of *Phellodendron amurense*: Usually thinner than bark of *Phellodendron chinense*, about 2~4 mm thick. Outer surface dark yellowish-brown, with irregular longitudinal fissures, occasionally remained with dark gray and thick cork cortex, tenacious, lenticels small and infrequently visible. Inner surface yellowish-green or yellowish-brown. Texture light and hard, fracture bright yellow or yellowish-green.

Microscopic identification:

1. **Transverse section:**
   (1) Bark of *Phellodendron chinense*: The outer part of bark incompletely removed, cork composed of several layers of rectangular cells, containing brown contents. Phelloderm cells contain prisms of calcium oxalate. Cortex relatively narrow, scattered with fiber bundles and stone cell groups, stone cells mostly branched, wall extremely thickened, striations distinct. Phloem occupied the most part of the bark, a few of stone cells presented at the outer part, fiber bundles arranged tangentially in an interrupted layer (hard phloem), surrounded by parenchymatous cells containing prisms of calcium oxalate. Rays 2~4 rows of cells wide, usually curved and slender. Parenchymatous cells contain fine starch granules and prisms of calcium oxalate, mucilage cells can be seen everywhere.
   (2) Bark of *Phellodendron amurense*: Cork cells square, cortex relatively broad, stone cells less than *Phellodendron chinense*, stone cells rare at the outer part of phloem. Rays relatively straight, hard phloem less developed. The other characters similar to bark of *Phellodendron chinense*.
2. **Powder:**
   (1) Bark of *Phellodendron chinense*: Stone cells mostly branched, round ones 40~128 μm in diameter, pit canals visible. Yellow mucilage cells mostly singly scattered, gradually swollen when moistened with water, becoming subrounded or oblong, 40~72 μm

in diameter, wall thin, occasionally split, lumen contains irregular mucilage contents.

(2) Bark of *Phellodendron amurense*: Greenish-yellow or yellow. Stone cells abundant, light yellow, oblong, fusiform, long strip-shaped or irregular branch-shaped, 35~80 μm in length, some branched, the end obtusely acute, wall thickened, with distinct striations. Fibers light yellow, 16~38 μm in diameter, usually in bundles, surrounded by cells containing prisms of calcium oxalate, forming crystal fibers. Prisms of calcium oxalate extremely numerous, 12~30 μm in diameter. Starch granules spheroidal, not over 10 μm in diameter. Mucilage cells visible, subspheroidal, 32~42 μm in diameter.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 5 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of berberine chloride and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-butanol, glacial acetic acid, and water (7:1:2) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 14.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 8.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 10.0 ppm (General rule 2251, 6301)

Assay:

1. Berberine chloride:

(1) Mobile phase: Add 3.4 g potassium dihydrogen phosphate and 1.7 g sodium lauryl sulfate in a 1,000 mL solution of acetonitrile and water (1:1). The ratio may be adjusted, if necessary.

(2) Reference standard solution: Weigh accurately a quantity of berberine chloride and dissolve in methanol to produce a solution containing 0.1 mg per mL.

(3) Sample solution: Weigh accurately 0.5 g of the powdered sample, accurately add 30 mL of the solution of methanol and dilute hydrochloric acid (100:1), heat under reflux for 30 minutes, cool, filter. Repeat the extraction of the residue one more time. Combine the filtrate, transfer to 100-mL volumetric flask, make up to volume with methanol, mix well, filter and use the successive filtrate.

(4) Chromatographic system: The liquid chromatography is equipped with an UV detector (345 nm) and a column packing L1. The column temperature is maintained at 35°C. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of berberine chloride should not be less than 5,000.

(5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Berberine chloride (%)=10 (r_U/r_S) (C_S) / (W)

r_U: peak area of berberine chloride of sample solution

r_S: peak area of berberine chloride of reference standard solution

C_S: concentration of berberine chloride of reference standard solution (mg/mL)

W: weight of test sample (g) calculated with dried sample.

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place, and protect from insects.

Usage: Heat-clearing medicinal (Heat-clearing and dampness-drying medicinal).

Property and flavor: Cold; bitter.

Meridian tropism: Kidney and bladder meridians.

Effects: Clear heat and dry dampness, Purge fire and detoxicate, relieve deficiency heat.

Administration and dosage: 3~12 g.

【Decoction pieces】

PHELLODENDRI CORTEX

It contains not less than 14.0% of dilute ethanol-soluble extractives, not less than 6.0% of water extractives and not less than 1.2% of berberine, calculated with berberine chloride.
Raw medicinal materials are processed to remove impurities, clean selection, soften thoroughly, cut into thin slices, and dry, mostly slivers. Outer surface yellowish-brown or tan, occasionally remained with grayish-brown cork cortex, cut surface fibrous. Showing lobe-like layers, odour slight, taste bitter.

Thin layer chromatographic identification test: The method is the same as that for crude herb.
Impurities and other requirements: Methods and specifications are the same as those for crude herb.
Assay: The method is the same as that for crude herb.
Storage: The method is the same as that for crude herb.
Usage: Heat-clearing medicinal (Heat-clearing and dampness-drying medicinal).
Property and flavor: Cold; bitter.
Meridian tropism: Kidney and bladder meridians.
Effects: Clear heat and dry dampness, Purge fire and detoxicate, remove deficiency heat.
Administration and dosage: 3~12 g.

PHRAGMITIS RHIZOMA
蘆根
Lu Gen / Lu Gen
Reed Rhizome

Reed rhizome is the dried rhizome of *Phragmites australis* (Cav.) Trin. ex Steud. (Fam. Gramineae).
It contains not less than 9.0% of dilute ethanol-soluble extractives and not less than 9.0% of water extractives.
Description: Cylindrical, some slightly flattened, varying in length; thick one cut into small pieces, 3~5 cm in length, 1~2 cm in diameter. Externally yellowish- white, with longitudinal wrinkles and furrows, nodes distinct, annular, bearing remains of buds and stem scars. Texture tenacious, uneasily broken, fracture whitish, hollowed, 1~2 mm thick, showing small pores arranged in a ring in the margin (aerenchyma). Odour slight; taste slightly bitter.

Microscopic identification:
Transverse section:
Rhizome of *Phragmites australis*: Epidermis composed of 1 layer of slightly flatten cells, outer walls thickened and slightly lignified, covered with orange-yellow cuticles. Hypodermal fibers 3~4 layers, subpolygonal, wall slightly thickened and lignified. Cortex relatively broad, with numerous subsquare large air cavities, arranged in a ring; endodermis indistinct. Vascular bundles of stele 3~4 arranged in a ring, the outermost row with relatively small vascular bundles, arranged among air cavities, between the outer and inner rows of vascular bundles scattered with fiber bundles arranging in a ring; vascular bundles in closed collateral type, surrounded by fibers of vascular bundle sheath, protoxylem vessels small, deutoxylem composed of 2 large vessels, phloem cells relatively small. Pith large in the center, hollowed.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 15 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-butanol, glacial acetic acid, and water (7:1:2) as the developing solvent. Apply 10 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with *p*-anisaldehyde/H_2SO_4 TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:
1. Total ash: Not more than 12.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 6.0% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:
1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place, and protect from mold and insects.
Usage: Heat-clearing medicinal (Heat-clearing and fire-purging medicinal).
Property and flavor: Cold; sweet.
Meridian tropism: Lung and stomach meridians.
Effects: Clear lung heat, dispel phlegm and expel pus, moisten dryness and relieve cough, clear stomach heat, engender body fluid and stop thirsting and eliminate vexation, stop vomiting, promote urination.

Administration and dosage: 15~30 g.

PHYTOLACCAE RADIX
商陸
Shang Lu / Shang Lu
Pokeberry Root

Pokeberry root is the dried root of *Phytolacca americana* L. or *Phytolacca acinosa* Roxb. (Fam. Phytolaccaceae). It contains not less than 19.0% of dilute ethanol-soluble extractives and not less than 22.0% of water extractives and not less than 0.2% of esculentoside A.

Description: Irregular piece, the appearance is brownish yellow, and the cut surface is not flat. The xylem is raised to form a number of raised concentric rings. Hard, odor slight, chewed for a long time, tongue is asleep.

Microscopic identification:
Transverse section:
Phytolaccae radix: The outermost cork cell sequence, phelloderm narrow, the vascular bundle structure is a 3 generation structure, and there are several concentric layer loops. The vascular bundles of each ring are parallel vascular bundles, the outer side is phloem, the inner side is xylem, and the inner ring is xylem. Between the parenchyma. Parenchyma cells contain large amounts of starch granules, and some contain calcium oxalate needle bundles.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of esculentoside A and dissolve in methanol to produce a solution containing 0.5 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, methanol, and water (10:2:1) as the developing solvent. Apply 5 μL of each of the sample solution and reference drug solution and 2 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 9.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 15.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
1. Esculentoside A:
   (1) Mobile phase: A solution of methanol and 0.1% phosphoric acid (60:40). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of esculentoside A and dissolve in methanol to produce a solution containing 0.1 mg per mL.
   (3) Sample solution: Weigh accurately 1.0 g of the powdered sample and place it in a 50-mL conical flask with a stopper, then add accurately 25 mL of 75% methanol, ultrasonicate for 30 minutes, filter. Repeat the extraction of the residue one more time, combine the filtrate, evaporate the filtrate to a small amount and transfer to 25-mL volumetric flask, make up to volume with 75% methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (203 nm) and a column packing L1. The column temperature is maintained at 35℃. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of esculentoside A should not be less than 2,000.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   Esculentoside A (%)=2.5(r_U/r_S) (C_S) / (W)

   r_U: peak area of esculentoside A of sample solution
   r_S: peak area of esculentoside A of reference standard solution
   C_S: concentration of esculentoside A of reference standard solution (mg/mL)
   W: weight of test sample (g) calculated with dried sample.

Storage: Store in a ventilated and dry place, and protect from mold and insects.
Usage: Purgative medicinal (Offensive purgative and water-expelling medicinal).

Property and flavor: Cold; bitter.
Meridian tropism: Lung, spleen, kidney, and large intestine meridians.
Effects: Expel water by purgation, remove swelling and disperse stagnation.
Administration and dosage: 3~10 g; used an appropriate amount for external use.
Precaution and warning: Forbit to use during pregnancy.

PINELLIAE RHIZOMA
半夏
Ban Sia / Ban Xia
Pinellia Tuber

Pinellia tuber is the dried tuber of *Pinellia ternata* (Thunb.) Makino (Fam. Araceae).
It contains not less than 3.5% of dilute ethanol-soluble extractives and not less than 9.0% of water extractives.

Description: Spheroidal, hemispheric or oblique, 0.8~2 cm in diameter, with externally yellow spots. Apex flattened and rounded at the top, with pocked and yellowish-brown scars of leaves or buds, surrounded densely by pocked and dotted scars of fibrous root, base obtuse and rounded, relatively smooth. Texture hard and starchy, fracture white or pale yellow, fracture reniform, whitish, starchy, decrepit or dried improperly pinellia tuber with grayish-white or yellow lines. Odour with a strong irritant leading to sneezing; taste pungent, viscous and numb on chewing.

Microscopic identification:
1. **Transverse section:**
   Tuber of *Pinellia ternata*: The cork as the outermost layer (only some part of cork remained on unprocessed banxia of market medicinal material), composed of 8~11 layers of cells, arranged tangential densely, cell subsquare, rectangular or long-flat shaped, 2~6 μm in width, 10~50 μm in length, lignified; the inner part parenchymatous cells present, subrounded, ovate, oblong, polygonal or irregular shaped, filled with starch granules, subrounded to ovate, polygonal or irregular shaped, some starch granules linear or burst-like shaped, hilum or stellated; large starch granules with distinct striations, usually in individual or compound granules, composed of 2~8 components, 2~30 μm in diameter. Cortex scattered with mucilage cells, containing raphides of calcium oxalate, 1~2 μm in diameter, 20~50 μm in length; when slicing, raphides bundles usually scattered onto adjacent parenchymatous cells. Vascular bundles as in 3 types of collateral, radial or amphivasal. Vessels thick-walled, 4~60 μm in diameter, mainly in spiral, rare in annular, lignified distinct or indistinct with striations distinct.
2. **Powder:** White. Extremely numerous starch granules present as the majority proportion of the powder, subrounded, oblong, polygonal or irregular, occasionally linear or burst-like shaped; hilum stellate, larger starch granules with distinct striations, usually in individual or compound, granules composed of 2~8 components, 2~30 μm in diameter. Raphides of calcium oxalate numerous, as singly scattered, several in bundles or remained in mucilage cells; raphides extremely fine, some fracture-shaped, 1~2 μm in diameter, 2~50 μm in length. Vessels mainly in spiral, rare in annular vessels, 4~60 μm in diameter, lignified distinct or indistinct.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter, evaporate to 3 mL and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of petroleum ether (30~60℃), ethyl acetate, acetone, and formic acid (30:6:4:0.5) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:
1. Loss on drying: Not more than 14.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 5.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 3.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 5.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:
1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from insects.

Usage: Phlegm-dispelling medicinal (Dampness and phlegm eliminating medicinal).
Property and flavor: Warm; pungent; toxic.
Meridian tropism: Spleen, stomach, and lung meridians.
Effects: Dry dampness to resolve phlegm, downbear counterflow to stop vomiting, disperse focal distention and dissipate bind.
Administration and dosage: 3~11.5 g, generally processed before application; used an appropriate amount for external use.
Precaution and warning: Unprocessed one toxic, processed before application, Incompatible with *Aconitum* sp.

PIPERIS FRUCTUS
胡椒
Hu Jiao / Hu Jiao
Pepper

Pepper is the dried and almost ripe or ripe fruit of *Piper nigrum* L. (Fam. Piperaceae). The former is commonly known as "Black Pepper", and the latter is commonly known as "White Pepper".
Black pepper contains not less than 10.0% of dilute ethanol-soluble extractives and not less than 6.0% of water extractives; white pepper contains not less than 7.0% of dilute ethanol-soluble extractives, not less than 1.0% of water extractives and not less than 3.3% of piperine.

Description:
1. Black Pepper (almost ripe fruit): Spheroidal, 0.3~0.6 cm in diameter. Externally blackish-brown, with reticulated wrinkles, apex remained with a fine protuberant stylopodium, base with a scar of fruit axis. Texture of exocarp and sarcocarp loose and fragile, easily exfoliated. Texture of endocarp relatively hard, fracture yellowish-white, starchy, center hollow, apex with a tiny embryo. Odour aromatic; taste pungent.
2. White Pepper (ripe fruit): Exocarp removed, spheroidal or long-spheroidal, 0.3~0.5 cm in diameter. Externally grayish-white, smooth, apex slightly dented and flattened, base slightly acute, occasionally with blackish-brown striations, with numerous light linear striations around. The character of endocarp and seed the same as that for the black pepper.

Microscopic identification:
1. **Transverse section:**
Black Pepper (almost ripe fruit): Exocarp composed of over 10 rows of epidermal cells and 2~3 rows of hypodermal cells; epidermal cells subrectangular or subpolygonal, with outer walls wary, arranged tangentially, containing dark brown to sub-black contents; hypodermal cells suboblong, containing yellowish-brown contents and stone cell groups, with distinct lumina and pit canals, some containing brown contents. Mesocarp composed of 10~20 rows of parenchymatous cells, large oil cells and fine vascular bundles scattered, parenchymatous cells relatively small at the inner side, elongated tangentially, with walls slightly lignified, the innermost row of lignified parenchymatous cells accompanied by oil cells, arranged in an interrupted ring. Endocarp composed of 1 row of subrectangular stone cells, with thin outer wall and thick inner wall. 2~3 flattened-rectangular cells existed at outer testa, containing brown contents; membrane transparent cell layer existed at inner testa. Perisperm composed of broad parenchymatous tissue, 1~2 layers of aleurone grains existed at the outer side, containing starch granules; starch parenchymatous cells existed at the inner side, containing starch granules, scattered with oil cells. Endosperm composed of parenchymatous cells.
2. **Powder:**
Black Pepper (almost ripe fruit): Grayish-black. Stone cells of pericarp subrounded or rectangular, 15~80 μm in diameter, with distinct lumina and pit canals, some containing brown contents. Parenchymatous cells of mesocarp rectangular or polygonal, containing yellowish-brown contents and starch granules. Sclerenchymatous cells with one end blunt, 8~16 μm in diameter. Stone cells of endocarp subrectangular, 30~50 μm in length and 30~35 μm in width, with thin outer wall and thick inner wall. Vessels spiral, 10~20 μm in diameter. Starch granules subrounded, 2~6 μm in diameter.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, cool, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of piperine in an amber volumetric flask, and dissolve in absolute ethanol to produce a solution containing 4.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of toluene, ethyl acetate, and acetone (7:2:1) as the developing solvent. Apply 2 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat until the spots become visible, examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 14.0% for white pepper dry at 105℃ for 5 hours (General rule 6015).

2. Total ash: Not more than 7.0% for black pepper; not more than 3.0% for white pepper (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% for black pepper; not more than 1.0% for white pepper (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)
9. Aflatoxins
   (1) Aflatoxins (sum of B_1, B_2, G_1 and G_2): Not more than 10.0 ppb (General rule 6307).
   (2) Aflatoxin B_1: Not more than 5.0 ppb (General rule 6307).

Assay:

1. Piperine:
   (1) Mobile phase: A solution of methanol and water (60:40). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of piperine, and dissolve in 75% methanol to produce a solution containing 0.1 mg per mL.
   (3) Sample solution: Weigh accurately 0.1 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 20 mL of 75% methanol, ultrasonicate for 30 minutes. Centrifuge for 10 minutes, transfer the supernatant to a 50-mL volumetric flask. Repeat the extraction of the residue one more time. Combine the supernatant and make up to volume with 75% methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (343 nm) and a column packing L1. The column temperature is maintained at 25°C. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of piperine should not be less than 1,500.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   Piperine (%)=5(r_U/r_S) (C_S) / (W)

   r_U: peak area of piperine of sample solution

   r_S: peak area of piperine of reference standard solution

   C_S: concentration of piperine of reference standard solution (mg/mL)

   W: weight of test sample (g) calculated with dried sample.

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place or preserve in a well-closed container.
Usage: Interior-warming medicinal.
Property and flavor: Hot; pungent.
Meridian tropism: Stomach and large intestine meridians.
Effects: Warm the middle to dissipate cold.
Administration and dosage: 0.6~1.5 g, it is used in powder for oral administration and an appropriate amount for external use.

PLANTAGINIS HERBA
車前草
Che Cian Cao / Che Qian Cao
Plantago Herb

Plantago herb is the dried herb of *Plantago asiatica* L. or *Plantago depressa* Willd. (Fam. Plantaginaceae).
It contains not less than 4.0% of dilute ethanol-soluble extractives, not less than 10.0% of water extractives and not less than 0.1% of plantamajoside.

Description:

1. Herb of *Plantago asiatica*: 10~18 cm in height. Roots tiny, fibrous. Leaves crumpled, grayish-green, broadly ovate or elliptical as whole, 5~12 cm in length, 2~8 cm in width, with 5~7 longitudinal veins, petioles slender and long. Spikes several, terminal. Capsules circumscissile, calyx persistent at the apex of scape. Odour slight; taste slightly bitter, viscous.

2. Herb of *Plantago depressa*: Main roots conical, straight and long. Leaves oblong or lanceolate, 5~10 cm in length, 1~3 cm in width, narrow, with 5~7-nerved at the base. Spikes terminal, dense at the upper, loose at the lower.

Microscopic identification:

1. **Transverse section:**
   (1) Leaf of *Plantago asiatica*: Upper epidermis composed of 1 row of cells, subrounded or subsquare, 25 μm in diameter, with cuticle striations, anticlinal walls undulate. Palisade tissue composed of 1~2 rows of rectangular cells, arranged densely. Spongy tissue with cells subrounded. Vascular bundles collateral; xylem vessels spiral, 5~20 μm in diameter. Lower epidermis composed of 1 row of cells, cells relatively small, stomata anomocytic. Glandular hairs with 2 cells in the head, elliptical, with a unicellular stalk, 10~30 μm in diameter, containing yellowish-brown secretions. Non-glandular hairs rare, 2~10

cells, walls slightly thickened and with faint warty.

(2) Herb of *Plantago depressa*: Non-glandular hairs composed of 5~20 cells, 350~900 μm in length, walls filled with faint warty.

2. **Powder:**

(1) Herb of *Plantago asiatica*: Grayish-green. Epidermal cells of leaf subpolygonal in surface view, anticlinal walls undulate, with stomata. The upper epidermal cells with cuticle striations. Vessels spiral, 5~20 μm in diameter. Fibers slender, with walls slightly thickened and lignified, containing oblique pits. Glandular hairs with 2 cells in the subrounded head, 10~30 μm in diameter, 15~50 μm in length, with a unicellular stalk, containing yellowish-brown secretions. Non-glandular hairs composed of 2~10 cells, about 18 μm in diameter, walls with faint warty. Pollen grains pale yellow or colorless, subrounded, 20~25 μm in diameter, with warty sculptures on the surface. Stomata anomocytic, with 3~5 subsidiary cells, 15~35 μm in length, 15~30 μm in diameter.

(2) Herb of *Plantago depressa*: Brownish-green. The head of glandular hairs 18~27 μm in diameter, 15~40 μm in length; the head and stalk all containing pale brown secretions. Non-glandular hairs composed of 5~20 cells, 10~25 μm in diameter, walls slightly thickened, with relatively large and dense warty.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of plantamajoside and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, methanol, formic acid, and water (18:3:1.5:1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 14.0% dry at 105°C for 5 hours (General rule 6015).
2. Total ash: Not more than 15.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 5.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:

1. Plantamajoside:

(1) Mobile phase: A solution of acetonitrile and 0.1% formic acid (14:86). The ratio may be adjusted, if necessary.

(2) Reference standard solution: Weigh accurately a quantity of plantamajoside, and dissolve in 60% methanol to produce a solution containing 0.1 mg per mL.

(3) Sample solution: Weigh accurately 1.0 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 20 mL of 60% methanol, ultrasonicate for 30 minutes. Centrifuge for 10 minutes, transfer the supernatant to a 50-mL volumetric flask. Repeat the extraction of the residue one more time. Combine the supernatant and make up to volume with 60% methanol, mix well, filter and use the successive filtrate.

(4) Chromatographic system: The liquid chromatography is equipped with an UV detector (330 nm) and a column packing L1. The column temperature is maintained at 25°C. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of plantamajoside should not be less than 3,000.

(5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Plantamajoside (%)=5(r_U/r_S) (C_S) / (W)

r_U: peak area of plantamajoside of sample solution

r_S: peak area of plantamajoside of reference standard solution

C_S: concentration of plantamajoside of reference standard solution (mg/mL)

W: weight of test sample (g) calculated with dried sample.

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place, and protect from moisture.
Usage: Dampness-dispelling medicinal (Dampness-draining diuretic medicinal).
Property and flavor: Cold; sweet.
Meridian tropism: Liver, kidney, lung and small intestine meridians.
Effects: Induce diuresis and relieve strangury, clear heat and detoxicate, cool the blood.
Administration and dosage: 9~30 g.

PLANTAGINIS SEMEN
車前子
Che Cian Zih / Che Cian Zi
Plantago Seed

Plantago seed is the dried ripe seed of *Plantago asiatica* L. or *Plantago depressa* Willd. (Fam. Plantaginaceae).
It contains not less than 6.0% of dilute ethanol-soluble extractives, not less than 6.0% of water extractives, not less than 4.0% (v/w) of swelling capacity and not less than 0.4% of verbascoside.

Description:
1. Seed of *Plantago asiatica*: Ellipsoid or irregularly oblong, slightly flattened, 1.10~2.10 mm in length, 0.60~1.20 mm in width, relatively large. Externally brown or darkish-brown, with a pale yellow concave pointed hilum on one side. Fracture grayish-white. Odour slight; taste weak, viscous on chewing.
2. Seed of *Plantago depressa*: Flattened oblong, 0.85~1.75 mm in length, 0.65~0.90 mm in width, relatively small. Externally brownish-red or brown, with a white concave pointed hilum in the center.

Microscopic identification:
1. **Transverse section:**
   Plantaginis semen: Testa composed of 2 layers of cells; outer layer is mucilaginous layer, walls extremely thin, melted and swelled when moistened with water; inner layer is pigmented, polygonal or subsquare, the cells contain brown pigments. Endosperm composed of 3~5 rows of cells, suboval or subrounded, containing fatty oil. Cotyledon cells arranged in order, subrounded, containing aleurone grains and fatty oil. The differences between *Plantago asiatica* and *Plantago depressa* is *Plantago depressa* with small pigment cells, outer walls flat and subrectangular.
2. **Powder:**
   (1) Seed of *Plantago asiatica*: Dark yellowish-brown. Outer epidermal cells of testa subsquare or subrectangular in sectional view, walls thin; subrectangular in surface view, 25~75 μm in length, 3~18 μm in diameter. Inner epidermal cells of testa yellowish-brown, subrectangular, 28~85 μm in length, 7~29 μm in diameter, walls thin and slightly curved. Endosperm cells with walls thickened, polygonal or subrounded, lumen filled with aleurone grains and fatty oil. Cotyledon cells subrounded or suboval, containing aleurone grains and oil droplets.
   (2) Seed of *Plantago depressa*: Dark yellowish-brown. Inner epidermal cells of testa relatively small, 11~45 μm in length, 5~15 μm in diameter.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 1 mL of methanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, glacial acetic acid, formic acid, and water (8:1:1:2) as the developing solvent. Apply 8 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with vanillin/H_2SO_4 TS, heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:
1. Loss on drying: Not more than 12.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 6.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 3.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)
9. Swelling capacity: Weigh accurately 1.0 g of powdered sample, carry out the method for determination of swelling capacity (General rule THP5001).

Assay:
1. Verbascoside:
   (1) Mobile phase: Methanol as the mobile phase A, and 0.5% acetic acid as the mobile phase B.

(2) Reference standard solution: Weigh accurately a quantity of verbascoside, transfer to an amber volumetric flask, and dissolve in 60% methanol to produce a solution containing 0.1 mg per mL.

(3) Sample solution: Weigh accurately 1.0 g of powdered sample, in a conical flask with stopper, add 50 mL of 60% methanol, weigh, heat under reflux for 2 hours, cool, weigh again, replenish the loss of weight with 60% methanol, mix well and filter, use the successive filtrate.

(4) Chromatographic system: The liquid chromatography is equipped with an UV detector (254 nm) and a column packing L1. Program the chromatographic gradient system as follows.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~1	5	95
1~40	5→60	95→40

(5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Verbascoside (%)=5(r_U/r_S) (C_S) / (W)

r_U: peak area of verbascoside of sample solution

r_S: peak area of verbascoside of reference standard solution

C_S: concentration of verbascoside of reference standard solution (mg/mL)

W: weight of test sample (g) calculated with dried sample.

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place, and protect from moisture.

Usage: Dampness-dispelling medicinal (Dampness-draining diuretic medicinal).

Property and flavor: Cold; sweet.

Meridian tropism: Liver, kidney, lung, and bladder meridians.

Effects: Induce diuresis and relieve strangury, dispel wind and antidiarrheal, clear liver to improve vision, clear lung and resolve phlegm.

Administration and dosage: 5~15 g, wrap-decocted.

PLATYCLADI CACUMEN
側柏葉
Ce Bo Ye / Ce Bo Ye
Chinese Arborvitae Twig

Chinese arborvitae twig and leaf is the dried twig and leaf of *Platycladus orientalis* (L.) Franco (Fam. Cupressaceae). It contains not less than 15.0% of dilute ethanol-soluble extractives, not less than 11.0% of water extractives, not less than 0.2% of quercitrin and not less than 0.05% of amentoflavone.

Description: Twigs flattened, vary in length. Leaves small, scale-shaped, decussate, close to twigs, externally dark green or yellowish-green, facial leaves rhomboid, and glandular groove at center abaxially. Texture fragile, easily broken.

Microscopic identification:

1. **Transverse section:**
   (1) Twig of *Platycladus orientalis*: Epidermis composed of 1 row of subsquare cells, wall thick, covered with cuticle scattered with sandy crystals and prisms of calcium oxalate, stomata sunken. Hypodermal fibers 1~2 layers, located underneath the epidermis, arranged discontinuously, with thickened wall, slightly lignified to lignified. Cortex composed of large parenchymatous cells, cells vary in size, containing resin canals. Vascular bundles arranged in a ring, phloem scattered with fibers, small pith located in the center, rays distinct.
   (2) Leaf of *Platycladus orientalis*: Palisade tissue composed of 1 row of short-cylindrical cells; spongy tissue composed of subrounded cells. Leaf vein vascular bundles collateral, outside accompanied by a subrounded large resin canal.
2. **Powder:** Pale green. Stomata extremely numerous, sunken, with large subsidiary cells, dumbbell-shaped in lateral view. Epidermal cells subsquare, wall thickened, cuticle scattered with small prisms of calcium oxalate and sandy crystals, 1.5~7.5 μm in diameter. Tracheids mainly spiral, bordered-pitted and singly-pitted, 5~13 μm in diameter. Parenchymatous cells contain resin canals, 105~120 μm in diameter. Phloem fibers slender, fusiform, mostly broken and singly scattered.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, cool, filter, and make up the filtrate to 10 mL.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of quercitrin and dissolve in methanol to

produce a solution containing 0.1 mg per mL.

4. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, acetone, formic acid, and water (20:2:1:1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 254 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 11.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 10.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 4.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 10.0 ppm (General rule 2251, 6301)

Assay:

1. Quercitrin and amentoflavone:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and 0.1% phosphoric acid as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of quercitrin and amentoflavone and dissolve in methanol to produce a solution containing 30 μg and 5μg per mL of each.
   (3) Sample solution: Weigh accurately 0.5 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 25 mL of 75% methanol, vortex oscillation for 30 seconds, ultrasonicate for 30 minutes. Centrifuge for 10 minutes, use the supernatant. Repeat the extraction of the residue one more time. Combine the supernatant, transfer to a 50-mL volumetric flask and make up to volume with 75% methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (330 nm) and a column packing L1. The column temperature is maintained at room temperature. The flow rate is about 1 mL/min.Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of quercitrin and amentoflavone should not be less than 10,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~20	5→50	95→50
20~30	50→100	50→0
30~35	100	0

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Quercitrin or amentoflavone (%)= 0.005 (r_U/r_S) (C_S) / (W)
   r_U: peak area of quercitrin or amentoflavone of sample solution
   r_S: peak area of quercitrin or amentoflavone of reference standard solution
   C_S: concentration of quercitrin or amentoflavone of reference standard solution (μg/mL)
   W: weight of test sample (g) calculated with dried sample.
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place.
Usage: Blood-regulating medicinal (Hemostatic medicinal).
Property and flavor: Cold; bitter and astringent.
Meridian tropism: Lung, liver and large intestine meridians.
Effects: Cool the blood to hemostatic，resolve phlegm to suppress cough, promote hair growth and blacken hair.
Administration and dosage: 6~12 g, used an appropriate amount for external use.

PLATYCLADI SEMEN
柏子仁
Bo Zih Ren / Bo Zi Ren
Platycladi Seed

Platycladi seed is the dried ripe seed of *Platycladus orientalis* (L.) Franco (Fam. Cupressaceae).
It contains not less than 4.0% of dilute ethanol-soluble extractives and not less than 5.0% of water extractives.

Description: Narrowly ovate or oblong, 0.4~0.7 cm in length, 0.15~0.3 cm in diameter. Externally pale yellow or yellowish-white as fresh, darkened into yellowish-brown after store, oily, covered with membranous tegmen, apex slightly acute, subround-triangle, with a small dark brown dot, base obtusely round, color relatively paler. Fracture creamy white to yellowish-white, endosperm developed, cotyledon 2 or more, oily. Odor slightly aromatic; taste

weak and oily. The better character as plumping, yellowish-white, oily without weeping, without shells and impurities.

Microscopic identification:
Transverse section:
Seed of *Platycladus orientalis*: Endotesta composed of 1 row of cells, flattened-rectangular, outer wall slightly thickened. Endosperm developed, parenchymatous cells of endosperm and cotyledon contain fatty oil and aleurone grains.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 5 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of *β*-sitosterol and dissolve in ethanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of dichloromethane and methanol (14:1) as the developing solvent. Apply 5 μL of each of the sample solution and reference drug solution and 2 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 8.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 16.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 6.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)
9. Aflatoxins
   (1) Aflatoxins (sum of B_1, B_2, G_1 and G_2): Not more than 10.0 ppb (General rule 6307).
   (2) Aflatoxin B_1: Not more than 5.0 ppb (General rule 6307).

Assay:
1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place, and protect from insects and oil seeping.
Usage: Tranquillizing medicinal (Heart-nourishing tranquillizing medicinal).
Property and flavor: Neutral; sweet.
Meridian tropism: Heart, kidney, and large intestine meridians.
Effects: Calm the mind, moisten the intestine and relax the bowel, antihidrotics.
Administration and dosage: 3~12 g.

PLATYCODONIS RADIX
桔梗
Jie Geng / Jie Geng
Platycodon Root

Platycodon root is the dried root of *Platycodon grandiflorus* (Jacq.) A.DC. (Fam. Campanulaceae).
It contains not less than 22.0% of dilute ethanol-soluble extractives, not less than 35.0% of water extractives and not less than 0.1% of platycoside E.

Description: Cylindrical or long fusiform, slightly twisted, occasionally branched, 6~25 cm in length, 0.5~2.5 cm in diameter. Apex with a relatively short rhizome (Lutou), rhizome scattered with several crescent-shaped stem scars. Externally white or pale yellow, or yellowish-brown to grayish-brown when unpeeled, with irregularly longitudinal wrinkles and furrows, with transverse lenticel-like scars. Texture hard and fragile, fracture uneven, with radial cleft, bark whitish, cambium ring distinct, wood pale yellow. Odour slight; taste slightly sweet and then bitter.

Microscopic identification:
1. **Transverse section:**
   Root of *Platycodon grandiflorum*: Several layers of cork cells observed in without removal of outer bark, fine prisms or raphides of calcium oxalate occasionally found. Cortex narrow, usually showing clefts. Phloem broad, scattered with laticiferous tubes, with slightly thick walls, containing granular yellow contents; laticiferous tube groups usually accompanied by sieve tube cells. Cambium in a ring. Xylem vessels singly scattered or severally grouped, arranged radially. Parenchymatous cells contain inulin.
2. **Powder:** Yellowish-white. Inulin abundant (mounting with ethanol TS), fan-shaped or subrounded crystals. Laticiferous tubes usually linked into reticular-shaped, 14~25 μm in diameter,

tubes containing yellow oil droplets-like granules. Scalariform and reticulate vessels commonly present, bordered-pitted vessels rarely present.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 5 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of platycoside E and dissolve in methanol to produce a solution containing 0.2 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, glacial acetic acid, formic acid, and water (3:1:1:1) as the developing solvent. Apply 2 μL of each of the sample solution and reference drug solution and 1 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Total ash: Not more than 6.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 5.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:

1. Platycoside E:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and water as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of platycoside E, and dissolve in 70% methanol to produce a solution containing 0.2 mg per mL.
   (3) Sample solution: Weigh accurately 1.0 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 50 mL of 75% methanol, ultrasonicate for 30 minutes. Centrifuge for 10 minutes, filter the supernatant. Repeat the extraction of the residue one more time. Combine the filtrate, evaporate the filtrate to a small amount, transfer to 5-mL volumetric flask and make up to volume with 75% methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: It is equipped with an evaporative light-scattering detector (ELSD) and a column packing L1. The column temperature is maintained at 35℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of platycoside E should not be less than 5,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~25	20→25	80→75
25~33	25	75

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from moisture and insects.
Usage: Phlegm-dispelling medicinal (Heat-phlegm clearing and resolving medicinal).
Property and flavor: Neutral; bitter and pungent.
Meridian tropism: Lung meridians.
Effects: Diffuse the lung, dispel phlegm, soothe the throat, expel pus.
Administration and dosage: 3~10 g.

【Decoction pieces】

PLATYCODONIS RADIX

It contains not less than 22.0% of dilute ethanol-soluble extractives, not less than 35.0% of water extractives and not less than 0.1% of platycoside E.

Raw medicinal materials are processed to remove impurities, clean selection, soften thoroughly, cut into thin slices, and dry, mostly elliptical oblique slice or irregular thick slices, outer bark usually removed, occasionally with patches of cork remained. Cut surface sub-white, narrow in bark part; with a brown and obvious cambium ring; pale yellow, broad and much cracked in wood part. Odour slight; taste sweetish then bitter.

Thin layer chromatographic identification test: The method is the same as that for crude herb.
Impurities and other requirements: Methods and specifications are the same as those for crude herb.
Assay: The method is the same as that for crude herb.
Storage: The method is the same as that for crude herb.

Usage: Phlegm-dispelling medicinal (Heat-phlegm clearing and resolving medicinal).
Property and flavor: Neutral; bitter and pungent.
Meridian tropism: Lung meridians.
Effects: Diffuse the lung, dispel phlegm, soothe the throat, expel pus.
Administration and dosage: 3~10 g.

POGONATHERI HERBA
筆仔草
Bi Zai Tsao / Bi Zai Cao
Golden Hair Grass

Golden hair grass is the dried herb of *Pogonatherum crinitum* (Thunb.) Kunth (Fam. Gramineae).
It contains not less than 7.0% of dilute ethanol-soluble extractives and not less than 6.0% of water extractives and not less than 0.04% of chlorogenic acid.

Description: Mixed segments of roots, stems, leaves and inflorescences. Root yellowish white whiskers. The stem is thin and round, smooth, and the section is obviously enlarged. The cut surface is white and hollow. The leaves are broken. Spikes, dense golden yellow long awns, shaped like cat tails. Odor slight and the taste is bitter.

Microscopic identification:

1. **Transverse section:**
   (1) Root of *Pogonatherum crinitum*: The epidermis consists of 1 row oblong cells; the lower part is a sclerenchyma composed of 1~3 columns of elliptical sclerenchyma cells. Cortex consists of 2~4 columns parenchyma cells, and the starch granules are scattered. The endothelium is composed of subrectangular cells, and its cell wall is thick and membranous, and the degree of thickening is different. Vascular bundles are about 4~7 and arranged radially. The pith is composed of parenchyma cells, sometimes thickened.
   (2) Stem of *Pogonatherum crinitum*: The epidermis consists of 1 column of closely arranged oblong cells, the outer wall is thickened, with a stratum corneum; below it is 4~7 columns of fibers, arranged in a wheel shape. Vascular bundles are vertical, scattered in the fibrous layer and the parenchyma, the xylem near the pith, and the phloem near the epidermis. The parenchyma is composed of subround cells, and the cells near the fibers are thickened. Pith is often hollow and ruptured.
   (3) Leaf of Pogonatheri herba: Upper epidermis consists of vesicular cells and epidermal cells. collenchyma can be seen on the inner side of the upper and lower epidermis. The mesophyll tissue consists of a palisade tissue and a sponge tissue. The vascular bundles are vertical and surrounded by a bundle of vascular bundles of thick-membrane cells. The epidermis cells are oblong.
2. **Powder**: Brownish-green. The short bristles are single cells, conical. Non-glandular hairs are single-celled and slender, sometimes containing pale yellow substances. The roots are spindle-shaped, arranged closely. The epidermal cells of the leaves are composed of long cells, and the vertical wall is thin and wavy. There are pairs of orthosilicic acid cells and short cells between the long cells, cells are closely arranged. The stomata are located on the upper and lower epidermis, and the guard cells are dumbbell-shaped. The stemsclerenchyma cells are subrectangular, the wall is thick, the pits are slanted, and the pores are fine. The stem fiber cells are rectangular in shape, the wall is thin, the pits are oblique point, and the pores are obvious and sparse. The fiber is accompanied by a catheter, which is bundled; it is bright yellow under a polarizing microscope. The starch granules are subspherical or irregular in shape; they are black cross under a polarizing microscope. The conduits are mostly annular and spiral conduits.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 1 mL of methanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of chlorogenic acid and dissolve in methanol to produce a solution containing 0.5 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and the upper layer of butyl acetate, formic acid, and water (7:3:2.5) as the developing solvent. Apply 5 μL of each of the sample solution and reference drug solution and 1 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 9.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 18.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 14.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).

5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Chlorogenic acid:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and 0.1% phosphoric acid as the mobile phase B
   (2) Reference standard solution: Weigh accurately a quantity of chlorogenic acid and dissolve in 50% ethanol to produce a solution containing 5 μg per mL.
   (3) Sample solution: Weigh accurately 0.2 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 20 mL of 50% ethanol, ultrasonicate for 30 minutes, centrifuge for 10 minutes. Transfer the supernatant to a 25-mL volumetric flask and make up to volume with 50% ethanol, mix well, filter and use the filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (326 nm) and a column packing L1. The column temperature is maintained at 35℃. The flow rate is about 1 mL/min Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of chlorogenic acid should not be less than 5,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~10	10→15	90→85
10~30	15→35	85→5

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Chlorogenic acid (%)=0.0025(r_U/r_S) (C_S) / (W)
   r_U: peak area of chlorogenic acid of sample solution
   r_S: peak area of chlorogenic acid of reference standard solution
   C_S: concentration of chlorogenic acid of reference standard solution (μg/mL)
   W: weight of test sample (g) calculated with dried sample.

Storage: Store in a cool and dry place.
Usage: Heat-clearing medicinal (Heat-clearing and detoxicating medicinal).
Property and flavor: Cool, sweet.
Effects: Clear heat and detoxicate, drain dampness, induce diuresis, relieve strangury, cool the blood.
Administration and dosage: 9~30 g.

POGOSTEMONIS HERBA
廣藿香
Guang Huo Siang / Guang Huo Xiang
Cablin Patchouli Herb

Cablin patchouli herb is the dried aerial part of *Pogostemon cablin* (Blanco) Benth. (Fam. Labiatae).
Description: Stems slightly square, frequently branched, branches slightly curved, 30~60 cm in length, 0.2~0.7 cm in diameter; externally pubescent; texture fragile, easily broken, fracture medullated in the center; old stems subcylindrical, 1~1.2 cm in diameter, covered with grayish-brown cork. Leaves opposite, crumpled into masses, ovate or elliptical as whole, 4~9 cm in length, 3~7 cm wide; grayish-white pubescences on both surfaces; apex short-acute or obtuse-rounded, base cuneate or obtusely rounded, margin irregularly serrate; petioles slender, 2~5 cm in length, pubescent. Odour aromatic, characteristic; taste slightly bitter.

Microscopic identification:

1. **Transverse section:**
   Stem of *Pogostemon cablin*: Epidermis composed of 1 row of arranging irregularly cells, with non-glandular hairs, 1~5 row of celled, beneath the epidermis showing 3~5 rows of cork cells. The outer part of cortex showing 4~10 rows of collenchymatous cells, the inner part of cortex showing parenchymatous cells, containing large intercellular spaces with interspace glandular hairs inside, the head unicellular, elongated-rounded or subrounded, 75~195 μm in length, containing yellow to yellowish-green volatile oil, the stalk short, 1~2 row of celled, mostly linked with cortex cells, parenchymatous cells also contain raphides of calcium oxalate, about 15 μm in length. Pericyclic fibers in bundles. Phloem narrow. Xylem well developed at the 4 corners, composed of vessels, xylem parenchymatous cells and xylem fibers, all lignified. Pith slightly lignified, containing raphides of calcium oxalate and flaky crystals, starch granules rare.
2. **Powder:** Pale brown. Non-glandular hairs 1- to 8-celled, straight or acute at the apex, 97~590 μm in length, wall with spiny protuberance, some lumens contain yellowish-brown contents, some cells contain fine raphides crystals at the base. Glandular scales with head 8-celled, 37~70 μm in diameter; the stalk unicellular, extremely short. Interspace glandular hairs present in intercellular spaces of mesophyll or parenchyma tissue of stem, the head unicellular, irregular sac-shaped, 23~43 μm in length, 13~50 μm in diameter, containing golden oil contents; the stalk short, 1~2 row of celled. Glandular hairs with the head 2 row of celled or

occasionally unicellular; the stalk 1~3 row of celled, extremely short. Raphides of calcium oxalate fine, scattered in mesophyll, parenchymatous cells of stem or fibers, 3~27 μm in length. Epidermal cells of leaf irregular, stomata diacytic. Pericyclic fibers singly scattered or several in bundles, pale yellow or yellowish-green, long-fusiform, 11~37 μm in diameter, lignified, pits relatively sparse, occasionally with septa, lumen mostly containing yellowish-brown contents, occasionally with fine granular crystals. Xylem fibers in bundles, 13~35 μm in diameter, walls lignified, pits obliquely cleft-shaped or V-shaped, usually with septa, linking with rays cells. Vessels bordered-pitted, reticulate, spiral or annular. Parenchymatous cells of pith large, with pits, some cells contain fine raphides crystals.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of patchouli alcohol and dissolve in ethyl acetate to produce a solution containing 2.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of petroleum ether (30~60℃), ethyl acetate, and glacial acetic acid (95:5:0.2) as the developing solvent. Apply 8 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 5% $FeCl_3$/EtOH TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
2. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
3. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
4. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
5. Lead (Pb): Not more than 10.0 ppm (General rule 2251, 6301)

Storage: Store in a cool and dry place.
Usage: Dampness-dispelling medicinal (Dampness-resolving with aroma medicinal).
Property and flavor: Mild warm; pungent.
Meridian tropism: Spleen, stomach, and lung meridians.
Effects: Transforms dampness, stop vomiting, release exterior to dispel summerheat.
Administration and dosage: 4.5~11.5 g.

POLYGALAE RADIX
遠志
Yuan Jhih / Yuan Zhi
Polygala Root

Polygala root is the dried root of *Polygala tenuifolia* Willd. or *Polygala sibirica* L. (Fam. Polygalaceae).

Description: Slender, cured and cylindrical, with 1 to numerous lateral roots. Main root 10~20 cm in length, 2~10 mm in diameter; externally pale grayish-brown, with longitudinal furrows and dented transverse fissures, easily broken, fracture non-fibrous, margin irregular and undulated. Cork pale grayish-brown, cortex thick, with numerous large broken space. Wood pale brown, round or elliptical, often split along the primary pith ray to cuneiform. Odour slightly stinking; taste slightly pungent.

Microscopic identification:
Transverse section:
Polygalae radix: Cork composed of several rows of pale brown cells. Cortex composed of several rows of parenchymatous cells, with clefts. Phloem relatively broad. Cambium in a distinct ring. Xylem well developed, rays present in 1~2 rows. Parenchymatous cells contain oil droplets; some cells inside phloem contain clusters of calcium oxalate.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 0.5 g of powdered sample to 20 mL of 70% methanol, ultrasonicate for 30 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 1 mL of methanol.
2. Reference drug solution: Take 0.5 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of polygalaxanthone III and dissolve in methanol to produce a solution containing 0.5 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and the lower layer of a solution of ethyl acetate, ethanol, and water (10:2:1) as the developing solvent. Apply 5 μL of each of the sample solution and reference drug solution and 2 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained

from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Foreign matter: Not more than 10.0%, including stems (General rule 6005).
2. Total ash: Not more than 6.0% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 5.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)
8. Pesticide residues:
   (1) The total DDT content: Not more than 0.2 ppm (General rule 6305).
   (2) The total BHC content: Not more than 0.2 ppm (General rule 6305).
9. Aflatoxins
   (1) Aflatoxins (sum of B_1, B_2, G_1 and G_2): Not more than 10.0 ppb (General rule 6307).
   (2) Aflatoxin B_1: Not more than 5.0 ppb (General rule 6307).

Storage: Store in a ventilated and dry place, and protect from mold and insects.
Usage: Tranquillizing medicinal (Heart-nourishing tranquillizing medicinal).
Property and flavor: Warm; bitter and punent.
Meridian tropism: Heart, kidney, and lung meridians.
Effects: Calm the mind, resolve phlegm to open the orifices, disperse abscesses.
Administration and dosage: 3~12 g.

POLYGONATI ODORATI RHIZOMA
玉竹
Yu Jhu / Yu Zhu
Fragrant Solomonseal Rhizome

Fragrant solomonseal rhizome is the dried rhizome of *Polygonatum odoratum* (Mill.) Druce (Fam. Liliaceae).
It contains not less than 46.0% of dilute ethanol-soluble extractives and not less than 46.0% of water extractives.

Description: Long cylindrical, slightly compressed, few branched, varying in length, 0.3~1.6 cm in diameter. Externally pale yellowish-brown, with longitudinal wrinkles and slightly protuberant annulations, exhibiting fibrous root scars and a disk-like stem scar. Texture hard or pliable when moistened, fracture horny. Odour slight; taste sweetish and viscous on chewing.

Microscopic identification:
Transverse section:
Rhizome of *Polygonatum odoratum*: Epidermal cells arranged in order, suboblate in shape, outer walls slightly thickened, horny. The spaces between cortex and stele are indistinct. Parenchymatous cells scattered with numerous subrounded mucilage cells, 60~190 μm in diameter, containing raphides of calcium oxalate. Collateral vascular bundles scattered.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of ethanol, ultrasonicate for 30 minutes, evaporate the filtrate to dryness, and dissolve the residue in 1 mL of 70% ethanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and the supernatant of *n*-butanol, glacial acetic acid, and water (4:1:5) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with α-naphthol/MeOH TS and heat at 105℃ until the spots become visible. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:
1. Total ash: Not more than 4.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:
1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a ventilated and dry place, and protect from mold and insects.
Usage: Tonifying and replenishing medicinal (Yin-tonifying medicinal).
Property and flavor: Mild cold; sweet.

Meridian tropism: Lung and stomach meridians.
Effects: Nourishe yin and moisten lung, engender fluid to stop thirsting, nourish stomach.
Administration and dosage: 6~12 g

POLYGONATI RHIZOMA
黃精
Huang Jing / Huang Jing
Solomonseal Rhizome

Solomonseal rhizome is the dried rhizome of *Polygonatum cyrtonema* Hua, *Polygonatum sibiricum* Redouté or *Polygonatum kingianum* Collett & Hemsl. (Fam. Liliaceae).
It contains not less than 39.0% of dilute ethanol-soluble extractives and not less than 39.0% of water extractives.

Description:
1. Rhizome of *Polygonatum cyrtonema* (Jiang Sing Huang Jing or Bai Ji Huang Jing): Flattened, elongated and connected in groups of several tubercles. Fleshy. Up to about 10 cm in length as whole, 1~2.5 cm in width, often 5 tubercles connected in a group, the both sides with short branches, the shape just like Bletillae Rhizoma, 2.5~7.5 cm in width, the upper nodes relatively small. Externally grayish-yellow or yellowish-brown, with irregular wrinkles, the upper part of nodes with discoidal stem scars, 0.8~1.5 cm in diameter, scattered with numerous dots of vascular bundles. The upper part of short branches with bud scars. The whole with undulating annulations, distinct at the lower part. Internodes 0.2~1 cm in length, scattered with fine and round root scars. Texture hard, fracture horny. Odour slight; taste slightly sweet and viscous on chewing.
2. Rhizome of *Polygonatum sibiricum* (Ji Tou Huang Jing): Slender and cylindrical, slightly flattened, up to about 10 cm in length, 0.5~1.5 cm in diameter. One side or both sides slightly swollen as the head of chicken or with short branches, 1.5~2 cm in width. Externally yellowish-white or grayish- yellow, with longitudinal wrinkles and round stem scars. Internodes 0.3~1.5 cm in length. Stem scars 5~8 mm in diameter.
3. Rhizome of *Polygonatum kingianum* (Da Huang Jing): Tuberculated or moniliform, up to more than 10 cm in length, 2~6 cm in width. Externally pale yellow to yellowish-brown, with irregular wrinkles and discoidal stem scars with a sunken circumference.

Microscopic identification:
1. **Transverse section:**
   (1) Rhizome of *Polygonatum cyrtonema*(iang Sing Huang Jing 、 Bai Ji Huang Jing): Epidermis composed of 1 layer of cells, covered with cuticle. Cortex relatively narrow, cell boundaries indistinct with stele. Vascular bundles of stele scattered, mostly in collateral type, amphivasal type occasionally found. Parenchyma tissue scattered with mucilage cells, 51~323 μm in length, 22~158 μm in diameter, containing raphides of calcium oxalate, 60~156 μm in length.
   (2) Rhizome of *Polygonatum sibiricum*(Ji Tou Huang Jing): Vascular bundles mostly collateral, amphivasal type rare, relatively small at the outer part, gradually larger inward; mucilage cells 96~253 μm in length, 44~187 μm in diameter, raphides of calcium oxalate 68~161 μm in length.
   (3) Rhizome of *Polygonatum kingianum*(Da Huang Jing): Vascular bundles mostly amphivasal, collateral type rare; mucilage cells 115~210 μm in length, 81~160 μm in diameter, raphides bundles 115~204 μm in length.
2. **Powder:** Pale grayish-yellow. Epidermal cells subsquare, subrectangular or irregular, 30~90 μm in length, 20~30 μm in width. Cortex cells subrounded or irregular, 70~150 μm in length, 75~90 μm in width. Vessels bordered-pitted or spiral, 150~225 μm in length, 15~30 μm in diameter. Raphides crystals scattered or in bundles, about 150 μm in length.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 15 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-butanol, glacial acetic acid, and water (7:1:2) as the developing solvent. Apply 10 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with *p*-anisaldehyde/H_2SO_4 TS and heat at 105℃ until the spots become visible. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:
1. Total ash: Not more than 4.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 4.0% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule

6301).

7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

※Note: "When this TCM herb is sold commercially, the limits of heavy metals, sulfur dioxide and aflatoxins should follow the food standard."

Assay:

1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from mold and insects.
Usage: Tonifying and replenishing medicinal (Yin-tonifying medicinal).
Property and flavor: Neutral; sweet.
Meridian tropism: Spleen, lung, and kidney meridians.
Effects: Nourishe yin and moisten lung, invigorating spleen for benefiting qi.
Administration and dosage: 9~15 g.

POLYGONI AVICULARIS HERBA
萹蓄
Pian Syu / Pian Xu
Common Knotgrass Herb

Common knotgrass herb is the dried aerial part of *Polygonum aviculare* L. (Fam. Polygonaceae).
It contains not less than 7.0% of dilute ethanol-soluble extractives and not less than 6.0% of water extractives and not less than 0.09% of myricitrin.

Description: Stem is cylindrical, slightly flat with branches, 1~4 mm in diameter. pidermal grayish green to reddish brown, with fine micro-protrusion longitudinal lines; the nodes are slightly enlarged, with a pale brown membranous stiletto sheath, 0.4~5 cm in length. Hard and brittle, the section of the pith is white. Leaves alternate, nearly sessile or with short stalks, leaves often sessate or shrunk, broken, intact, flattened, lanceolate, Whole edge, 0.5~3.8 cm in length, 1~7 mm in wide. Both sides are grayish green to yellowish green or brownish green. The flower is small, bunch is born in the leaf axil . Odor slight and the taste is bitter.

Microscopic identification:

1. **Transverse section:**
   (1) Stem of *Polygonum aviculare*: The epidermal cells are single-rowed, subrectangular, and the outer layer is horny, sometimes containing brown to brownish-yellow. The cortical fiber bundles are intermittently arranged in a ring. The cortex is composed of a series of parenchyma cells, the cells are radially extended, and some cells contain calcium oxalate clusters. The mid-column sheath fiber bundles are also intermittently arranged in a ring. The phloem is narrow; the layer loop is formed; the xylem catheter is radially arranged. The pith is large and consists of large parenchyma cells, sometimes with scattered calcium oxalate clusters.
   (2) Leaf of *Polygonum aviculare*: The upper and lower epidermis are each composed of one column of cells. The vertical wall of the cell is nearly straight, and the inner side has a palisade tissue. Some parenchyma cells contain calcium oxalate clusters. The main vascular bundle is in a vertical shape, and sclerenchyma can be seen in the periphery of the main vein. Collenchyma can be seen on the inner and lower epidermis of the vein.
2. **Powder:** Grayish-green to brownish-green. The fiber is slender, 6~28 μm in diameter; it is yellowish-white under a polarizing microscope. The calcium oxalate cluster crystal, 9~59 μm in diameter; it is bright white under a polarizing microscope. The catheter is mainly spiral and textured catheter, 3~51 μm in diameter. The stomata are inequalities, there are 3 auxiliary cells. Pollen grains yellow to yellowish-white, elliptical, subspheroidal or blunt-triangular, 19~36 μm in diameter, with 3 germination holes.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of 70% ethanol, ultrasonicate for 30 minutes, centrifuge for 10 minutes, evaporate the supernatant to dryness, and dissolve the residue in 1 mL of 70% ethanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of myricitrin and dissolve in ethanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, ethanol, formic acid, and water (25:1:1:1) as the developing solvent. Apply 5 μL of each of the sample solution and reference drug solution and 2 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 254 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 11.0% dry at 105°C for 5 hours (General rule 6015).
2. Total ash: Not more than 11.0% (General rule 6007).

3. Acid-insoluble ash: Not more than 3.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Myricitrin:
   (1) Mobile phase: Methanol as the mobile phase A, and 0.2% phosphoric acid as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of myricitrin and dissolve in methanol to produce a solution containing 10 μg per mL.
   (3) Sample solution: Weigh accurately 0.5 g of powdered sample and place it in a 125-mL conical flask with a stopper, then add accurately 45 mL of 60% methanol, stand for 1 hour, heat under reflux for 30 minutes, cool to room temperature, centrifuge for 15 minutes. Transfer the supernatant to a 50-mL volumetric flask and make up to volume with 60% methanol, mix well, filter and use the filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (352 nm) and a column packing L1. The column temperature is maintained at 35℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of myricitrin should not be less than 3,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~35	40→53	60→47

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content
   Myricitrin (%)=0.005(r_U/r_S) (C_S) / (W)
   r_U: peak area of sinapine thiocyanate of sample solution
   r_S: peak area of sinapine thiocyanate of reference standard solution
   C_S: concentration of sinapine thiocyanate of reference standard solution (μg /mL)
   W: weight of test sample (g) calculated with dried sample.

Storage: Store in a ventilated and dry place.

Usage: Dampness-dispelling medicinal (Dampness-draining diuretic medicinal).
Property and flavor: Mild cold; bitter.
Meridian tropism: Bladder meridians.
Effects: Induce diuresis and relieve strangury, kill worms, relieve itching.
Administration and dosage: 9~40 g.

POLYPORUS
豬苓
Jhu Ling / Zhu Ling
Agaric

Agaric is the dried sclerotium of *Polyporus umbellatus* (Pers.) Fr. (Fam. Polyporaceae).
It contains not less than 0.07% of ergosterol.

Description: Irregular-shaped, strip-shaped, subround or compressed-lumped, occasionally branched, 5~25 cm in length, 2~6 cm in diameter. Externally black, grayish-black or brownish-black, crumpled or warty. Texture light and hard, fracture whitish or pale brown, slightly granular and tenacious. Odour slight; taste weak. The better character as large, externally black, fracture white and texture light.

Microscopic identification:

1. **Transverse section:**
   Sclerotium of *Polyporus umbellatus*: All composed of densely interweaved hyphae. The outer layer 27~54 μm thick, hyphae brown; the inner hyphae colorless, sinuous, 2~10 μm in diameter, occasionally septa visible, with branches or tubercular swellings. Numerous prisms of calcium oxalate among the hyphae, mostly in octahedron cubes, regular octahedrons or irregular polyhedrons, up to 68 μm in length, 3~60 μm in diameter, occasionally with several crystals aggregated.
2. **Powder:** Yellowish-white. Hyphae scattered or aggregated into masses, mostly colorless, less yellowish-brown. Prisms of calcium oxalate mostly in octahedron cubes, regular octahedrons or irregular polyhedrons, 3~68 μm in diameter.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 1 mL of methanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of ergosterol and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of petroleum ether (30~60 ℃) and ethyl acetate (3:1) as the developing solvent.

Apply 8 μL of each of the sample solution and reference drug solution and 5 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with vanillin/H_2SO_4 TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 15.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 12.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 3.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 5.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:

1. Ergosterol:
   (1) Mobile phase: Methanol as the mobile phase.
   (2) Reference standard solution: Weigh accurately a quantity of ergosterol and dissolve in methanol to produce a solution containing 50 μg per mL.
   (3) Sample solution: Weigh accurately 0.5 g of the powdered sample and place it in a conical flask with stopper, accurately add 10 mL of methanol, weigh, ultrasonicate for 1 hour, cool, weigh again, replenish the loss of the weight with methanol, mix well, filter and use the filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (283 nm) and a column packing L1. The column temperature is maintained at 25℃. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of ergosterol should not be less than 5,000.
   (5) Procedure: Inject accurately 20 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   Ergosterol (%)=0.001(r_U/r_S) (C_S) / (W)

   r_U: peak area of ergosterol of sample solution
   r_S: peak area of ergosterol of reference standard solution
   C_S: concentration of ergosterol of reference standard solution (μg /mL)
   W: weight of test sample (g) calculated with dried sample.

Storage: Store in a ventilated and dry place, and protect from moisture and color changing.
Usage: Dampness-dispelling medicinal (Dampness-draining diuretic medicinal).
Property and flavor: Neutral; sweet and bland.
Meridian tropism: Kidney and bladder meridians.
Effects: Induce diuresis to drain dampness.
Administration and dosage: 6~15 g.

PORIA
茯苓
Fu Ling / Fu Ling
Indian Bread

Indian bread is the dried sclerotium of *Wolfiporia extensa* (Peck) Ginns (*Poria cocos* (Schwein.) F.A.Wolf) (Fam. Polyporaceae).
It contains not less than 0.04% of pachymic acid.

Description:

1. Ge Ling: Subspheroidal, ellipsoid, oblate or irregular-shaped masses, variable in size. Small ones such as a fist, and the larger one up to 30 cm in diameter or larger, up to several catty in weight. Externally thin, brown to blackish-brown, rough, with wrinkles and shrunken, occasionally partly exfoliated. Texture hard and compact, fracture granular, the outer layer pale red, with tiny honeycomb-like holes, inner part white, rarely reddish, some showing the penetrating roots in the center. Odour slight; taste weak and viscous on chewing.
2. Fu Ling Pi (the outer of Poria): Irregular-shaped pieces, externally brown to blackish-brown, inner white or pale brown, texture relatively soft and slightly tenacious.
3. Fu Ling Kuai (sliced pieces of Poria): Occurring in cubic pieces, 3~4 cm in length, about 7 mm in width, white, pale red or pale brown.
4. Fu Ling Pian (peeled and cubic Poria): Occurring in thick slices, white, pale red or pale brown, smooth and delicate, easily broken.

Microscopic identification:
Powder: Grayish-white. Irregularly granular masses and branched masses colorless, dissolved gradually on mounting in chloral hydrate solution. Hyphae colorless or pale brown, slender, slightly curved, branched, 3~8 μm (rarely up to 16 μm) in diameter.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minute, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference

drug and the method of preparation is the same as which is described above.

3. Reference standard solution: Weigh accurately a quantity of pachymic acid and dissolve in methanol to produce a solution containing 0.2 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of toluene, ethyl acetate, and formic acid (20:5:0.5) as the developing solvent. Apply 5 μL of each of the sample solution and reference drug solution and 2 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Total ash: Not more than 3.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 5.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:

1. Pachymic acid:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and 0.1% phosphoric acid as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of pachymic acid and dissolve in methanol to produce a solution containing 50 μg per mL.
   (3) Sample solution: Weigh accurately 2.0 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 20 mL of methanol, ultrasonicate for 30 minutes, filter with filter paper. Repeat the extraction of the residue one more time. Combine the filtrate, evaporate the supernatant to a small amount and transfer to 25-mL volumetric flask, make up to volume with methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (203 nm) and a column packing L1. The column temperature is maintained at room temperature. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of pachymic acid should not be less than 10,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~20	70→100	30→0

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Pachymic acid (%)=0.0025(r_U/r_S) (C_S) / (W)

r_U: peak area of pachymic acid of sample solution

r_S: peak area of pachymic acid of reference standard solution

C_S: concentration of pachymic acid of reference standard solution (μg/mL)

W: weight of test sample (g) calculated with dried sample.

Storage: Refrigerate or store in a cool and dry place, and protect from insects.
Usage: Dampness-dispelling medicinal (Dampness-draining diuretic medicinal).
Property and flavor: Neutral; sweet and bland.
Meridian tropism: Heart, lung, spleen, and kidney meridians.
Effects: Induce diuresis to drain dampness, fortify the spleen and stomach, calm the mind.
Administration and dosage: 9~30 g.

【Decoction pieces】

PORIA

It contains not less than 0.04% of pachymic acid.
Raw medicinal materials are processed to remove impurities, put in water, clean selection and steam briefly after softened. After peeling cut into pieces or thick slices, and then dry. Mostly irregular flakes or cubes of varying thickness, white, fine and powdery feeling. Texture crunchy, easy to break, margin occasionally yellowish-brown. Odour slight, taste slight, and chewing stick teeth slightly.

Thin layer chromatographic identification test: The method is the same as that for crude herb.
Impurities and other requirements: Methods and specifications are the same as those for crude herb.
Assay: The method is the same as that for crude herb.
Storage: The method is the same as that for crude herb.
Usage: Dampness-dispelling medicinal (Dampness-draining diuretic medicinal).
Property and flavor: Neutral; sweet and bland.
Meridian tropism: Heart, lung, spleen, and kidney meridians.
Effects: Induce diuresis to drain dampness, fortify the spleen and stomach, calm the mind.
Administration and dosage: 9~30 g.

PORIA CUM PINI RADIX
茯神
Fu Shen / Fu Shen
Root Poria

Root poria is the dried sclerotium of *Wolfiporia extensa* (Peck) Ginns (*Poria cocos* (Schwein.) F.A.Wolf) (Fam. Polyporaceae), part with pine roots in the middle.
It contains not less than 0.05% of pachymic acid.
Description: Subspherical, elliptical or irregular dry slabs, 0.5~0.3 cm in wide, thin and rough outer skin, tan to dark brown, obvious wrinkled texture, weight, firm texture. Section granular, some have cracks, white or grayish white inside, pine roots in the middle, light pine body, no skin, slightly resembling dead wood. Odor slight, taste light.

Microscopic identification:
Powder: Grayish-white rind is composed of numerous myceliums, inside and see most of the subovate or irregular granules, xylem in the middle, powder grayish-white, irregular granules mass and branches mass, colorless, hyphae colorless or pale brown, slender and slightly curved, partially branched, 3~4 μm in diameter.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 5 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of pachymic acid and dissolve in methanol to produce a solution containing 0.2 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of toluene, ethyl acetate, and formic acid (20:5:0.5) as the developing solvent. Apply 5 μL of each of the sample solution and reference drug solution and 2 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 19.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 1.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 0.5% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
1. pachymic acid:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and 0.1% phosphoric acid as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of pachymic acid and dissolve in methanol to produce a solution containing 50 μg per mL.
   (3) Sample solution: Weigh accurately 2.0 g of the powdered sample and place it in a 50-mL conical flask, then add accurately 20 mL of methanol, ultrasonicate for 30 minutes, filter with filter paper. Repeat the extraction of the residue one more time. Combine the filtrate, evaporate the filtrate to a small amount and transfer to 25-mL volumetric flask, make up to volume with methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (203 nm) and a column packing L1. The column temperature is maintained at room temperature. The flow rate is about 1 mL/min Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of pachymic acid should not be less than 10,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~20	70→100	30→0

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Pachymic acid (%)=0.0025(r_U/r_S) (C_S) /(W)
   r_U: peak area of pachymic acid of sample solution
   r_S: peak area of pachymic acid of reference standard solution
   C_S: concentration of pachymic acid of reference standard solution (μg/mL)
   W: weight of test sample (g) calculated with dried sample.

Storage: Store in a ventilated and dry place, and protect from moisture and insects.
Usage: Tranquillizing medicinal (Heart-nourishing tranquillizing medicinal).
Property and flavor: Neutral; sweet and bland.

Effects: Calm the mind and drain dampness.
Administration and dosage: 9~30 g.

PORIAE CUTIS
茯苓皮
Fu Ling Pi / Fu Ling Pi
Tuckahoe Peel

Tuckahoe peel is the dried sclerotium of *Wolfiporia extensa* (Peck) Ginns (*Poria cocos* (Schwein.) F.A.Wolf) (Fam. Polyporaceae).
It contains not less than 5.0% of dilute ethanol-soluble extractives and not less than 3.0% of water extractives and not less than 0.1% of polyporenic acid C.

Description: Long strips or irregular pieces, varying size. Outer epidermis tan to dark brown, verrucose; inner epidermis pale brown or grayish brown, often has a white or reddish subcutaneous part. Texture soft, slightly elastic. Odor slight, taste light, chewing gum is sticky.

Microscopic identification:
Powder: Grayish-white. numerous hyphae, colorless, pale brown or brown, slender, slightly curved, sometimes with branches, 3~8 μm in diameter and 16 μm in part. Granular agglomerates are irregular in shape, colorless. Branched mass colorless,10~24 μm in diameter.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of polyporenic acid C and dissolve in methanol to produce a solution containing 0.1 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of cyclohexane, dichloromethane, ethanol, and glacial acetic acid (13:8:1:1) as the developing solvent. Apply 8 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 254 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 13.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 7.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 6.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
1. Polyporenic acid C:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and 0.1% phosphoric acid as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of polyporenic acid C and dissolve in 75% methanol to produce a solution containing 0.2 mg per mL.
   (3) Sample solution: Weigh accurately 0.2 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 20 mL of 75% methanol, ultrasonicate for 30 minutes. Centrifuge for 10 minutes, transfer the supernatant to a 50-mL volumetric flask. Repeat the extraction of the residue one more time. Combine the supernatant and make up to volume with 75% methanol, mix well, filter and use the filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (242 nm) and a column packing L1. The column temperature is maintained at 25℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of polyporenic acid C should not be less than 10,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~45	50→75	50→25
45~50	75→95	25→5

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Polyporenic acid C (%)=0.005(r_U/r_S) (C_S) / (W)
   r_U: peak area of polyporenic acid C of sample solution
   r_S: peak area of polyporenic acid C of reference standard solution
   C_S: concentration of polyporenic acid C of reference standard solution (μg/mL)
   W: weight of test sample (g) calculated with dried sample.

Storage: Store in a ventilated and dry place, and protect from moisture and insects.
Usage: Dampness-dispelling medicinal (Dampness-draining diuretic medicinal).
Property and flavor: Neutral; sweet and bland.
Meridian tropism: Lung, spleen, and kidney meridians.
Effects: Induce diuresis to alleviate edema.
Administration and dosage: 15~30 g.

PORTULACAE HERBA
馬齒莧
Ma Chih Sian / Ma Chi Xian
Parslane Herb

Parslane herb is the dried aerial part of *Portulaca oleracea* L. (Fam. Portulacaceae).
It contains not less than 13.0% of dilute ethanol-soluble extractives and not less than 10.0% of water extractives.

Description: Mostly crumpled and rolled into masses. Stems cylindrical, 15~30 cm in length, 0.1~0.2 cm in diameter. Externally yellowish-brown or brown, with distinctly longitudinal furrows, texture fragile, easily broken, fracture yellow. Leaves margin entire, opposite or alternate, easily broken, when whole, obovate, 1~2.5 cm in length, 0.5~1.5 cm in width, greenish-brown. Capsules elliptical or conical, operculum hat-shaped, containing numerous fine black seeds. Odor slight; taste slightly sour, with stickiness.

Microscopic identification:
1. **Transverse section:**
   Stem of *Portulaca oleracea*: Subrounded, epidermis composed of 1 row of subsquare cells or subrectangular cells, purplish-red, covered with thick cuticle. Cortex is wider, outer is 1-3 rows of collenchyma, composed of 8~9 layers of parenchymatous cells, occupied 1/2 portion of the stem cross section radius, parenchymatous cells are subrounded or subsquare, with distinct intercellular spaces, clusters of calcium oxalate can be seen. Collateral vascular bundles, the vessel exist in bundles, 8~15 arranged in a ring. Cambium distinct in the bundles, 1~3 rows. Xylem cells subrounded, subpolygonal or subsquare. Pith in the center are subrounded parenchymatous cells, cells are subrounded, subpolygonal or subsquare, containing clusters of calcium oxalate.
2. **Powder:** Grayish-green. Epidermal cells of leaf polygonal, subsquare or irregular in shape, with stomata. Epidermal cells of stem square, arranged in order, coriaceous, stomata occasionally found. Heteromorphic stone cells subsquare or strip-shaped. Vessels mainly reticulate, spiral or annular. Fibers and tracheids contain pits. Clusters of calcium oxalate numerous, varying in size, 7~108 μm in diameter, crystal body of large clusters relatively big, angles obtuse. Prisms of calcium oxalate occasionally can be seen, 8~69 μm wide, 86~125 μm long, some aggregated to clusters.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 2.0 g of powdered sample to 15 mL of methanol, stand for 30 minutes, ultrasonicate for 30 minutes, filter, the filtrate add 0.5 g of activated carbon, mix well then filter, add 2 mL of methanol, wash twice, evaporate the filtrate to 5 mL.
2. Reference drug solution: Take 2.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of dichloromethane, methanol, and formic acid (4:1:0.2) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 20% H_2SO_4/EtOH TS and heat at 105°C until the spots become visible. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:
1. Loss on drying: Not more than 15.0% dry at 105°C for 5 hours (General rule 6015).
2. Total ash: Not more than 19.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 3.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:
1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place, and protect from moisture.
Usage: Heat-clearing medicinal (Heat-clearing and detoxicating medicinal).
Property and flavor: Cold; sour.
Meridian tropism: Liver and large intestine meridians.

Effects: Clear heat and detoxicate, cool the blood to hemostatic, stop dysentery.
Administration and dosage: 9~15 g.

PRINSEPIAE NUX
蕤仁
Ruei Ren / Rui Ren
Prinsepia Space Insert Nut

Prinsepia space insert nut is the dried mature fruit core of *Prinsepia uniflora* Batalin or *Prinsepia uniflora* Batalin var. *serrata* Rehder (Fam. Rosaceae).
It contains not less than 4.0% of dilute ethanol-soluble extractives and not less than 3.0% of water extractives.

Description: The ovate or flat heart-shaped fruit core, 7~10 mm in length, 6~8 mm in wide, 3~5 mm in thick, with a tip tip and a slight asymmetry on both sides. The surface is pale yellowish brown to dark brown, there are obvious dark reticular grooves, some have taupe flesh sticking, hard, slightly Odour slightly bitter taste.

Microscopic identification:
Transverse section:
Mature fruit core of *Prinsepia uniflora*: It consists of multiple layers of closely arranged stone cells. The stone cells are mostly oblong, elongated, and a few subround. Occasionally, the cell contains yellowish brown matter. The outer skin of the seed coat is 3 to 4 columns of brown cells. The inner epidermis of the seed coat is 1 column of colorless large parenchyma cells, the perisperm is decadent, and the endosperm is 1 column, and brown oil drops are visible.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 1 mL of methanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of protocatechuic acid and dissolve in methanol to produce a solution containing 0.1 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane, ethyl acetate, and formic acid (5:5:0.2) as the developing solvent. Apply 8 μL of each of the sample solution and reference drug solution and 2 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 254 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 10.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 5.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Storage: Store in a ventilated and dry place, and protect from mold and insects.
Usage: Heat-clearing medicinal (Heat-clearing and dampness-drying medicinal).
Property and flavor: Mild cold; sweet.
Meridian tropism: Liver meridians.
Effects: Emolliate the liver to improve vision, dispel wind and disperse heat.
Administration and dosage: 5~12 g.

PRUNELLAE SPICA
夏枯草
Sia Ku Cao / Xia Ku Cao
Prunella Spike

Prunella spike is the dried fruit cluster of *Prunella vulgaris* L. (Fam. Labiatae).
It contains not less than 3.0% of dilute ethanol-soluble extractives, not less than 4.0% of water extractives and not less than 0.2% of rosmarinic acid.

Description: Dried fruit cluster, corolla often fallen off. Clavate, slightly compressed, 1.5~8 cm in length, 0.8~1.5 cm in diameter; brown or pale brown. The whole spike composed of several or up to ten whorls of persistent calyx and bracts, interwhorl 5~7 mm in length, each whorl with 6 persistent calyxes, about 1 cm in length, bilabiate, with four brown ovate nutlets, apex protuberant, the lower of whorl with two opposite bracts; bracts fan-shaped, about 8 mm in length, about 1.2 cm in width, apex acuminate, the upper with distinct striations of vein, the lower with white hairs. Texture light. Odour aromatic; taste weak.

Microscopic identification:
Powder: Dark brown. Outer epidermal cells weird, the surface cells are prolonged, and the vertical wall is deeply undulated, up to about 121 μm in length and 31~57 μm in diameter, walls slightly thickened, unlignified , lumen containing pale yellow and yellowish brown contents. Non-glandular hairs mostly broken, intact 1~14 row of

cell,Unicellular mostly present, conical, 16~54 cm in length, multicellular often have one or several cells contracting, up to about 2.1 mm in length, epidermal cells with fine warty, some lumina contain yellow contents. Glandular hairs are oblong and flat, with 1~2 columns of cells, and the single cells are elongated into hooks, up to about 39 μm in diameter, intracellular cavity filled with yellow secretions, and the stems are 1~2 columns of cells. Glandular scales subrounded head, 4 columns of cells, 32~62 μm in diameter, contain yellow secretions. Peripheral wall of the pericarp cell is wavy or deep undulating, and the stellate branches of the cell, some lumina filled with yellow contents. Parenchymatous cells of mesocarp subpolygon, contain sandy crystals. Epidermal cells of testa subpolygonal , wall fine curved strip mesh thickening. The epithelial cells of the bracts subpolygonal, the vertical wall is straight or slightly curved, and the surface has fine horny stripes, some lumina contain yellow or yellowish-brown contents. Stomata diacytic.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of rosmarinic acid and dissolve in methanol to produce a solution containing 0.1 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of toluene, ethyl acetate, and formic acid (6:3:1) as the developing solvent. Apply 5 μL of the sample solution and reference drug solution and 2 μL of the reference standard solution to the plate. Once the top of solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. Or spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:

1. Loss on drying: Not more than 15.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 14.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 6.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:

1. Rosmarinic acid:
   (1) Mobile phase: A solution of methanol and 0.1% formic acid (42:58). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of rosmarinic acid and dissolve in dilute ethanol to produce a solution containing 20 μg per mL.
   (3) Sample solution: Weigh accurately 0.5 g of powdered sample and place it in a conical flask with stopper, add accurately 45 mL of 50% ethanol, ultrasonicate for 30 minutes, filter with filter paper. Repeat the extraction of the residue one more time, combine the filtrate, transfer the filtrate to a 100-mL volumetric flask and make up to volume with 50% ethanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (330 nm) and a column packing L1. The column temperature is maintained at 35℃. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of rosmarinic acid should not be less than 6,000.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Rosmarinic acid (%)=0.01(r_U/r_S) (C_S) / (W)
   r_U: peak area of rosmarinic acid of sample solution
   r_S: peak area of rosmarinic acid of reference standard solution
   C_S: concentration of rosmarinic acid of reference standard solution (μg/mL)
   W: weight of test sample (g) calculated with dried sample.
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place.
Usage: Heat-clearing medicinal (Heat-clearing and fire-purging medicinal).
Property and flavor: Cold; pungent and bitter.
Meridian tropism: Liver and gallbladder meridians.
Effects: Clear liver and purge fire, improve vision, dissipate binds to alleviate edema.
Administration and dosage: 9~15 g.

PRUNI SEMEN
郁李仁
Yu Li Ren / Yu Li Ren
Chinese Dwarf Cherry Seed

Chinese dwarf cherry seed is the dried mature seed of *Prunus humilis* Bunge, *Prunus japonica* Thunb., *Prunus pedunculata* (Pall.) Maxim. (Fam. Rosaceae) , the first two commonly known as " Siao Li Ren ", and the latter one commonly known as " Da Li Ren."
It contains not less than 10.0% of dilute ethanol-soluble extractives and not less than 12.0% of water extractives and not less than 2.0% of amygdalin.

Description:
1. Seed of Siao Li Ren: Oval, 5~8 mm in length, 3~5 mm in diameter. Epidermis yellowish white or pale brown, one end pointed, other end obtuse. Tip end has a linear umbilical cord, center of the round end has a dark compositing point, plurality of longitudinal vascular bundle veins are arranged upward from the merging point. Seed coat thin, cotyledon 2, milky white, oily. Odor slight, taste bitter.
2. Seed of Da Li Ren: 6~10 mm in length, 5~7 mm in diameter; Epidermis yellowish brown.

Microscopic identification:
1. **Transverse section:**
   Pruni semen: Epidermis 1 column of parenchyma cells, intercellular spaces, stone cells oblong or subround, single or 2~4 connected, lower half is embedded between the parenchyma cells and has pits. Vascular bundle passes through the seed coat. Below 3~5 rows of shrunken parenchyma cells. Endosperm consists of 1 column of waste cells. Endoderm cells are 7~9 columns. Two cotyledons, composed of parenchyma cells, filled aleurone and oil droplets. Primary vascular bundle is scattered in the cotyledons.
2. **Powder:** Brown. Ectodermal pebbles of the seed coat are round, long-elliptical, subrectangular, clam-shell or subsquare, radial length of 37~100 μm, bottom width of 36~102 μm, which protrudes from the epidermis layer in a half-moon shape. Semi-circular, subsquare or arched. Starch granules mostly single, subspheroidal, oval, elliptical or rounded; less compound and semi-compound. Catheter is interspersed with epidermal cells and cotyledon cells of the seed coat. Fine calcium oxalate crystals are present in cotyledon cells.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 0.5 g of powdered sample to 10 mL of methanol, ultrasonicate for 15 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 1 mL of methanol.
2. Reference drug solution: Take 0.5 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of amygdalin and dissolve in methanol to produce a solution containing 2.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of dichloromethane, ethyl acetate, methanol, and water (15:40:22:10) as the developing solvent. Apply 5 μL of each of the sample solution and reference drug solution and 2 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 7.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 3.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 0.5% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
1. Amygdalin:
   (1) Mobile phase: Acetonitrile as the mobile phase A and 0.1% phosphoric acid as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of amygdalin and dissolve in 75% methanol to produce a solution containing 0.1 mg per mL.
   (3) Sample solution: Weigh accurately 0.2 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 20 mL of 75% methanol, ultrasonicate for 30 minutes. Centrifuge for 10 minutes, transfer the supernatant to a 50-mL volumetric flask. Repeat the extraction of the residue one more time. Combine the supernatant and make up to volume with 75% methanol, mix well, filter and use the filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (210 nm) and a column packing L1. The column temperature is maintained at

40℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of amygdalin should not be less than 2,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~20	5→18	95→82
20~30	18→95	82→5

(5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Amygdalin (%)=5(r_U/r_S) (C_S) / (W)

r_U: peak area of amygdalin of sample solution

r_S: peak area of amygdalin of reference standard solution

C_S: concentration of amygdalin of reference standard solution (mg/mL)

W: weight of test sample (g) calculated with dried sample.

Storage: Refrigerate or store in a cool and dry place, and protect from insects.
Usage: Purgative medicinal (Laxative medicinal).
Property and flavor: Neutral; pungent, bitter and sweet.
Meridian tropism: Spleen, large intestine, and small intestine meridians.
Effects: Moisten the intestine and relax the bowel, induce diuresis to alleviate edema.
Administration and dosage: 5~12 g.
Precaution and warning: Use cautiously during pregnancy.

PSEUDOSTELLARIAE RADIX
太子參
Tai Zih Shen / Tai Zi Shen
Heterophylly Falsestarwort Root

Heterophylly falsestarwort root is the dried root tuber of *Pseudostellaria heterophylla* (Miq.) Pax (Fam. Caryophyllaceae).
It contains not less than 26.0% of dilute ethanol-soluble extractives and not less than 27.0% of water extractives.

Description: Fusiform or slat-shaped, about 2~6 cm in length, 3~6 mm in diameter. Externally yellowish-white, translucent, with fine longitudinal wrinkles and dented rootlet scars. Root stock obtuse, remained with stem scars, the bottom tapering. Texture fragile, easily broken, fracture pale yellow. Odour slight; taste slightly bitter.

Microscopic identification:

1. **Transverse section:**
Root tuber of *Pseudostellaria heterophylla*: Cork composed of 3~6 rows of subsquare cells. Cortex composed of 5~8 rows of subsquare or polygonal parenchymatous cells, containing starch granules and clusters of calcium oxalate. Vascular bundles radially disposed. Phloem relatively narrow. Cambium in a distinct ring. Xylem broad. Xylem parenchymatous cells with distinct intercellular spaces filled with abundant starch granules, and clusters of calcium oxalate. Vessels individually scattered or grouped in 2~3, arranged radially, mainly spiral and annular, 8~30 μm in diameter. Pith small.
2. **Powder:** Pale yellow. Starch granules mainly in individual, subrounded, with distinct striation and hilum. Vessels mainly spiral and annular, 8~30 μm in diameter, slightly lignified. Clusters of calcium oxalate 50 μm in diameter.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and evaporate the filtrate to dryness, dissolve the residue in 1 mL of methanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-butanol, glacial acetic acid, and water (4:1:1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 1% ninhydrin/EtOH TS and heat at 105℃. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:

1. Loss on drying: Not more than 13.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 4.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:

1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place, and protect from moisture and insects.
Usage: Tonifying and replenishing medicinal (Qi-tonifying medicinal).
Property and flavor: Neutral; sweet and mild bitter.
Meridian tropism: Spleen and lung meridians.
Effects: Greatly tonify the original qi, tonify qi to engender fluid.
Administration and dosage: 9~30 g.

PTERIS MULTIFIDAE HERBA
鳳尾草
Fong Wei Tsao / Feng Wei Cao
Chinese Brake Herb

Chinese brake herb the dried herb of *Pteris multifida* Poir. (Fam. Pteridaceae).
It contains not less than 3.0% of dilute ethanol-soluble extractives and not less than 3.0% of water extractives and not less than 0.01% of rhoifolin

Description: 30~70 cm in high, short rhizomes, erect, densely-lanceolate brown-black scales. One-pinnate compound leaf, pale green or grayish green, clumped; leaf type II, thin paper, glabrous, vegetative leaf blade stalk short and stalked; 10~25 cm in leaf length, Broad ovate, 2~3 pairs of lateral feathers, upper feathers growing downward, wings on both sides, sharp margins on leaf margins; spore leaflets longer and narrower, longer ovate, lower culms, usually two or three differences, The base of the remaining base has a handle, and the bases of the other feathers are extended, and narrow fins are formed on the two sides of the leaf shaft. The fins are tapered at the apex of the fins and have a fine serration to the entire edge; The lateral veins are single or bifurcated; the shape of the sporangia is linear, and the spikes along the edge of the spore surface continue to be born, Odor slight , taste light or slight astringent.

Microscopic identification:
1. **Transverse section:**
   (1) Petiole of *Pteris multifida*: Petiole is trapezoidal. The epidermis consists of 1 row of round cells , slightly thick outer wall. The basic tissue consists of sclerenchyma cells and parenchyma cells; sclerenchyma is located on the outside. It consists of 4~6 sclerenchyma cells; the parenchyma cells are located inside. The outer tough surrounding vascular bundle has a V-shape with an endothelial layer outside.
   (2) Leaf of *Pteris multifida*: The nutrient leaf cross-section, the main vein is raised on the upper side, and the groove is visible. The upper and lower epidermis cells are square and arranged neatly and tightly. Sclerenchyma are visible on the main vein and on the inner side of the epidermis, composed of 3~4 sclerenchyma cells. Palisade tissue of the mesophyll and spongy tissue of the mesophyll are not obvious. , and the cells contain chloroplasts. The main vein is surrounded by a tough vascular bundle, and the xylem is V-shaped. The spore leaves are transversely cut, similar to the nutrient leaves, but slightly larger than the nutrient leaves.
2. **Powder:** Brown. The cork cells are reddish brown cells are subsquare to rectangular. The coarse mesh scales are brown or grayish green, 160~780 μm in length. The glandular hairs are spindle-shaped, apex obtuse, sessile, and cells contain brown secretions. Multicellular non-glandular hairs are 280~350 μm in length. The sporangium is oblong or subround, with a longitudinal cell subrectangular, a pale yellow wall, a thin outer wall, and thickened inner walls and side walls; The cell on the other side of the longitudinal cell is subround, has a thin wall, which is conducive to the spores dispersion. Spore subtriangle, 30~50μm in diameter, with three cracks, the surface has warty or granular protrusions of varying sizes. Most of the dummy pipes are reticulate orscalariform, 15~35 μm in diameter. The tracheid are mostly fusiform or elongated, with a tip that is tapered and often bundled; the color is microscopic under a polarizing microscope.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 1 mL of methanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of rhoifolin and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, acetone, formic acid, and water (6:3:1:1.5) as the developing solvent. Apply 2 μL of each of the sample solution and reference drug solution and 1 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 13.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 14.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 8.0% (General

rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
Rhoifolin:
1. Mobile phase: Acetonitrile as the mobile phase A, and water as the mobile phase B.
2. Reference standard solution: Weigh accurately a quantity of rhoifolin and dissolve in 50% methanol to produce a solution containing 2 μg per mL.
3. Sample solution: Weigh accurately 0.5 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 15 mL of 50% methanol, ultrasonicate for 30 minutes, centrifuge for 15 minutes. Transfer the supernatant to a 50-mL volumetric flask. Repeat the extraction of the residue two more times, combine the supernatant, and make up to volume with 50% methanol, mix well, filter and use the filtrate.
4. Chromatographic system: The liquid chromatography is equipped with an UV detector (337 nm) and a column packing L1. The column temperature is maintained at 35°C. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of rhoifolin should not be less than 2,500.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~5	5→20	95→80
5~30	20→22	80→78

5. Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Rhoifolin (%)=0.005(r_U/r_S) (C_S) / (W)

r_U: peak area of rhoifolin of sample solution
r_S: peak area of rhoifolin of reference standard solution
C_S: concentration of rhoifolin of reference standard solution (μg /mL)
W: weight of test sample (g) calculated with dried sample.

Storage: Store in a cool and dry place, and protect from mold.
Usage: Heat-clearing medicinal (Heat-clearing and detoxicating medicinal).
Property and flavor: Cold; bitter.
Meridian tropism: Liver, kidney, and large intestine meridians.
Effects: Clear heat and detoxicate, cool the blood to hemostatic, drain dampness to alleviate edema.
Administration and dosage: 10~20 g.

PUERARIAE FLOS
葛花
Ge Hua / Ge Hua
Lobed Kudzuvine Flower

Lobed kudzuvine flower the dried flowers and buds of *Pueraria montana* (Lour.) Merr. var. *lobata* (Willd.) Maesen & S.M.Almeida ex Sanjappa & Predeep (*Pueraria lobata* (Willd.)Ohwi) or *Pueraria montana* (Lour.) Merr. var. *thomsonii* (Benth.) M.R.Almeida (*Pueraria thomsonii* Benth.) (Fam. Leguminosae).
It contains not less than 26.0% of dilute ethanol-soluble extractives and not less than 20.0% of water extractives and not less than 1.4% of the total amount of tectoridin and tectorigenin.

Description: Irregular oblate or slightly flat kidney, 0.5 ~1.5 cm in length. Sepals grayish green, and even synthetic cylindrical base, calyx teeth 5 crack tip, lobes lanceolate, connate teeth 2, Both inside and outside are obviously yellowish white and pilose, and there are two lanceolates at the base to form a diamond-shaped bracteoles, sometimes with small pedicels. Petals 5 pieces, nearly equal in length, slightly protruding outside or covered with calyx, pale blue-purple or pale brown, rarely scattered. There are 10 stamens, 9 of which are commissure. The pistil is slender and flat, slightly curved. Odor slightly light.

Microscopic identification:
Powder: Dark brown. The cortical epithelial cells are papillary, 30-44 μm in diameter. Non-glandular hairs, mostly single cells, colorless or yellowish brown, apex tip, about 60~100 μm in length, smooth outer wall. Glandular hairs are rod-shaped, colorless or contain pale yellow contents, multi-cell head, stalk 1~2 cells, many and small. The outer wall cells of the pollen sac are arranged in a fan shape. There are many pollen grains, which are round and have a smooth outer wall with 3 germination holes. There are many crystals of calcium oxalate, ranging from 12.5~37.5 μm, which are bright yellow-white under a polarizing microscope. The catheter is spiral.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, centrifuge, filter the supernatant and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of tectoridin and tectorigenin in methanol to produce a solution containing 0.5 mg per mL of each.

4. Procedure: Use silica gel F_{254} as the coating substance and a solution of dichloromethane, ethyl acetate, methanol, and water (3:8:4:2) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 254 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 12.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 10.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Tectoridin and tectorigenin:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and 0.1% phosphoric acid as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of tectoridin and tectorigenin and dissolve in 50% ethanol to produce a solution containing 40 μg and 50 μg per mL of each.
   (3) Sample solution: Weigh accurately 0.2 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 20 mL of 50% ethanol, ultrasonicate for 30 minutes, centrifuge for 10 minutes. Transfer the supernatant to a 50-mL volumetric flask. Repeat the extraction of the residue one more time, combine the supernatant, and make up to volume with 50% ethanol, mix well, filter and use the filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (263 nm) and a column packing L1. The column temperature is maintained at 35℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of tectoridin and tectorigenin should not be less than 20,000 of each.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~30	10→62	60→38
30~40	62→95	38→5
40~45	95	5

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Tectoridin or tectorigenin (%)=0.005(r_U/r_S) (C_S) / (W)
   r_U: peak area of tectoridin or tectorigenin of sample solution
   r_S: peak area of tectoridin or tectorigenin of reference standard solution
   C_S: concentration of tectoridin or tectorigenin of reference standard solution (μg /mL)
   W: weight of test sample (g) calculated with dried sample.

Storage: Refrigerate or store in a cool and dry place.
Usage: Heat-clearing medicinal (Heat-clearing and fire-purging medicinal).
Property and flavor: Neutral; sweet.
Effects: Curing handover and benefiting spleen, stop thirsting.
Administration and dosage: 3~12 g.

PUERARIAE RADIX
葛根
Ge Gen / Ge Gen
Pueraria Root

Pueraria root is the dried root of *Pueraria montana* (Lour.) Merr. var. *lobata* (Willd.) Maesen & S.M.Almeida ex Sanjappa & Predeep (*Pueraria lobata* (Willd.)Ohwi) (Fam. Leguminosae). It contains not less than 8.0% of dilute ethanol-soluble extractives, not less than 8.0% of water extractives and not less than 2.5% of puerarin.

Description:

1. Root of *Pueraria montana*: Subcylindrical, often in obliquely or longitudinally cut pieces, 5~35 cm in length, 0.5~1 cm thick, whitish or pale brown. The outer bark occasionally remained with brown cork. Fracture yellowish-white, rough, strongly fibrous, with concentric rings formed by fibers and vascular bundles. Texture lax. Odour slight; taste slight.

Microscopic identification:

1. **Transverse section:**
   Puerariae radix: The skin has been removed. If there is a residue, there are stone cells in the cortex. The xylem vessel group and the wood fiber bundle are arranged alternately, vessel diameter up to 300 μm, surrounded by parenchyma cells containing prisms of calcium oxalate (crystal fibres). Rays wide, contain 3~8 layers of cells. parenchyma cells

contain few starch granules.

2. **Powder:** Pale brown, yellowish-white or pale yellow. Starch granules extremely numerous, simple granules spheroidal, semicircular or polygonal, 3~37 μm in diameter, hilum dotted, cleft-shaped or stellate; compound granules composed of 2~10 components. Fibers mostly in bundles, walls thickened and lignified, surrounded by cells mostly containing prisms of calcium oxalate, forming crystal fibers, walls of crystal-containing cells lignified and thickened. Stone cells rare, subrounded or polygonal, 38~70 μm in diameter. Bordered-pitted vessels relatively large, hexagonal or oblong ones arranged extremely dense.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 0.1 g of powdered sample, add 10 mL of 70% ethanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 0.1 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of puerarin and dissolve in methanol to produce a solution containing 0.2 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, methanol, and water (12:2:1) as the developing solvent. Apply 2 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The bluish-white spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 14.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 6.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 400 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 5.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:

1. Puerarin:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and 0.1% formic acid as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of puerarin, and dissolve in 30% ethanol to produce a solution containing 60μg per mL.
   (3) Sample solution: Weigh accurately 0.1 g of the powdered sample. Add accurately 20 mL of 30% ethanol, ultrasonicate for 30 minutes, filter with filter paper. Repeat the extraction of the residue one more time. Combine the filtrate and transfer to 50-mL volumetric flask and make up to volume with 30% ethanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (250 nm) and a column packing L1. The column temperature is maintained at 35℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of puerarin should not be less than 5,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~40	10→35	90→65

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   Puerarin (%)=0.005(r_U/r_S) (C_S) / (W)

   r_U: peak area of puerarin of sample solution

   r_S: peak area of puerarin of reference standard solution

   C_S: concentration of puerarin of reference standard solution (μg /mL)

   W: weight of test sample (g) calculated with dried sample.
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from insects.

Usage: Exterior-releasing medicinal (Pungent-cold exterior-releasing medicinal).

Property and flavor: Cool, sweet and pungent.

Meridian tropism: Spleen and stomach meridians.

Effects: Promote sweating to release the flesh, engender fluid, outthrust rashes, antidiarrheal.

Administration and dosage: 9~15 g.

【Decoction pieces】

PUERARIAE RADIX

It contains not less than 8.0% of dilute ethanol-soluble extractives, not less than 8.0% of water extractives and not less than 2.5% of puerarin.

Raw medicinal materials are processed to remove impurities, clean selection, soften thoroughly, cut into thin slices, and dry, mostly irregular thick slices or cubes. Surface sub-white or pale brown, rough, fibrous, starchy, odour slight, taste slightly sweet.

Thin layer chromatographic identification test: The method is the same as that for crude herb.

Impurities and other requirements: Methods and specifications are the same as those for crude herb.

Assay: The method is the same as that for crude herb.

Storage: The method is the same as that for crude herb.

Usage: Exterior-releasing medicinal (Pungent-cold exterior-releasing medicinal).

Property and flavor: Cool, sweet and pungent.

Meridian tropism: Spleen and stomach meridians.

Effects: Promote sweating to release the flesh, engender fluid, outthrust rashes, andidiarrheal.

Administration and dosage: 9~15 g.

PUERARIAE THOMSONII RADIX
粉葛
Fen Ge/ Fen Ge
Edible Kudzuvine Root

Edible kudzuvine root is the dried root of *Pueraria montana* (Lour.) Merr. var. *thomsonii* (Benth.) M.R.Almeida (*Pueraria thomsonii* Benth.) (Fam. Leguminosae).

It contains not less than 8.0% of dilute ethanol-soluble extractives, not less than 8.0% of water extractives and not less than 0.16% of puerarin.

Description: Cylindrical to subfusiform, 12~15 cm long, 4-8 cm in diameter, some in longitudinally or obliquely cut thick slices, varying in size. Weaker fiber and some are woolly. Heavy, texture hard and starchy, odourless; taste slightly sweetish.

Microscopic identification:

1. **Transverse section:**
   Root of *Pueraria montana*: Vessels relatively small, 76 μm in diameter; less xylem fibers; parenchyma cells of xylem contain numerous starch granules.
2. **Powder:** Colour pale brown, yellowish-white or pale yellow. Numerous starch granules, single round sphere, semicircle or polygon, 3-37 μm in diameter, with hilum dotted, cleft or asteroidal hilum; compound granules composed of 2-10 simple granules. Fibres mostly in bundles, with thickened walls, lignified, surrounded by cells mostly containing prisms of calcium oxalate, forming crystal fibres; crystal cells with lignified and thickened walls. Stone cells infrequently visible, subrounded or polygonal, 38-70 μm in diameter, bordered pitted vessels relatively large, hexagonal or oval, arranged very densely.

Thin layer chromatographic identification test (General rule 1621.3)

1. Sample solution: Add 2.0 g of powdered sample to 10 mL of 70% ethanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 2.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of puerarin and dissolve in methanol to produce a solution containing 0.2 mg per mL.
4. Procedure: Use silica gel F254 as the coating substance and a solution of ethyl acetate, methanol, and water (12: 2: 1) as the developing solvent. Apply 2 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 14.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 6.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 400 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 5.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Puerarin:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and 0.1% formic acid as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of schisandrin A and dissolve in 30% ethanol to produce a solution containing 30 μg per mL.
   (3) Sample solution: Weigh accurately 1.0 g of the powdered sample, add accurately 20 mL of 30% ethanol, ultrasonicate for 30 minutes, filter with filter paper, use the filtrate. Repeat the extraction of the residue one more time. Combine the filtrate, transfer to 50-mL volumetric flask, make up to volume with 30%

ethanol, mix well, filter and use the successive filtrate.

(4) Chromatographic system: The liquid chromatography is equipped with an UV detector (250 nm) and a column packing L1. The column temperature is maintained at 35℃. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of puerarin should not be less than 5,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~40	10→35	90→65

(5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Puerarin (%)=0.005 (r_U/r_S) (C_S) / (W)

r_U: peak area of puerarin of sample solution

r_S: peak area of puerarin of reference standard solution

C_S: concentration of puerarin of reference standard solution (μg/mL)

W: weight of test sample (g) calculated with dried sample.

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011)
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from insects.
Usage: Exterior-releasing medicinal (Pungent-cold exterior-releasing medicinal).
Property and flavor: Pungent and Cool, sweet.
Meridian tropism: Spleen and stomach meridians.
Effects: Promote sweating to release the flesh, engender fluid, outthrust rashes, antidiarrheal.
Administration and dosage: 9~15 g.

PULSATILLAE RADIX
白頭翁
Bai Tou Wong / Bai Tou Weng
Chinese Pulsatilla Root

Chinese pulsatilla root is the dried root of *Pulsatilla chinensis* (Bunge) Regel (Fam. Ranunculaceae).
It contains not less than 4.6% of pulsatilla saponin B_4.

Description: Long cylindrical or conical, slightly curved, occasionally tortuous into slight flat, 5~20 cm in length, 0.4~2 cm in diameter, occasionally 2~3 branches at the middle or lower part. Externally yellowish-brown or brown, relatively rougher, with irregularly and longitudinally wrinkles or furrows, bark easily dehiscent or exfoliated, the exposed wood yellow, some exhibiting longitudinally, protuberant and reticulations, usually with decayed depressed holes near root stock. Root stock slightly swollen, occasionally branched, some showing sheath-like pedicel bases and leaves, with white tomenta. Texture hard and fragile, fracture slightly even, yellowish-white, cracks between bark and wood. Odour slight; taste slightly bitter and astringent.

Microscopic identification:

1. **Transverse section:**
   Root of *Pulsatilla chinensis*: Epidermis, cortex and endodermis usually fallen off. Phloem broad, outer layers of phloem cells brown, with suberized walls; phloem fibers singly scattered or several in bundles, walls relatively thickened, some roots without fibers. Cambium presents in a distinct ring. Xylem rays relatively broad; vessels singly scattered or several in groups; walls of xylem fibers thickened and unlignified. Parenchymatous cells usually present in the center of thick roots.
2. **Powder:** Grayish-yellowish-white. Phloem fibers fusiform, 100~390 μm in length, 16~42 μm in diameter, walls 6~13 μm thick, lignified, occasionally with dense striations, pit canals distinct; few fibers extremely short, stone cell-shaped. Non-glandular hairs unicellular, slender, 13~33 μm in diameter, walls 2~14 μm thick, lignified, a few unlignified, occasionally spiral or double spiral striations present on the surface. Bordered-pitted, reticulate and spiral vessels 10~72 μm in diameter. Suberized cells in subpolygonal with relatively less starch granules, simple granules about 22 μm in diameter, compound granules composed of 2~4 components.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 10 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and the supernatant of *n*-butanol, acetic acid, and water (4:1:2) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with a 10% solution of H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:

1. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
2. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).

3. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
4. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
5. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:

1. Pulsatilla saponin B_4:
   (1) Mobile phase: A solution of methanol and water (64:36). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of pulsatilla saponin B_4 and dissolve in methanol to produce a solution containing 0.4 mg per mL.
   (3) Sample solution: Weigh accurately 0.2 g of powdered sample and place it in a conical flask with a stopper, add 10 mL of methanol, stopper tightly, ultrasonicate for 25 minutes, cool, filter and transfer the filtrate to 25-mL volumetric flask, wash the container and residue with a small quantity of mobile phase, combine the washings to the same volumetric flask, make up to volume with mobile phase, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (201 nm) and a column packing L1. The number of theoretical plates of the peak of pulsatilla saponin B_4 should not be less than 3,000.
   (5) Procedure: Inject accurately 20 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Pulsatilla saponin B_4: (%)= 2.5(r_U/r_S) (C_S) / (W)
   r_U: peak area of pulsatilla saponin B_4 of sample solution
   r_S: peak area of pulsatilla saponin B_4 of reference standard solution
   C_S: concentration of pulsatilla saponin B_4 of reference standard solution (mg/mL)
   W: weight of test sample (g) calculated with dried sample

Storage: Store in a ventilated and dry place.
Usage: Heat-clearing medicinal (Heat-clearing and detoxcating medicinal).
Property and flavor: Cold; bitter.
Meridian tropism: Stomach and large intestine meridians.
Effects: Clear heat and detoxicate, cool the blood and stop dysenter.
Administration and dosage: 9~15 g.

PYROLAE HERBA
鹿銜草
Lu Sian Tsao / Lu Xian Cao
Chinese Pyrola Herb

Chinese pyrola herb is the dried herb of *Pyrola calliantha* Andres or *Pyrola decorata* Andres (Fam. Pyrolaceae).
It contains not less than 7.0% of dilute ethanol-soluble extractives and not less than 4.0% of water extractives and not less than 0.08% of monotropein.

Description: Slender. Stems cylindrical with longitudinal edges. Leaves basal, long ovoid or suborbicular, 2~8 cm in length, brown, entire or sparsely serrate, margin slightly volume.

Microscopic identification:
Transverse section:
Leaf of Pyrolae herba: Upper epidermis is covered with the stratum corneum, the stomata are visible in the epidermis, and the inner epidermis has 1 to 3 collenchymatous cell s. The palisade cells are not obvious, and the spongiocyte are subround, Containing calcium oxalate clusters, the rib are vascular bundles, the xylem is crescent-shaped, the phloem is narrow, and the parenchyma cells contain reddish brown or brownish yellow matter. The catheter is a threspiral vessel.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 1 mL of methanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of monotropein and dissolve in methanol to produce a solution containing 0.5 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, formic acid, and water (4:1:1) as the developing solvent. Apply 2 μL of each of the sample solution and reference drug solution and 1 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 14.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 6.0% (General rule 6007).

3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
Monotropein:
1. Mobile phase: A solution of methanol and 0.1% phosphoric acid (5:95). The ratio may be adjusted, if necessary.
2. Reference standard solution: Weigh accurately a quantity of monotropein and dissolve in water to produce a solution containing 50 μg per mL.
3. Sample solution: Weigh accurately 2.0 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 15 mL of water, ultrasonicate for 30 minutes, filter with filter paper. Repeat the extraction of the residue two more times. Combine the filtrate, transfer the filtrate to a 50-mL volumetric flask and make up to volume with methanol, mix well, filter and use the successive filtrate.
4. Chromatographic system: The liquid chromatography is equipped with an UV detector (235 nm) and a column packing L1. The column temperature is maintained at 35℃. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of monotropein should not be less than 3,000.
5. Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   Monotropein (%)=0.005(r_U/r_S) (C_S) / (W)

   r_U: peak area of monotropein of sample solution

   r_S: peak area of monotropein of reference standard solution

   C_S: concentration of monotropein of reference standard solution (μg/mL)

   W: weight of test sample (g) calculated with dried sample.

Storage: Store in a ventilated and dry place, and protect from moisture.
Usage: Dampness-dispelling medicinal (Wind-dampness-dispelling medicinal).
Property and flavor: Warm; sweet and bitter.
Meridian tropism: Liver and kidney meridians.
Effects: Tonify deficiency and replenish kidney, strengthen sinew and bone, dispel wind and eliminate dampness, invigorate blood to regulate menstruation, suppress cough and hemostatic.
Administration and dosage: 9~20 g.

PYRROSIAE FOLIUM
石韋
Shih Wei / Shi Wei
Pyrrosia Leaf

Pyrrosia leaf is the dried leaf of *Pyrrosia sheareri* (Baker) Ching, *Pyrrosia lingua* (Thunb.) Farw. or *Pyrrosia petiolosa* (Christ) Ching (Fam. Polypodiaceae).
It contains not less than 0.2% of chlorogenic acid.

Description:
1. Leaf of *Pyrrosia sheareri*: Fronds slightly crumpled, lanceolate as whole, 10~25 cm in length, 3~5 cm in width, apex acuminate, base auriculate oblique, margin entire, edges usually rolled inwards. Upper surface yellowish-green or grayish-green, sparsely black rounded pits; lower surface densely covered with reddish-brown stellate hairs, occasionally the area between the lateral veins completely covered with brown round spotted sori. Stipes with 4 ribs, 10~20 cm in length, 1.5~3 mm in diameter, slightly twisted, grooved longitudinally. Fronds coriaceous. Odour slight; taste slightly astringent and bitter.
2. Leaf of *Pyrrosia lingua*: Fronds lanceolate or oblong-lanceolate, 8~12 cm in length, 1~3 cm in width, base cuneate and symmetrical. Sori closely and regularly arranged between the lateral veins. Stipes 5~10 cm in length, about 1.5 mm in diameter.
3. Leaf of *Pyrrosia petiolosa*: Fronds mostly rolled into a quill, oblong or ovate-oblong as whole, 3~8 cm in length, 1~2.5 cm in width, base cuneate and symmetrical. Lower surface with indistinct lateral veins and completely covered with sori. Stipes 3~12 cm in length, about 1 mm in diameter.

Microscopic identification:
1. **Transverse section:**

   Pyrrosiae Folium: Epidermis composed of 1 row of pale brown cells, cells square, subsquare or subrounded, covered with cuticle. Sclerenchyma underneath epidermis, composed of about 10 layers of cells, arranged in a ring. Phloem fibers of cortex 5~8 layered, lignified, yellowish-brown, cells subrounded, subsquare, subovate or subpolygonal. Cortex subrounded, suboblong, subovate, subrectangular or subpolygonal, with distinct intercellular spaces. The same size of 2 ovoid and large vascular bundles scattered among cortex, amphicribral, surrounded by endodermis containing heteromorphic stone cells; 6~7 ovoid and small vascular bundles, amphicribral, also surrounded by endodermis containing heteromorphic stone cells. The heteromorphic stone cells subovoid with inner walls thickened and outer walls thinned, extremely lignified, red to yellowish-brown. Vascular bundles amphicribral, composed of phloem parenchymatous cells, vessels and fibers; phloem parenchymatous cells subrounded, subovate or subovoid, with outer cells slightly larger and inner cells relatively small;

xylem composed of vessels and fibers, arranged in slightly U shape, 7~45 μm in diameter.

2. **Powder:** Yellowish-brown. Sporangia ovoid with stalk, red to yellowish-brown, lignified, subrectangular or subsquare in longitudinal view, lateral and inner walls thickened, outer walls thinned; flat-rectangular in surface view, 36~80 μm in length, 28~35 μm in diameter, central part relatively thick, marginal part thin. Spores numerous, elliptical in sectional view, subrounded or bean-shaped in longitudinal view, 36~48 μm in size, 50~80 μm in length, clefts about the half size of spores, outer walls 2~3 μm thick with warty protuberance. Stellate hairs numerous, extremely large, pale yellowish-brown, accompanying with 5~9 hair cells varying in length, radially arranged in upper and lower layers, cells lanceolate, 160~290 μm in length, 25~70 μm in diameter. Upper epidermal cells of leaf subpolygonal or subrectangular in surface view, anticlinal walls slightly thickened, covered with yellowish-brown non-glandular hairs, easily broken, reticulate scars at base. Lower epidermal cells of leaf subpolygonal or subrectangular in surface view, anticlinal walls relatively thinned; stomata numerous, subrounded, 30~40 μm in diameter, with 3~6 subsidiary cells. Epidermal cells of stipe flat-rectangular or subrectangular in longitudinal view, occasionally with subrounded stomata. Heteromorphic stone cells accompany with endodermis, pale red to dark red, 20~75 μm in diameter, with distinct pits. Fibers long, mostly in bundles, pale yellow, slightly lignified.

Identification:
Check flavonoid: Take 5.0 g of powdered sample in a Soxhlet extractor, reflux and extract with methanol, place 2 mL of extract in a test tube, add a few magnesium powder, add 1~2 drops of hydrochloric acid, except *Pyrrosia petiolosa*, a pink color is produced along the test tube wall for *Pyrrosia sheareri* and *Pyrrosia lingua*.

Impurities and other requirements:
1. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
2. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
3. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
4. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
5. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:
Chlorogenic acid:
1. Mobile phase: A solution of acetonitrile and 0.5% phosphoric acid solution (11:89). The ratio may be adjusted, if necessary.
2. Reference standard solution: Weigh accurately a quantity of chlorogenic acid, transfer to an amber volumetric flask, and dissolve in 50% methanol to produce a solution containing 40 μg per mL.
3. Sample solution: Weigh accurately 0.2 g of powdered sample and place it in a conical flask with a stopper, add accurately 25 mL of 50% methanol, weigh, ultrasonicate for 45 minutes, cool, weigh again, replenish the loss of the weight with 50% methanol, mix well, filter and use the successive filtrate.
4. Chromatographic system: The liquid chromatography is equipped with an UV detector (326 nm) and a column packing L1. The number of theoretical plates of the peak of chlorogenic acid should not be less than 2,000.
5. Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Chlorogenic acid: (%)= 0.0025(r_U/r_S) (C_S) / (W)

r_U: peak area of chlorogenic acid of sample solution

r_S: peak area of chlorogenic acid of reference standard solution

C_S: concentration of chlorogenic acid of reference standard solution (μg/mL)

W: weight of test sample (g) calculated with dried sample.

Storage: Store in a ventilated and dry place, and protect from moisture and color changing.
Usage: Dampness-dispelling medicinal (Dampness-draining diuretic medicinal).
Property and flavor: Mild cold; sweet and bitter.
Meridian tropism: Lung, and bladder meridians.
Effects: Induce diuresis and relieve strangury, clear heat and hemostatic.
Administration and dosage: 6~12 g.

QUISQUALIS FRUCTUS
使君子
Shih Jyun Zih / Shi Jun Zi
Rangooncreeper Fruit

Rangooncreeper fruit is the dried ripe fruit of *Quisqualis indica* L. (Fam. Combretaceae).
It contains not less than 6.0% of water extractives of the dried ripe fruit and not less than 0.2% of trigonelline of the seed.

Description: Fruit ellipsoidal or ovate, attenuate at the both ends, 5-ribbed in longitudinally, occasionally 4 to 9-ribbed, 2.5~4 cm in length, 1.5~1.8 cm in diameter. Externally purplish-brown or blackish-brown, smooth, slightly lustrous. Apex narrowly acute, base slight obtuse rounded, with a distinct rounded scar of fruit stalk. Texture hard and light. Seed long-ellipsoidal, 1~2 cm in length; externally blackish-brown, with longitudinal wrinkles and

furrows; testa thin, easily stripped; cotyledons 2, thick, greenish-yellow. Odour slightly aromatic; taste slightly sweet.

Microscopic identification:

1. **Transverse section:**
   Fruit of *Quisqualis indica*: Epidermis of pericarp composed of 1 layer of cells, cells varying in shape, walls slightly thickened, covered with cuticle, lumen filled with yellowish-brown resin-like contents. Mesocarp composed of flaky and lignified reticulate fiber groups, scattered with parenchymatous cells, cells containing brown secretions. Epidermis of testa thin-walled, subrectangular, containing reddish-brown masses; inside showing reticulate layer, cells tangentially elongated, with reticulate striations, usually scattered with vascular bundles. Cotyledon cells contain fatty oil droplets and clusters of calcium oxalate.
2. **Powder:** Brown. Fibers mostly in bundles, some cross-overlapping, 10~20 μm in diameter, walls 3~18 μm thick, lignified, with relatively dense pit canals. Lignified cells mostly fusiform, acute, obtusely rounded or truncate at the end, some with one end expended and branched, 66~442 μm in length, 20~39 μm in diameter, walls 3~13 μm thick, lignified, with dense pit canals, some lumina contain yellowish-brown contents; other lignified cells subrectangular, up to about 440 μm in length, 36~65 μm in diameter, walls slightly thickened and lignified, pits mostly cruciate. Reticulate cells of testa subrounded or elliptical, 14~43 μm in diameter, walls slightly thickened and unlignified, with dense subpolygonal reticulate pits. Epidermal cells of testa subrectangular or subpolygonal in surface view, lumen containing reddish-brown masses. Cotyledon cells contain fatty oil droplets, some containing clusters of calcium oxalate, 3~11 μm in diameter.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 20 mL of ethyl ether, ultrasonicate for 10 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 2 mL of ethyl acetate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of petroleum ether (30~60°C) and ethyl acetate (4:1) as the developing solvent. Apply 1~2 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with-10% H_2SO_4/EtOH TS and heat at 105°C until the spots become visible. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:

1. Loss on drying: Not more than 15.0% dry at 105°C for 5 hours (General rule 6015).
2. Total ash: Not more than 12.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 4.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)
9. Aflatoxins
   (1) Aflatoxins (sum of B_1, B_2, G_1 and G_2): Not more than 10.0 ppb (General rule 6307).
   (2) Aflatoxin B_1: Not more than 5.0 ppb (General rule 6307).

Assay:

1. Trigonelline:
   (1) Mobile phase: A solution of acetonitrile and water (80:20). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of trigonelline and dissolve in 50% methanol to produce a solution containing 0.1 mg per mL.
   (3) Sample solution: Weigh accurately 0.5 g of powdered sample and place it in a conical flask with a stopper, add accurately 20 mL of 50% methanol, weigh, ultrasonicate for 30 minutes, cool, weigh again, replenish the loss of weight with 50% methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (265 nm) and a column packing L18. The number of theoretical plates of the peak of trigonelline should not be less than 4,000.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Trigonelline (%)==2(r_U/r_S) (C_S) / (W)
   r_U: peak area of trigonelline of sample solution
   r_S: peak area of trigonelline of reference standard solution
   C_S: concentration of trigonelline of reference standard solution (mg/mL)
   W: weight of test sample (g) calculated with dried sample

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).

Storage: Store in a ventilated and dry place, and protect from moisture and insects.
Usage: Worm-expelling medicinal.
Property and flavor: Warm; sweet.
Meridian tropism: Spleen and stomach meridians.
Effects: Kill worms and disperse accumulation.
Administration and dosage: 5~10 g.
Precaution and warning: Taking too much immature fruits can cause hiccups.

RAPHANI SEMEN
萊菔子
Lai Fu Zih / Lai Fu Zi
Radish Seed

Radish seed is the dried ripe seed of *Raphanus sativus* L. (Fam. Cruciferae).
It contains not less than 13.0% of dilute ethanol-soluble extractives and, less than 16.0% of water extractives and not less than 0.4% of sinapine thiocyanate.

Description: Subglobular or subovate, slightly flattened, about 0.3~0.6 cm in length, 0.25~0.3 cm in width. Externally smooth, yellowish-brown, with several longitudinal furrows on one side and a brown, protuberant and dotted hilum at one end. Texture hard, kernel yellowish-white, slightly fleshy, and oily. Odour slight; taste slightly pungent.

Microscopic identification:
1. **Transverse section:**
   Seed of *Raphanus sativus*: The outermost layer was 1 layer of epidermal cells, hypodermis composed of 1 layer of half-moon shaped giant cells with thin walls; inside showing 1 layer of reddish-brown palisade cells, lignified, about 11 μm in width, 10~20 μm in height; inside showing pigment layer, containing reddish-brown contents. Endosperm cells 1 row, flattened. Cotyledon and radical cells contain aleurone grains and fatty oil.
2. **Powder:** Yellowish-brown. Palisade cells of testa flaky, reddish-brown, subpolygonal. Endosperm cells flattened, containing aleurone grains and fatty oil droplets.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 5 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of sinapine thiocyanate and dissolve in methanol to produce a solution containing 0.5 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and the upper layer of a solution of ethyl acetate, formic acid, and water (10:2:3) as the developing solvent. Apply 2 μL of each of the sample solution and reference drug solution and 1 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 8.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 8.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 4.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:
1. Sinapine thiocyanate:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and 0.1% phosphoric acid as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of sinapine thiocyanate, and dissolve in water to produce a stock solution containing 1.0 mg per mL and dissolve in 75% ethanol to produce a solution containing 0.2 mg per mL.
   (3) Sample solution: Weigh accurately 1.0 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 25 mL of 75% ethanol, ultrasonicate for 30 minutes, filter with filter paper. Repeat the extraction of the residue one more time. Combine the filtrate and evaporate to a small amount, transfer to 25-mL volumetric flask and make up to volume with 75% ethanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (326 nm) and a column packing L1. The column temperature is maintained at 35℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The ratio may be adjusted,

if necessary. The number of theoretical plates of the peak of sinapine thiocyanate should not be less than 10,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~28	5→15	95→85
28~60	15→65	85→35

(5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Sinapine thiocyanate (%)=2.5 (r_U/r_S) (C_S) / (W)

r_U: peak area of sinapine thiocyanate of sample solution

r_S: peak area of sinapine thiocyanate of reference standard solution

C_S: concentration of sinapine thiocyanate of reference standard solution (mg/mL)

W: weight of test sample (g) calculated with dried sample.

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a ventilated and dry place, and protect from mold and insects.
Usage: Disgestant medicinal.
Property and flavor: Neutral; pungent and sweet.
Meridian tropism: Lung, spleen, and stomach meridians.
Effects: Promote digestion, resolve flatulent, direct qi downward, stabilize panting, resolve phlegm.
Administration and dosage: 4.5~12 g.

REHMANNIAE RADIX
地黃
Di Huang / Di Huang
Rehmannia Root

Rehmannia root is the dried root tuber of *Rehmannia glutinosa* Libosch. (Fam. Scrophulariaceae). Dried ones commonly known as "Sheng Di Huang (dried rehmannia root tuber)".
Sheng Di Huang contains not less than 60.0% of dilute ethanol-soluble extractives, not less than 60.0% of water extractives, not less than 0.20% of catalpol and not less than 0.02% of verbascoside.

Description: Irregular masses or oblong, swollen in the center, slightly tapering at both ends, 6~12 cm in length, 3~6 cm in diameter. Some small, slat-shaped, slightly compressed or twisted. Externally grayish-black or grayish-brown, extremely shrunken, with irregular transverse wavy lines. Texture heavy, soft and tenacious, uneasily broken, fracture grayish-black, brownish-black or jet-black, lustrous, viscous. Odourless; taste slightly sweet.

Microscopic identification:

1. **Transverse section:**
Root tuber of *Rehmannia glutinosa*: Cork composed of several layers of tangential extension cells. In the cortex, parenchymatous cells arranged loosely; scattered with many secretory cells, have oil contents (oil contents is orange-yellow or orange-red). Phloem is wider and contains much less quantity of secretory cells. Cambium present in a ring. Xylem rays relatively broad; vessels arranged sparsely, single scattered or several together, arranged radially.
2. **Powder:** Brownish-yellow. Cork cells generally brownish-black. Parenchymatous cells usually contain brown and subrounded nucleiform contents, occasionally prisms of calcium oxalate present. Secretory cells contain orange-yellow oil droplets or orange-yellow granules. Vessels reticulated and bordered-pitted.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 50 mL of 80% methanol, ultrasonicate for 30 minutes, filter, evaporate the filtrate to dryness, dissolve the residue in 5 mL of water, extract shaking for four times each with 10 mL of *n*-butanol saturated with water, combine the *n*-butanol extracts, evaporate to dryness, dissolve the residue in 2 mL of methanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of verbascoside and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, methanol, and formic acid (16:0.5:2) as the developing solvent. Apply 5 μL of each of the sample solution and reference drug solution and 2 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with *p*-anisaldehyde/H_2SO_4 TS and heat at 105°C until the spots become visible. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Total ash: Not more than 6.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 2.5% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).

4. Arsenic (As): Not more than 5.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:

1. Catalpol:
   (1) Mobile phase: A solution of acetonitrile and 0.1% phosphoric acid (1:99). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of catalpol and dissolve in mobile phase to produce a solution containing 30 μg per mL.
   (3) Sample solution: Cut a quantity of Sheng Dihuang into small pieces (about 5 mm), dry under reduced pressure at 80℃ for 24 hours and grind into coarse powder. Weigh accurately 0.8 g of the powdered sample and place it in a conical flask with a stopper, add accurately 50 mL of methanol and weigh. Heat under reflux for 1.5 hours, cool and weigh again, replenish the loss of weight with methanol, mix well and filter. Evaporate accurately 10 mL of the successive filtrate nearly to dryness, dissolve the residue in the mobile phase, transfer to a 10-mL volumetric flask, make up to volume with mobile phase, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (210 nm) and a column packing L1. The number of theoretical plates of the peak of catalpol should not be less than 5,000.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   Catalpol: (%)= 0.005(r_U/r_S) (C_S) / (W)

   r_U: peak area of catalpol of sample solution
   r_S: peak area of catalpol of reference standard solution
   C_S: concentration of catalpol of reference standard solution (μg/mL)
   W: weight of test sample (g) calculated with dried sample
2. Verbascoside:
   (1) Mobile phase: A solution of acetonitrile and 0.1% acetic acid (16:84). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of verbascoside and dissolve in mobile phase to produce a solution containing 10 μg per mL.
   (3) Sample solution: Weigh accurately 20 mL of the successive filtrate obtained from the sample solution prepared for the assay test of catalpol, evaporate to dryness under reduced pressure. Dissolve the residue in mobile phase and transfer to a 5-mL volumetric flask, make up to volume with mobile phase, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (334 nm) and a column packing L1. The number of theoretical plates of the peak of verbascoside should not be less than 5,000.
   (5) Procedure: Inject accurately 20 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   Verbascoside: (%)= 0.00125(r_U/r_S) (C_S) / (W)

   r_U: peak area of verbascoside of sample solution
   r_S: peak area of verbascoside of reference standard solution
   C_S: concentration of verbascoside of reference standard solution (μg/mL)
   W: weight of test sample (g) calculated with dried sample.
3. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
4. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from mold and insects.
Usage: Heat-clearing medicinal (Heat-clearing and blood-cooling medicinal).
Property and flavor: Cold sweet and bitter.
Meridian tropism: Heart, liver, kidney, and small intestine meridians.
Effects: Clear heat and generate fluid, cool the blood, hemostatic.
Administration and dosage: 9~30 g.
Precaution and warning: Used with caution in spleen deficiency and diarrhea.

REYNOUTRIAE MULTIFLORAE CAULIS
首烏藤
Shou Wu Teng / Shou Wu Teng
Fleeceflower Stem

Fleeceflower stem is the dried lianoid stem of *Reynoutria multiflora* (Thunb.) Moldenke (*Polygonum multiflorum* Thunb.) (Fam. Polygonaceae).
It contains not less than 13.0% of dilute ethanol-soluble extractives, not less than 7.0% of water extractives and not less than 0.2% of 2,3,5,4'-tetrahydroxystilbene-2-*O*-*β*-D-glucoside.

Description: Long cylindrical, frequently twisted, occasionally branched, 0.4~0.7 cm in diameter. Externally

purplish-brown, slightly rough, with twisted longitudinal wrinkles and nodes. Nodes swollen, with scars of lateral branches. Cork thin and easily exfoliated to scaly. Texture hard and fragile, easily broken, fracture even, bark reddish-brown, wood pale yellow, vessel pores and ray distinct, pith loose and whitish. Odour slight; taste slightly bitter and astringent.

Microscopic identification:

1. **Transverse section:**
   Lianoid stem of *Reynoutria multiflora*: Outermost layer composed of 3~4 rows of cork cells, containing reddish-brown contents. Cortex relatively narrow, cells irregular in shape, containing yellowish-brown contents and clusters of calcium oxalate. Pericycle fiber bundles arranged in an interrupted ring, walls of fibers relatively thickened and lignified, lumen large, stone cell groups present among the fiber bundles. Phloem relatively broad, cells irregular in shape, arranged densely. Cambium in a ring. Xylem vessels subrounded, singly scattered or 2 in groups, mostly bordered-pitted. Pith relatively small, parenchymatous cells of pith usually hollow, containing clusters of calcium oxalate.
2. **Powder:** Reddish-brown. Cork cells subsquare, containing reddish-brown contents. Cortex cells irregular in shape, containing yellowish-brown contents and clusters of calcium oxalate, clusters 35~60 μm in diameter. Fiber bundles flaky, 5~10 μm in diameter, with walls thickened and lignified. Vessels bordered-pitted, 20~110 μm in diameter.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of ethanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of 2,3,5,4'-tetrahydroxystilbene-2-*O*-*β*-D-glucoside and dissolve in ethanol to produce a solution containing 0.1 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of dichloromethane, ethanol, and glacial acetic acid (10:5:0.4) as the developing solvent. Apply 5 μL of each of the sample solution and reference drug solution and 1 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 11.0% dry at 105°C for 5 hours (General rule 6015).
2. Total ash: Not more than 10.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 5.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:

1. 2,3,5,4'-Tetrahydroxystilbene-2-*O*-*β*-D-glucoside:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and 0.5% formic acid as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of 2,3,5,4'-tetrahydroxystilbene-2-*O*-*β*-D-glucoside, and dissolve in methanol to produce a solution containing 10 μg per mL.
   (3) Sample solution: Weigh accurately 0.2 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 20 mL of 75% methanol, ultrasonicate for 30 minutes. Centrifuge for 10 minutes, transfer the supernatant to a 50-mL volumetric flask. Repeat the extraction of the residue one more time. Combine the supernatant and make up to volume with 75% methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (290 nm) and a a column packing L1. The column temperature is maintained at 35°C. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of 2,3,5,4'-tetrahydroxystilbene-2-*O*-*β*-D-glucoside should not be less than 8,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~18	17	83
18~30	17→35	83→65
30~40	35	65
40~50	35→95	65→5
50~60	95	5

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample

solution into the liquid chromatography apparatus, and calculate the content.

2,3,5,4'-Tetrahydroxystilbene-2-*O*-*β*-D-glucoside (%)=0.005(r_U/r_S) (C_S) / (W)

r_U: peak area of 2,3,5,4'-tetrahydroxy-stilbene-2-*O*-*β*-D- glucoside of sample solution

r_S: peak area of 2,3,5,4'-tetrahydroxy-stilbene-2-*O*-*β*-D- glucoside of reference standard solution

C_S: concentration of 2,3,5,4'-tetrahydroxy-stilbene-2-*O*-*β*-D- glucoside of reference standard solution (μg/mL)

W: weight of test sample (g) calculated with dried sample.

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place.
Usage: Tranquillizing medicinal (Heart-nourishing tranquillizing medicinal).
Property and flavor: Neutral; sweet.
Meridian tropism: Heart and liver meridians.
Effects: Nourish the heart to tranquilize, dispel wind tofree collateral vessels.
Administration and dosage: 9~15 g.

REYNOUTRIAE MULTIFLORAE RADIX
何首烏
He Shou Wu / He Shou Wu
Fleeceflower Root

Fleeceflower Root tuber is the dried root tuber of *Reynoutria multiflora* (Thunb.) Moldenke (*Polygonum multiflorum* Thunb.) (Fam. Polygonaceae).
It contains not less than 20.0% of dilute ethanol-soluble extractives, not less than 20.0% of water extractives and not less than 1.0% of 2,3,5,4'-tetrahydroxystilbene-2-*O*-*β*-D-glucoside.

Description: Irregular fusiform or in masses, 6.5~15 cm in length, 4~12 cm in diameter. Externally reddish-brown, lumpy, with irregular wrinkles and in longitudinal furrows, lenticels transverse, with distinct rootlet scars at both ends and fibrous vascular bundles. Texture compact, uneasily broken, fracture pale reddish-brown, starchy, bark scattered with 4~11 abnormal vascular bundles, forming brocaded patterns, cambium ring in central part distinctly, some containing a woody core. Odour slight; taste slightly bitter and astringent.

Microscopic identification:

1. **Transverse section:**
   (1) Root tuber of *Reynoutria multiflora*: Cork composed of several layers of cells filled with reddish-brown contents. The outer part of phloem surrounded by 2 types of allotype vascular bundles, single or compound, both collateral. The central cambium in a ring, vessels relatively less, surrounded by tracheids and a few xylem fibers, primary xylem existed in the center. Parenchymatous cells contain starch granules and clusters of calcium oxalate.
   (2) **Powder:** Yellowish-brown. Starch granules numerous, simple granules spheroidal or hemispheroidal, 5~27 μm in diameter, hilum cleft-shaped or stellated, striations indistinct; compound granules composed of 2~9 components. Clusters of calcium oxalate numerous, 10~110 μm in diameter. Bordered-pitted vessels vary in size, occasionally xylem fibers present.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of 2,3,5,4'-tetrahydroxystilbene-2-*O*-*β*-D-gluco-side and dissolve in methanol to produce a solution containing 0.1 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of toluene, ethanol, and glacial acetic acid (6:3:1) as the developing solvent. Apply 2 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 10.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 4.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 5.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:

1. 2,3,5,4'-Tetrahydroxystilbene-2-*O*-*β*-D-glucoside:
   (1) Mobile phase: A solution of acetonitrile and 0.1% formic acid (17:83). The ratio varies as required
   (2) Reference standard solution: Weigh accurately a quantity of 2,3,5,4'- tetrahydroxy stilbene-2-*O*-*β*-D-glucoside and dissolve in 50% ethanol to produce a solution containing 40 μg per mL.
   (3) Sample solution: Weigh accurately 0.2 g of the powdered sample and placeit it in a 50-mL centrifuge tube, add 20 mL of 50% ethanol, ultrasonicate for 30 minutes, filter with filter paper, use the filtrate. Repeat the extraction of the residue one more time, combine the filtrate, transfer to 50-mL volumetric flask, make up to volume with 50% ethanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (290 nm) and a column packing L1. The column temperature is maintained at room temperature. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of 2,3,5,4'-tetrahydroxystilbene-2-*O*-*β*-D-glucoside should not be less than 5,000.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   2,3,5,4'-Tetrahydroxystilbene-2-*O*-*β*-D-glucoside(%)=0.005(r_U/r_S) (C_S) / (W)
   r_U: peak area of 2,3,5,4'-tetrahydroxystilbene -2-*O*-*β*-D-glucoside of sample solution
   r_S: peak area of 2,3,5,4'-tetrahydroxystilbene -2-*O*-*β*-D-glucoside of reference standard solution
   C_S: concentration of 2,3,5,4'-tetrahydroxy-stilbene-2-*O*-*β*-D-glucoside of reference standard solution (μg/mL)
   W: weight of test sample (g) calculated with dried sample.
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from insects.
Usage: Tonifying and replenishing medicinal (Blood-tonifying medicinal).
Property and flavor: Mild warm; bitter, sweet and astringent.
Meridian tropism: Liver and kidney meridians.
Effects: Tonify qi and enriching blood, interrupt malaria, detoxicate, moisten the intestine and relax the bowels.
Administration and dosage: 3~6 g.

【Decoction pieces】

REYNOUTRIAE MULTIFLORAE RADIX

It contains not less than 20.0% of dilute ethanol-soluble extractives, not less than 20.0% of water extractives and not less than 1.0% of 2,3,5,4'-Tetrahydroxystilbene-2-*O*-*β*-D-glucoside.
Raw medicinal materials are processed to remove impurities, clean selection, soak briefly, soften thoroughly, cut into thin slices, and dry, mostly irregular thick slices, partly cut into pieces, externally dark brown to reddish-brown, cut surface pale yellowish-brown to pale reddish-brown, starchy and brocaded pattern, texture hard and not easy to broken, odour slight; taste slightly, sweet and astringent.

Thin layer chromatographic identification test: The method is the same as that for crude herb.
Impurities and other requirements: Methods and specifications are the same as those for crude herb.
Assay: The method is the same as that for crude herb.
Storage: The method is the same as that for crude herb.
Usage: Tonifying and replenishing medicinal (Blood-tonifying medicinal).
Property and flavor: Mild warm; bitter, sweet and astringent.
Meridian tropism: Liver and kidney meridians.
Effects: Tonify qi and essence blood, interrupt malaria, detoxicate, moisten the intestine and relax the bowel.
Administration and dosage: 3~6 g.

REYNOUTRIAE RHIZOMA ET RADIX
虎杖
Hu Jhang / Hu Zhang
Giant Knotweed Rhizome and Root

Giant knotweed rhizome and root is the dried rhizome and root of *Reynoutria japonica* Houtt. (*Polygonum cuspidatum* Siebold & Zucc.) (Fam. Polygonaceae).
It contains not less than 20.0% of dilute ethanol-soluble extractives, not less than 12.0% of water extractives, not less than 0.6% of emodin and not less than 0.8% of polydatin.

Description: Cylindrical or irregular thick slices, varying in length, about 1~7 cm in length, 0.5~2.5 cm in diameter. Externally brown, with distinct longitudinal wrinkles, rootlet, rootlet scars and nodes. Texture hard, uneasily broken, fracture brownish-yellow, with pith or hollow, fibrous, bark thin, radial, and easily separated from wood. Odour slight; taste slightly bitter and astringent.

Microscopic identification:

1. **Transverse section:**
   Rhizome of *Reynoutria japonica*: Outermost layer of cork composed of 5~10 rows of flat cells, brownish-red. Cortex relatively narrow, cortex and phloem all scattered with fiber bundles and clusters of calcium

oxalate. Cambium in a ring. Xylem cells all lignified, containing xylem fibers, vessels relatively small, subpolygonal, several in a bundle or singly scattered in xylem fibers and xylem parenchymatous cells. Pith cells easily broken. Parenchymatous cells contain starch granules and clusters of calcium oxalate.

2. **Powder:** Yellowish-brown. Clusters of calcium oxalate extremely abundant, about 30~80 μm in diameter. Starch granules numerous, simple or compound granules composed of 4 components. Vessels bordered-pitted, mainly annular and reticulate, about 30~34 μm in diameter. Xylem rays with cell walls lignified and thickened, cells subrectangular, with dense pits.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Sample solution: Add 0.2 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 0.2 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of emodin, physcion and polydatin in methanol to produce a solution containing 1.0 mg per mL of each.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of dichloromethane, acetone, acetic acid, and water (4:4:0.5:0.2) as the developing solvent. Apply 4 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 12.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 5.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:

1. Emodin:
   (1) Mobile phase: A solution of methanol and 0.1% phosphoric acid (80:20). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of emodin and dissolve in methanol to produce a solution containing 50 μg per mL.
   (3) Sample solution: Weigh accurately 0.1 g of powdered sample and place it in a conical flask with a stopper, add accurately 25 mL of methylene chloride and 20 mL of sulfuric acid (2.5 mol/L), and weigh. Heat under reflux at 80℃ for 2 hours, cool to room temperature, weigh again, replenish the loss of weight with methylene chloride, mix well. Separate the methylene chloride layer and evaporate accurately 10 mL to dryness. Dissolve the residue in methanol, transfer to a 10-mL volumetric flask, make up to volume with methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (254 nm) and a column packing L1. The column temperature is maintained at 25℃. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of emodin should not be less than 3,000.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Emodin (%)=0.00025(r_U/r_S) (C_S) / (W)
   r_U: peak area of emodin of sample solution
   r_S: peak area of emodin of reference standard solution
   C_S: concentration of emodin of reference standard solution (μg/mL)
   W: weight of test sample (g) calculated with dried sample.
2. Polydatin:
   (1) Mobile phase: A solution of acetonitrile and water (23:77). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of polydatin and dissolve in 50% ethanol to produce a solution containing 50 μg per mL.
   (3) Sample solution: Weigh accurately 0.1 g of powdered sample, add accurately 25 mL of 50% ethanol, and weigh. Heat under reflux for 30 minutes, cool to room temperature, weigh again, replenish the loss of weight with 50% ethanol, mix well, filter the supernatant, and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (306 nm) and a column packing L1.

The column temperature is maintained at 25℃. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of polydatin should not be less than 3,000.

(5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Polydatin (%)=0.0025(r_U/r_S) (C_S) / (W)

r_U: peak area of polydatin of sample solution

r_S: peak area of polydatin of reference standard solution

C_S: concentration of polydatin of reference standard solution (μg/mL)

W: weight of test sample (g) calculated with dried sample.

3. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
4. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from mold and insects.
Usage: Blood-regulating medicinal (Blood-activating and stasis-dispelling medicinal).
Property and flavor: Mild cold; mild bitter.
Meridian tropism: Liver, kidney, and lung gallbladder meridians.
Effects: Eliminate dampness and antiicteric, clear heat and detoxicate, dissipate stasis to relive pain, resolve phlegm to suppress cough.
Administration and dosage: 9~20 g.
Precaution and warning: Use cautiously during pregnancy.

RHAPONTICI RADIX
漏蘆
Lou Lu / Lou Lu
Uniflower Swisscentaury Root

Uniflower swisscentaury root is the dried root of *Rhaponticum uniflorum* (L.) DC. (Fam. Compositae).
It contains not less than 2.0% of dilute ethanol-soluble extractives, not less than 5.0% of water extractives and not less than 0.08% of *β*-ecdysterone.
Description: Conical or flatted lumps, slightly twisted, usually unbranched, 1~2.5 cm in diameter. Externally dark brown, grayish-brown or blackish-brown, rough, with irregular longitudinal furrows and rhombic and reticulate clefts. Outer bark easily exfoliated. Root stock swollen, with the remains of stems and scaly leaf bases, top with grayish-white pubescences. Texture light and fragile, easily broken. Bark with deep color, wood yellowish-white, arranged radially, ray mostly broken, center with star-shape and brown cleft. Odour characteristic; taste slightly bitter.

Microscopic identification:

1. **Transverse section:**
Root of *Rhaponticum uniflorum*: Epidermis usually fallen off, metaderm composed of several to 20 or more layers of brown cells, walls slightly thickened, lignified or suberized, elongated-rounded resin canals of fine roots arranged slightly in a ring. Phloem relatively broad, rays wide, phloem bundles and rays scattered with numerous oil cavities. Cambium in a ring. Xylem vessels abundant, arranged in multistrand type, the large vessel groups alternated with the small vessel groups, rays often with radial clefts, occasionally stellate clefts at center surrounded by suberized cells. Parenchyma tissue scattered with oil cavities, surrounded by secretory cells containing yellowish-brown secretions.
2. **Powder:** Brown. Reticulate and bordered-pitted vessels numerous, about 133 μm in diameter. Secretory canals long strip-shaped, 24~68 μm in diameter, containing reddish-brown secretions. Non-glandular hairs of root heads extremely long, lignified, 0.5~4 mm in length, 20~30 μm in diameter. Metaderm cells subsquare or rectangular, wall slightly thickened, reddish-brown, lignified and suberized.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 1 mL of methanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of β-ecdysterone and dissolve in methanol to produce a solution containing 0.2 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate and methanol (4:1) as the developing solvent. Apply 2 μL of each of the sample solution and reference drug solution and 1 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 15.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 22.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 5.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule

2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:
1. *β*-Ecdysterone:
   (1) Mobile phase: Methanol as the mobile phase A, and water as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of *β*-ecdysterone, and dissolve in methanol to produce a solution containing 20 μg per mL.
   (3) Sample solution: Weigh accurately 1.0 g of the powdered sample and place it in a 50-mL conical flask, then add accurately 15 mL of 30% ethanol, ultrasonicate for 30 minutes. Repeat the extraction of the residue two more times. Combine the extracts, filter to 50-mL volumetric flask with filter paper and make up to volume with 30% ethanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (247 nm) and a column packing L1. The column temperature is maintained at 30℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of *β*-ecdysterone should not be less than 10,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~10	30	70
10~30	30→50	70→50
30~40	50→100	50→0

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

$$\beta\text{-Ecdysterone (\%)} = 0.005(r_U/r_S)(C_S)/(W)$$

   r_U: peak area of *β*-ecdysterone of sample solution
   r_S: peak area of *β*-ecdysterone of reference standard solution
   C_S: concentration of *β*-ecdysterone of reference standard solution (μg /mL)
   W: weight of test sample (g) calculated with dried sample.
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place.
Usage: Heat-clearing medicinal (Heat-clearing and detoxicating medicinal).
Property and flavor: Cold; bitter.
Meridian tropism: Stomach meridians.
Effects: Clear heat and detoxicate, disperse abscesses and nodule, promote menstruation and lactation.
Administration and dosage: 5~9 g.
Precaution and warning: Use cautiously during pregnancy.

RHEI RADIX ET RHIZOMA
大黃
Da Huang / Da Huang
Rhubarb

Rhubarb is the dried and peeled root and rhizome of *Rheum palmatum* L., *Rheum tanguticum* Maxim. ex Balf. or *Rheum officinale* Baill. (Fam. Polygonaceae).
It contains not less than 35% of dilute ethanol-soluble extractives and not less than 1.5% of the total amount of aloe-emodin, rhein, emodin, chrysophanol, and physcion, rhaphonticin should not be detected.

Description: Subcylindrical with pores, 5~15 cm in length, 3~10 cm in diameter, or irregular pieces. Externally yellowish-brown, with light colored reticulations, occasionally with brownish-black patches of cork, covered with yellowish-brown powder. Fracture pale reddish-brown, granular, with numerous reddish-brown spots. In the cross-section, cambium annual and xylem arranged radially result in the formation of a wheel. Pith scattered with abnormal vascular bundles, called “Star Spots”. The abnormal vascular bundles of *Rheum palmatum* L., 2.5 mm in diameter, arranged in a discontinuous ring; the abnormal vascular bundles of *Rheum officinale* Baill., about 4 mm in diameter, scattered irregularly. Odour delicately aromatic; taste bitter and slightly astringent.

Microscopic identification:
1. **Transverse section**:
   Rhei Radix et Rhizoma: Cambium located in external or near external. The inner part of each abnormal vascular bundle presents phloem and outer part presents xylem, cambium located between xylem and phloem result in formation of a ring. The yellowish-brown rays arranged radically by 2~3 rows of parenchymatous cell, containing yellow crystals. Crystalline contents showing insolubility in ethanol, but soluble in water and chloral hydrate (TS), give a result of red in alkaline solution. Parenchymatous cells contain clusters of calcium oxalate and abundant starch granules. Phloem composed of parenchymatous cells, scattered with

sieve tube tissues. Xylem unlignified, up to 100 μm width; vessels mainly reticulated, some with spiral vessels, no existence of fibers and stone cells.

2. **Powder:** Orange-yellow or yellowish-brown. Parenchymatous cells abundant. Mostly contain unlignified reticulate vessels, up to 100 μm in diameter and some spiral and annular vessels. The contents seceded from pith cells are mostly yellow non-crystalline masses, soluble in dilute ammonia solution, gives a pink color; gives a dark-red color in potassium hydroxide solution. Clusters of calcium oxalate mostly in fragments, complete ones, 20~200 μm in diameter, mostly as 60~120 μm. Starch granules numerous, simple granules and compound granules, compound composed of 2~5 components, 30 μm in diameter. No existence of cork cells, stone cells and fibers in this sample.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 0.1 g of powdered sample to 20 mL of methanol, ultrasonicate for 30 minutes, filter, take 5 mL of the filtrate, evaporate to dryness, and dissolve the residue in 10 mL of water, add 1 mL of hydrochloric acid, place in a water bath (60℃) for 30 minutes, cool, extract by shaking twice each with 20-mL quantities of ethyl acetate, combine the ethyl acetate extracts, evaporate to dryness, and dissolve the residue in 1 mL of methanol.
2. Reference drug solution: Take 0.1 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of rhein and dissolve in methanol to produce a solution containing 0.1 mg per mL.
4. Procedure: Use silica gel F254 as the coating substance and a solution of *n*-hexane, ethyl acetate, and glacial acetic acid (15∶5∶0.3) as the developing solvent. Apply 2 μL of each of the sample solution, reference drug solution and reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Acid-insoluble ash: Not more than 1.5% (General rule 6007).
2. Foreign matter: Not more than 1.0% (General rule 6005).
3. Rhaponticin:
   (1) Sample solution: Add 0.5 g of powdered sample to 10 mL of ethanol, heat on the reflux for 10 minutes, filter and use the filtrate.
   (2) Procedure: Carry out the method for thin layer chromatography (General rule 1621.3), use silica gel F_{254} as the coating substance and a solution of isopropyl ether, *n*-butanol, and methanol (26:7:7) as the developing solvent. Apply 10 μL of the sample solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. Usually the blue-white fluorescence is present when R_f value between 0.3 to 0.6, but the bluish violet fluorescence should not be present.
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 5.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:

1. Aloe-emodin, rhein, emodin, chrysophanol, and physcion:
   (1) Mobile phase: A solution of methanol and 0.1% phosphoric acid (75:25). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of aloe-emodin, rhein, emodin, chrysophanol, and physcion and dissolve in methanol to produce a solution containing 40 μg per mL of each of aloe-emodin, rhein, emodin, chrysophanol and physcion.
   (3) Sample solution: Weigh accurately 0.15 g of powdered sample and place it in a 50-mL centrifuge tube, then add accurately 25 mL of methanol, ultrasonicate for 30 minutes. Centrifuge for 15 minutes, filter the supernatant with filter paper. Repeat the extraction of the residue one more time. Combine the filtrate, transfer to 25-mL volumetric flask and make up to volume with methanol, mix well, take 5 mL of the filtrate to a 50-mL round bottom flask, evaporate to dryness, add 10 mL of 8% (v/v) hydrochloric acid, ultrasonicate for 30 minutes, reflux for 1 hour, cool, extract three times with 10 mL of ethyl acetate, combine the ethyl acetate extracts, filter and evaporate the filtrate to dryness, transfer to a 10-mL volumetric flask, add methanol to volume and mix well. Filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (254 nm) and a column packing L1. The column temperature is maintained at room temperature. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of aloe-emodin, rhein, emodin,

chrysophanol and physcion should not be less than 5,000.

(5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Aloe-emodin, rhein, emodin, chrysophanol, or **physcion (%)=0.005 (r_U/r_S) (C_S) / (W)**

r_U: peak area of aloe-emodin, rhein, emodin, chrysophanol, or physcion of sample solution

r_S: peak area of aloe-emodin, rhein, emodin, chrysophanol, or physcion of reference standard solution

C_S: concentration of aloe-emodin, rhein, emodin, chrysophanol, or physcion of reference standard solution (μg/mL)

W: weight of test sample (g) calculated with dried sample.

2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Preserve in a light-resistant and well-closed container.
Usage: Purgative medicinal (Offensive purgative medicinal).
Property and flavor: Cold; bitter.
Meridian tropism: Spleen, stomach, large intestine, liver, and pericardium meridians.
Effects: Remove accumulation with purgation, purge fire, Clear heat and detoxicate, activate blood and eliminate stasis, clear heat and drain dampness.
Administration and dosage: 0.2~15 g, it should not be decocted long for purgation; used an appropriate amount for external use.

【Decoction pieces】

RHEI RADIX ET RHIZOMA

It contains not less than 35% of dilute ethanol-soluble extractives and not less than 1.5% of the total amount of aloe-emodin, rhein, emodin, chrysophanol and physcion, rhaphonticin should not be detected.
Raw medicinal materials are processed to remove impurities, clean selection, soften thoroughly, cut into thin slices, and dry, mostly irregular thick slices, fracture pale reddish-brown or yellowish-brown, granular, reddish-brown dots can be seen everywhere. Cut surface even, cambium ring and xylem have rims formed by radial arrangement into the surrounding area. The pith has a large number of stellate vascular bundle, called "star spots". Odour slight, taste bitter and slightly astringent.

Thin layer chromatographic identification test: The method is the same as that for crude herb.
Impurities and other requirements: Methods and specifications are the same as those for crude herb.
Assay: The method is the same as that for crude herb.
Storage: The method is the same as that for crude herb.
Usage: Purgative medicinal (Offensive purgative medicinal).
Property and flavor: Cold; bitter.
Meridian tropism: Spleen, stomach, large intestine, liver and pericardium meridians.
Effects: Remove accumulation with purgation, purge fire, Clear heat and detoxicate, activate blood and eliminate stasis, clear heat and drain dampness.
Administration and dosage: 0.2~15 g, it should not be decocted long for purgation; used an appropriate amount for external use.
Precaution and warning: Use cautiously during pregnancy and lactation.

RHODIOLAE CRENULATAE RADIX ET RHIZOMA
紅景天
Hong Jing Tian / Hong Jing Tian
Kirilow Rhodiola Root and Rhizome

Kirilow rhodiola root and rhizome is the dried root and rhizome of *Rhodiola crenulata* (Hook.f. & Thomson) H.Ohba (Fam. Crassulaceae).
It contains not less than 23.0% of dilute ethanol-soluble extractives and not less than 19.0% of water extractives and not less than 0.5% of salidroside.

Description: Cylindrical or irregular sheet, varying in length, mostly roots, occasionally root. Epidermis reddish brown to tan, cork is easily peeled off, leaving a few stem bases and most of the protrusions forming nodular stem marks. Epidermal reddish brown to pale brown, cortex layer visible. Light and brittle, easy break. Rose aroma.

Microscopic identification:
Transverse section:
Rhizome of *Rhodiola crenulata*: Cortex composed of several rows of cells, contain brown-red pigmentary cell layer. Cortical cells elliptical or round, of different sizes, rich in brown secretions and round ball , subround starch granules. Vascular bundles arranged in a circular shape, xylem catheter group distributed in an inverted cone shape, medulla occasionally surrounded by a tough surrounding vascular bundle, xylem catheter mostly thread or ring-shaped catheter.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 0.5 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, cool, filter, and make up the filtrate to 10 mL.
2. Reference drug solution: Take 0.5 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of salidroside and dissolve in methanol to produce a solution containing 0.5 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating

substance and the lower layer of dichloromethane, acetone, methanol, and water (6:1:3:1) as the developing solvent. Apply 5 μL of each of the sample solution and reference drug solution and 2 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 12.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 7.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

Salidroside:

1. Mobile phase: A solution of methanol and water (15:85). The ratio may be adjusted, if necessary.
2. Reference standard solution: Weigh accurately a quantity of salidroside and dissolve in methanol to produce a solution containing 0.15 mg per mL.
3. Sample solution: Weigh accurately 0.5 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 10 mL of methanol, ultrasonicate for 30 minutes. Centrifuge for 5 minutes, filter the supernatant with filter paper. Repeat the extraction of the residue one more time. Combine the filtrate, transfer to 50-mL volumetric flask and make up to volume with methanol, mix well, filter and use the successive filtrate.
4. Chromatographic system: The liquid chromatography is equipped with an UV detector (220 nm) and a column packing L1. The column temperature is maintained at 35℃. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of salidroside should not be less than 2,000.
5. Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   Salidroside (%)=2.5(r_U/r_S) (C_S) / (W)

   r_U: peak area of salidroside of sample solution

   r_S: peak area of salidroside of reference standard solution

   C_S: concentration of salidroside of reference standard solution (mg/mL)

   W: weight of test sample (g) calculated with dried sample.

Storage: Store in a ventilated and dry place, and protect from moisture and insects.

Usage: Tonifying and replenishing medicinal (Qi-tonifying medicinal).

Property and flavor: Neutral; bitter and sweet.

Meridian tropism: Lung and heart meridians.

Effects: Promote qi and activate blood, free pulse to calm panting.

Administration and dosage: 3~6 g.

RHOIS GALLA
五倍子
Wu Bei Zih / Wu Bei Zi
Chinese Gall

Chinese gall is the galls produced mainly by parasitic aphids of *Schlechtendalia chinensis* (Bell)on the leaves of *Rhus chinensis* Mill., *Rhus potaninii* Maxim. or *Rhus punjabensis* J.L.Stewart var. *sinica* (Diels) Rehder & E.H.Wilson (Fam. Anacardiaceae).

It contains not less than 47.0% of dilute ethanol-soluble extractives, not less than 40.0% of water extractives, not less than 50% of gallic acid and not less than 50.0% of tannins.

Description:

According to the different shapes, separate into “Jiao Bei” and “Du Bei”:

1. Jiao Bei: Rhombic, ovate or fusiform, 3~8 cm in length, 2~5 cm in diameter, commonly with several obtuse round branches. Externally grayish-yellow or pale yellowish-brown, with grayish-white soft and smooth tomentellate. Texture hard and fragile, hollow after broken, gall walls relatively thin, 1~2 mm thick, inner surface smooth, with black-brown killed aphids or black powdered aphid eggs, and 1~2 white silk, silk surface with numerous killed aphids, accompanied by white cream powder or crystalline wax-like material in the inner surface. Odour special; taste astringent.
2. Du Bei: Long round or fusiform, slightly flat, no branches. Externally dark gray yellowish-green, with numerous longitudinal striations, less tomentellate; gall walls about 3 mm thick.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 0.2 g of powdered sample to 5 mL of methanol, ultrasonicate for 15 minutes, filter and use the filtrate.

2. Reference drug solution: Take 0.2 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of gallic acid and dissolve in methanol to produce a solution containing 0.5 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of toluene, ethyl acetate, and formic acid (4:3:1) as the developing solvent. Apply 2 μL of each of the sample solution and reference drug solution and 1 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 254 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 14.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 3.5% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Gallic acid:
   (1) Mobile phase: Methanol as the mobile phase A, and 0.1% phosphoric acid as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of gallic acid, and dissolve in waterl to produce a solution containing 50 μg per mL.
   (3) Sample solution: Weigh accurately 0.5 g of the powdered sample and place it in a 100-mL round bottom flask, then accurately add 50 mL of 4N hydrochloric acid, heat under reflux for 4 hours, cool to room temperture, transfer 1 mL of the solution to 100-mL volumetric flask, make up to volume with 50% methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (217 nm) and a column packing L1. The column temperature is maintained at room temperature. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of gallic acid should not be less than 8,000

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~10	5→10	95→90
10~20	10→30	90→70

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Gallic acid : (%)=0.5 (r_U/r_S) (C_S) / (W)

r_U: peak area of gallic acid of sample solution

r_S: peak area of gallic acid of reference standard solution

C_S: concentration of gallic acid of reference standard solution (μg/mL)

W: weight of test sample (g) calculated with dried sample.

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).
4. Tannins:
   (1) Sample solution: Weigh accurately 2.0 g of powdered sample, transfer to a conical flask, add 150 mL of water, place in a water bath for 30 minutes, cool and transfer to 250-mL volumetric flask, add water to volume, filter and use the filtrate.
   (2) Determination of total water soluble portion: Weigh accurately 25 mL of the sample solution, evaporate to dryness, take the residue dry at 105℃ for 3 hours, weighed (T_1).
   (3) Determination of water soluble portion not combining with gelatin powder: Weigh accurately 100 mL of the sample solution, add 6.0 g of gelatin powder, shake for 15 minutes, filter, weigh accurately 25 mL of the filtrate, evaporate to dryness, take the residue dry at 105℃ for 3 hours, weighed (T_2).
   (4) Determination of water soluble portion combining with gelatin powder: Weigh accurately 100 mL of water, add 6.0 g of gelatin powder, shake for 15 minutes, filter, weigh accurately 25 mL of the filtrate, evaporate to dryness, take the residue dry at 105℃ for 3 hours, weighed (T_0).
   (5) Calculate the content of tannins as following formula:

$$\text{Content of tannins (\%)} = \frac{(T_1 - T_2 + T_0)\times 10}{W}\times 100$$

W is the weight of the sample taken (g).

Storage: Refrigerate or store in a cool and dry place, and protect from crush.
Usage: Astringent medicinal.
Property and flavor: Cold; sour and astringent.
Meridian tropism: Lung, large intestine, and kidney meridians.
Effects: Costrain lung to downbear fire, astringe the intestines and antidiarrheal, relieve sweating and hemostatic, astringes moisture and wound healing, secure essence.
Administration and dosage: 3~6 g, used an appropriate amount for external use.

ROSAE LAEVIGATAE FRUCTUS
金櫻子
Jin Ying Zih / Jin Ying Zi
Cherokee Rose Fruit

Cherokee rose fruit is the dried ripe fruit of *Rosa laevigata* Michx. (Fam. Rosaceae).
It contains not less than 36.0% of dilute ethanol-soluble extractives and not less than 34.0% of water extractives.

Description: Pseudocarp developed from receptacle, obovate, vase-shaped, 2~4 cm in length, 1~2 cm in diameter in the center. Externally dark red or reddish-brown, slightly lustrous, with a dish-like persistent calyx at the apex, swollen in the middle and the lower part gradually tapered, with bristles or protuberant brown small scars of the fallen bristles. Texture hard, fracture dark yellow, receptacle about 1.5 mm thick, with white or pale yellow tomenta, lustrous, composed of 30~50 yellow and hard nuts, fusiform, with 3~5 edges and longitudinal groove. Odour slightly sour; taste sweet and slightly astringent.

Microscopic identification:
1. **Transverse section:**
   Fruit of *Rosa laevigata*: Outer epidermis 1 row, covered with about 7 μm thick cuticle, cells subsquare, filled with brown contents. Parenchymatous cells of endodermis subrounded or polygonal, walls slightly thickened and lignified. Non-glandular hairs or their remains occasionally visible. Collateral vascular bundles scattered, phloem fine, with fiber bundles locate outside the phloem, vessels scattered or radially arranged.
2. **Powder:** Reddish-brown. Epidermal cells polygonal, walls thickened, with distinct pits and cell boundaries, containing reddish-brown contents. Parenchymatous cells oblong or polygonal, walls slightly thickened and lignified, with distinct pits. Non-glandular hairs unicellular or multicellular, walls thickened and slightly lignified, 500~1800 μm in length, 15~30 μm in diameter. Fiber bundles fusiform or strip-shaped, walls lignified with distinct pits, 15~25 μm in diameter. Vessels spiral, reticulated, pitted and annular, mainly spiral, 7~20 μm in diameter. Prisms of calcium oxalate squared or irregular in shape, 15~40 μm in diameter; clusters of calcium oxalate 25~60 μm in diameter, relatively rare. Pigments yellow or yellowish-brown, irregular in shape.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 2.0 g of powdered sample to 30 mL of ethanol, ultrasonicate for 30 minutes, filter, evaporate the filtrate to dryness, dissolve the residue in 20 mL of water, extract shaking twice each with 30 mL of ethyl acetate, combine the ethyl acetate extracts, evaporate to dryness, dissolve the residue in 2 mL of methanol.
2. Reference drug solution: Take 2.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, methanol, and water (9:0.8:0.6) as the developing solvent. Apply 10 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with a 10% solution of H_2SO_4/EtOH TS and heat at 105°C until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:
1. Total ash: Not more than 6.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:
1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place, and protect from moisture.
Usage: Astringent medicinal.
Property and flavor: Neutral; sour, sweet and astringent.
Meridian tropism: kidney, bladder, and large intestine meridians.
Effects: Tonify kidney and secure essence, reduce urination, astringe the intestines and antidiarrheal.

Administration and dosage: 6~12 g.

RUBI FRUCTUS IMMATURUS
覆盆子
Fu Pen Zih / Fu Pen Zi
Palmleaf Raspberry Fruit

Palmleaf raspberry fruit is the dried immature fruit of *Rubus chingii* Hu (Fam. Rosaceae).
It contains not less than 7.0% of dilute ethanol-soluble extractives and not less than 7.0% of water extractives.
Description: Aggregate fruit consisting of numerous small drupes, conical, flattened-conical or spheroidal, 4~9 mm in diameter, 5~12 mm in height. Externally grayish-green with grayish-white pubescences. Apex obtuse; base flattened, with brown involucre; involucre 5-lobed, the upper part covered with brown pubescences, the lower part with fruit stalks, stalk fragile and easily fallen. Drupelets easily fallen, with 3 ridges, lunate, dorsal surface densely covered with grayish-white pubescences, reticulate striations distinct on both side, containing 1 brown seed. Odour aromatic; taste sweet and slightly sour.

Microscopic identification:
1. **Transverse section:**
   (1) Fruit of *Rubus chingii*: Receptacle rounded, surrounded with numerous drupelets.
   (2) Drupelet of *Rubus chingii*: Exocarp composed of 1 layer of arranging neatly parenchymatous cells, elongated tangentially, the apical cells usually differentiated into unicellular non-glandular hairs, with scars remained of hairs. Mesocarp composed of 3~5 layers of oblong parenchymatous cells, some containing clusters of calcium oxalate. Endocarp relatively thick, with ridge-shaped protuberance, outer part composed of several layers of thickened cells, walls lignified, the outermost layer with relatively small cells, arranged neatly, inner part composed of several layers of fibers, horizontally lay or obliquely alternated. The outermost layer of testa composed of 1 layer of parenchymatous cells, tangentially elongated, lumen filled with brown pigments; inside showing 1~2 layers of compressed parenchymatous cells. Endosperm and cotyledons with thin walls, containing aleurone grains and fatty oil.
2. **Powder:** Pale brownish-yellow. Non-glandular hairs usually unicellular, cell walls extremely thickened and lignified, lumen indistinct, walls usually with spiral striations, the shape like stone cell, 80~400 μm in length, 10~20 μm in diameter. Epidermal cells of pericarp flaky, polygonal in surface view, scattered with single stone cells, subrounded, 10~25 μm in diameter. Fibers of pericarp in groups, arranged longitudinally or obliquely in crisscross pattern, 180~250 μm in length, 10~25 μm in diameter. Clusters of calcium oxalate usually visible, 20~50 μm in diameter.

Impurities and other requirements:
1. Loss on drying: Not more than 15.0% dry at 105°C for 5 hours (General rule 6015).
2. Total ash: Not more than 7.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:
1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place, and protect from insects.
Usage: Astringent medicinal.
Property and flavor: Warm; sweet and sour.
Meridian tropism: Liver, kidney, and bladder meridians.
Effects: Supplements liver and kidney, secure essence, reduce urination, assist yang, improve vision.
Administration and dosage: 6~12 g.

RUBIAE RADIX ET RHIZOMA
茜草
Cian Cao / Qian Cao
India Madder Root and Rhizome

India madder root and rhizome is the dried root and rhizome of *Rubia cordifolia* L. (Fam. Rubiaceae).
It contains not less than 6.0% of dilute ethanol-soluble extractives, not less than 6.0% of water extractives and not less than 0.4% of rubimaillin.

Description: Rhizomes nodular, 2~3 cm in length, the upper with stem bases, the lower with numerous fascicled roots. Roots slender cylindrical, undulate curved or occasionally branched, 10~20 cm in length, 1~4 mm in diameter; externally brownish-red or purplish-red, with fine longitudinal wrinkles and a few transverse furrows, occasionally bark exfoliated and exposed pink wood. Texture hard and fragile, fracture pale red. Odour slight; taste slightly bitter and with reddish saliva on chewing.

Microscopic identification:

1. **Transverse section:**
   Root of *Rubia cordifolia*: Cork composed of over 10 layers of cork cells. Cortex relatively narrow, cells elongated tangentially, mostly shrunken. Phloem cells relatively small, scattered with numerous raphides of calcium oxalate arranged axially. Cambium in a ring. Xylem vessels mostly singly scattered, distributed irregularly. Rays indistinct.
2. **Powder:** Dark brown. Odour slightly fragrant, taste bitter. Lignification reaction of powder is visible, huge vessel fragments showing strongly lignified, corners are walled; most obvious vessels are bordered-pitted, reticulate, and spiral vessels. The second are lignified fiber bundles and the fragments of tracheid. The other is the fragments of unlignified parenchyma cells, contain reddish-brown substance in the cells. Have large calcium oxalate needle bundles, but no starch granules.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 0.5 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 1 mL of methanol.
2. Reference drug solution: Take 0.5 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of petroleum ether (30~60℃) and acetone (4:1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:

1. Loss on drying: Not more than 15.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 16.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 6.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:

1. Rubimaillin:
   (1) Mobile phase: A solution of acetonitrile and 0.03% phosphoric acid (4:1). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of rubimaillin and dissolve in methanol to produce a solution containing 80 μg per mL.
   (3) Sample solution: Weigh accurately 0.2 g of the powdered sample, add 20 mL of methanol, ultrasonicate for 30 minutes, cool. Add methanol to 25 mL, mix well, filter and use the filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (250 nm) and a column packing L1.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Rubimaillin (%)=0.0025(r_U/r_S) (C_S) / (W)
   r_U: peak area of rubimaillin of sample solution
   r_S: peak area of rubimaillin of reference standard solution
   C_S: concentration of rubimaillin of reference standard solution (μg/mL)
   W: weight of test sample (g) calculated with dried sample
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place, and protect from mold.
Usage: Blood-regulating medicinal (Hemostatic medicinal).
Property and flavor: Cold; bitter.
Meridian tropism: Liver meridians.
Effects: Cool the blood to hemostatic, activate blood and eliminate stasis, promoting menstruation.
Administration and dosage: 6~12 g.

RUBRA PORIA
赤茯苓
Chih Fu Ling / Chih Fu Ling
Red Poria

Red poria is the dried sclerotium of *Wolfiporia extensa* (Peck) Ginns (*Poria cocos* (Schwein.) F.A.Wolf) (Fam. Polyporaceae).
It contains not less than 0.05% of pachymic acid.

Description: Subspherical, elliptical or irregular dry slabs, thickness of 0.5~0.3 cm, thin and rough outer skin, tan to dark brown, with obvious shrinkage texture, weight and

firm texture. Section granular, some have cracks, and the interior pale red or pale brown.

Microscopic identification:

1. **Transverse section:**
   Sclerotium of *Wolfiporia extensa*: Outer skin portion is composed of numerous myceliums, and most of the ovate or irregular granules are seen inside.
2. **Powder:** Grayish-white, irregular granular mass and branching mass, colorless, hyphae colorless or pale brown, slender and slightly curved, partially branched, 3~4 μm in diameter.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 5 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of pachymic acid and dissolve in methanol to produce a solution containing 0.2 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of toluene, ethyl acetate, and formic acid (20:5:0.5) as the developing solvent. Apply 5 μL of each of the sample solution and reference drug solution and 2 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 18.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 3.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Pachymic acid:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and 0.1% phosphoric acid as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of pachymic acid and dissolve in methanol to produce a solution containing 50 μg per mL.
   (3) Sample solution: Weigh accurately 2.0 g of the powdered sample and place it in a 50-mL conical flask, then add accurately 20 mL of methanol, ultrasonicate for 30 minutes, filter with filter paper. Repeat the extraction of the residue one more time. Combine the filtrate, evaporate the filtrate to a small amount and transfer to 25-mL volumetric flask, make up to volume with methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (203 nm) and a column packing L1. The column temperature is maintained at room temperature. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of pachymic acid should not be less than 10,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~20	70→100	30→0

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Pachymic acid (%)=0.0025(r_U/r_S) (C_S) / (W)

r_U: peak area of pachymic acid of sample solution

r_S: peak area of pachymic acid of reference standard solution

C_S: concentration of pachymic acid of reference standard solution (μg/mL)

W: weight of test sample (g) calculated with dried sample.

Storage: Store in a ventilated and dry place, and protect from moisture and insects.

Usage: Dampness-dispelling medicinal (Dampness-draining diuretic medicinal).

Property and flavor: Neutral; sweet.

Effects: Move water, clear damp-heat, fortify heart and moisten lung.

Administration and dosage: 6~15 g.

SALVIAE MILTIORRHIZAE RADIX ET RHIZOMA
丹參
Dan Shen / Dan Shen
Red Sage Root and Rhizome

Red sage root and rhizome is the dried root and rhizome of *Salvia miltiorrhiza* Bunge (Fam. Labiatae).
It contains not less than 46.0% of dilute ethanol-soluble extractives, not less than 50.0% of water extractives and not less than 0.15% of tanshinone II_A.

Description: Rhizomes short and stout, occasionally apex remained with stem base. Roots several, long cylindrical, slightly curved, some branched and with fibrous rootlets, 10~20 cm in length, 0.3~1 cm in diameter. Externally brownish-red or dark brownish-red, rough, longitudinally wrinkled. The bark of old roots loose, mostly purplish-brown, easily exfoliated to scaly. Texture hard and fragile, fracture loose, with clefts or slightly even and dense, bark brownish-red bark, wood grayish-yellow or purplish-brown, with yellowish-white vessels bundles arranged radially. Odour slight; taste slightly bitter and astringent. Cultivated form relatively stout, 0.5~1.5 cm in diameter, externally reddish-brown, longitudinally wrinkled, the bark closely adhering to wood and uneasily exfoliated, texture compact, fracture relatively even, slight horny.

Microscopic identification:

1. **Transverse section:**
   Root of *Salvia miltiorrhiza*: Cork composed of several layers of cells with orange or pale purplish-brown contents, occasionally with rhytidome tissue. Cortex broad and phloem narrow, sieve tube groups obvious, the shedding ones strip-shaped. Cambium arranged in a ring. Xylem extremely broad, vessels occurring near the cambium ring and gradually reduced near the central part of xylem, usually several tangentially connected, arranged alternately with parenchymatous cells of xylem arranged in layer. Xylem fibers accompany with vessels.
2. **Powder:** Reddish-brown. Stone cells mostly singly scattered or paired, subrounded, subrectangular, subfusiform or irregular, edge uneven, up to 257 μm long, 20~65 μm in diameter, the wall 5~16 μm thick, occasionally contain brown contents. Reticulate and bordered-pitted vessels 10~50 μm in diameter; reticulate vessel elements long-fusiform, acuminate or truncate at the end, with irregular thickened walls, pits narrow and thin, perforations in lateral walls. Xylem fibers usually in bundles, long fusiform, acuminate at the end, 18~25 μm in diameter, the wall 2~4 μm thick, pits oblique cleft-shaped or cruciate, pit canals sparse. Cork cells yellowish-brown, subsquare or polygonal in surface view, the wall slightly thickened, curved or straight, containing reddish-brown pigments, the pigments are dissolved after chloral hydrate solution is permeabilized.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 5 mL of ethyl acetate, ultrasonicate for 1 hour, filter, evaporate the filtrate to dryness, and dissolve the residue in 1 mL of methanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of tanshinone II_A and dissolve in methanol to produce a solution containing 0.1 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane: ethyl acetate (4:1) as the developing solvent. Apply 2 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution

Impurities and other requirements:

1. Loss on drying: Not more than 15.0% dry at 105°C for 5 hours (General rule 6015).
2. Total ash: Not more than 10.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 3.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 0.3 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:

1. Tanshinone II_A:
   (1) Mobile phase: A solution of methanol and water (80:20). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of tanshinone II_A, and dissolve in methanol to produce a solution containing 20 μg per mL.
   (3) Sample solution: Weigh accurately 1.0 g of powdered sample, add 30 mL of 70% methanol, ultrasonicate for 30 minutes, centrifugal filtration, transfer to 100-mL volumetric flask, Repeat the extraction of the residue two times. Combine the filtrate and make up to volume with 70% methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (270 nm) and a column packing L1.

The column temperature is maintained at room temperature. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of tanshinone II_A should not be less than 5,000.

(5) Procedure: Inject accurately 20 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Tanshinone II_A : (%)=0.01 (r_U/r_S) (C_S) / (W)

r_U: peak area of tanshinone II_A of sample solution

r_S: peak area of tanshinone II_A of reference standard solution

C_S: concentration of tanshinone II_A of reference standard solution (μg/mL)

W: weight of test sample (g) calculated with dried sample.

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from insects.
Usage: Blood-regulating medicinal (Blood-activating and stasis-dispelling medicinal).
Property and flavor: Mild cold; bitter.
Meridian tropism: Heart, pericardium, and liver meridians.
Effects: Activate blood and eliminate stasis, regulate menstruation to relieve pain, cool the blood to disperse abscesses, eliminates vexation and calming mental state.
Administration and dosage: 5~15 g.

【Decoction pieces】

SALVIAE MILTIORRHIZAE RADIX ET RHIZOMA

It contains not less than 46.0% of dilute ethanol-soluble extractives, not less than 50.0% of water extractives and not less than 0.12% of tanshinone II_A.
Raw medicinal materials are processed to remove impurities, clean selection, soften thoroughly, cut into thin slices, and dry, mostly subrounded or oval thick slices. Externally brownish-red or dark brownish-red, rough and longitudinal wrinkle. The cut surface is cracked or slightly flat and dense, few horny, surface brownish-red, xylem grayish-yellow or purplish-brown, have yellowish-white radial texture. Odour slight, taste bitter and astringent.

Thin layer chromatographic identification test: The method is the same as that for crude herb.
Impurities and other requirements: Methods and specifications are the same as those for crude herb.
Assay: The method is the same as that for crude herb.
Storage: The method is the same as that for crude herb.
Usage: Blood-regulating medicinal (Blood-activating and stasis-dispelling medicinal).
Property and flavor: Mild cold; bitter.
Meridian tropism: Heart, pericardium, and liver meridians.
Effects: Activate blood and eliminate stasis, regulate menstruation to relieve pain, cool the blood to disperse abscesses, eliminates vexation and calming mental state.
Administration and dosage: 5~15 g.

SANGUISORBAE RADIX
地榆
Di Yu / Di Yu
Great Burnet Root

Great burnet root is the dried root of *Sanguisorba officinalis* L. or *Sanguisorba officinalis* L. var. *longifila* (Kitag.)T.T.Yu & C.L.Li (Fam. Rosaceae).
It contains not less than 17.0% of dilute ethanol-soluble extractives, not less than 15.0% of water extractives, not less than 10.0% of tannins and not less than 1.0% of gallic acid.

Description:
1. Root of *Sanguisorba officinalis*: Cylindrical, slightly curved or twisted, 5~21 cm in length, 0.5~2 cm in diameter. Externally brown, rough, with longitudinal wrinkles, occasionally with lateral root or scars, root stock relatively thick, with stalk and petiole residues. Texture hard and fragile, fracture relatively even, slight starchy, pale yellow in bark, brownish-yellow or pink in wood, with radially striations. Odour slights; taste slightly bitter and astringent.
2. Root of *Sanguisorba officinalis* var. *longifolia*: Roots cylindrical or conical, curved or twisted, up to 20 cm in length, 0.6~2 cm in diameter. Externally reddish-brown or brownish-purple, with fine longitudinal wrinkles and transverse furrows. Texture hard and tenacious, uneasily broken, fracture distinct fibrous, cambium ring indistinct, yellow in bark, pale yellow in wood, with indistinct radial striations. Odour slight; taste slightly bitter and astringent.

Microscopic identification:
1. **Transverse section:**
   (1) Root of *Sanguisorba officinalis*: In phloem, fibers singly scattered, walls lignified; xylem fibers infrequent.
   (2) Root of *Sanguisorba officinalis* var. *longifolia*: Cork composed of several layers of brown cork cells. Cortex composed of 2~3 layers of oblong cells, elongated tangentially. Phloem broad, fibers numerous, singly scattered or several in bundles, walls unlignified; with many clefts at the outer Cambium in a ring. Xylem rays broad; xylem fiber bundles relatively more, surrounding vessels.

Parenchymatous tissue filled with clusters of calcium oxalate and starch granules.

2. **Powder:** Yellowish-brown to brown. Cork cells brownish-yellow, subrectangular, lumen occasionally contains yellow contents. Phloem fibers singly scattered or few in bundles, slender and curved, 10~30 μm in length. Starch granules abundant, suboblong, subpolygonal or irregular. Vessels mainly bordered-pitted, reticulate also present rarely. Clusters and prisms of calcium oxalate also present.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 0.5 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 0.5 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of gallic acid and dissolve in methanol to produce a solution containing 0.5 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of toluene, ethyl acetate, and formic acid (6:3:1) as the developing solvent. Apply 5 μL of the sample solution and reference drug solution and 2 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 254 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 12.0% dry at 105°C for 5 hours (General rule 6015).
2. Total ash: Not more than 10.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:

1. Gallic acid:
   (1) Mobile phase: A solution of methanol and 0.1% phosphoric acid (5:95). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of gallic acid and dissolve in water to produce a solution containing 30 μg per mL.
   (3) Sample solution: Weigh accurately 0.5 g of powdered sample and place it in a conical flask with a stopper, add 25 mL of 10% (v/v) solution of hydrochloric acid, heat under reflux for 3 hours, cool and filter to a 250-mL volumetric flask, wash the container and the residue with a quantity of water for several times, combine the washings to the same volumetric flask, make up to volume with water, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (272 nm) and a column packing L1. The column temperature is maintained at 23 ± 4°C. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of gallic acid should not be less than 5,000.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   Gallic acid: (%)=0.025 (r_U/r_S) (C_S) / (W)

   r_U: peak area of gallic acid of sample solution
   r_S: peak area of gallic acid of reference standard solution
   C_S: concentration of gallic acid of reference standard solution (μg/mL)
   W: weight of test sample (g) calculated with dried sample
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).
4. Tannins:
   (1) Sample solution: Weigh accurately 10.0 g of powdered sample (containing about 1.0 g tannins) and place it in a conical flask, add 150 mL of water, place in a water bath for 30 minutes, cool and transfer to 250-mL volumetric flask, make up to volume with water, mix well, filter and use the filtrate.
   (2) Determination of total water soluble portion: Weigh accurately 25 mL of the sample solution, evaporate to dryness, take the residue dry at 105°C for 3 hours, weighed (T_1).
   (3) Determination of water soluble portion not combining with gelatin powder: Weigh accurately 100 mL of the sample solution, add 6.0 g of gelatin powder, shake for 15 minutes, filter, weigh accurately 25 mL of the filtrate, evaporate to dryness, take the residue dry at 105°C for 3 hours, weighed (T_2).

(4) Determination of water soluble portion combining with gelatin powder: Weigh accurately 100 mL of water, add 6.0 g of gelatin powder, shake for 15 minutes, filter, weigh accurately 25 mL of the filtrate, evaporate to dryness, take the residue dry at 105℃ for 3 hours, weighed (T_0).

(5) Calculate the content of tannins as following formula:

$$\text{Content of tannins (\%)} = \frac{(T_1 - T_2 + T_0) \times 10}{W} \times 100$$

W is the weight of the sample taken (g).

Storage: Store in a ventilated and dry place, and protect from insects.
Usage: Blood-regulating medicinal (Hemostatic medicinal).
Property and flavor: Mild cold; bitter, sour and astringent.
Meridian tropism: Liver and large intestine meridians.
Effects: Cool the blood to hemostatic, disperse swelling to relieve pain, detoxicate and wound healing.
Administration and dosage: 9~15 g; used an appropriate amount for external use.

SAPOSHNIKOVIAE RADIX ET RHIZOMA
防風
Fang Fong / Fang Feng
Saposhnikovia Root and Rhizome

Saposhnikovia root and rhizome is the dried root of *Saposhnikovia divaricata* (Turcz.) Schischk. (Fam. Umbelliferae), commonly known as “Guan Fang Feng”. It contains not less than 20.0% of dilute ethanol-soluble extractives and not less than 18.0% of water extractives.

Description: Long conical or long cylindrical, gradually tapering towards the lower part, some slightly curved, 15~30 cm in length, 0.5~2 cm in diameter. Root stock 2~13 cm in length, with obvious dense annulations, commonly known as “Chiou Yin Tou”, some annulations marked by brown hair-like remains of leaf bases. Externally grayish-brown, rough, with in longitudinal wrinkles, numerous transverse-elongated lenticels and dotted protuberant of rootlet scars. Texture light and loose, easily broken, fracture uneven, bark pale brownish and cracked, commonly known as “Jiu Hua Shin”, scattered with yellowish-brown and tiny oil spots (secretory duct), wood pale yellowish, relatively thick one with a crack in the pith. Odour characteristic; taste sweetish and astringent.

Microscopic identification:

1. **Transverse section:**
   Root of *Saposhnikovia divaricata*: Cork composed of several layers of cells, phelloderm narrow. Cortex with relatively large elliptical vittae. Phloem relatively broad, scattered with numerous subrounded vittae surrounded by 4~8 secretory cells, golden-yellow secretions visible in vittae; phloem rays curved and becoming cleft in the outer part. Cambium distinct. Xylem vessels extremely abundant, arranged radially. Pith present at the center of root stock. A few stone cells scattered in the parenchymatous tissue.
2. **Powder:** Yellowish-brown. Vittae mostly broken, filled with golden-yellow, yellowish-brown or greenish-yellow strip-shaped secretions, wide or slender, 10~112 μm in diameter, surrounded by slender and shrunken parenchymatous cells, with indistinct cell boundaries. Reticulate vessels 14~103 μm in diameter, spiral, bordered-pitted or reticulate bordered-pitted vessels occasionally visible. Cork cells polygonal or subrectangular in surface view; rectangular in sectional view, walls curved and undulated, occasionally with short strip-shaped thickness. Fibers of leaf base mostly slender, 4~13 μm in diameter, walls extremely thickened, lumina narrow and fine. Parenchymatous cells of phloem mostly shrunken, some cells elongated, 5~18 μm in diameter, extremely fine oblique crossed striations faintly present.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Sample solution: Add 1.0 g of powdered sample to 20 mL of acetone, ultrasonicate for 20 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 1 mL of ethanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of 4'-*O*-β-D-Glucosyl-5-*O*-methylvisamminol and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of dichloromethane and methanol (4:1) as the developing solvent. Apply 5 μL of each of the sample solution and reference drug solution and 2 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 254 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 10.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 7.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 5.0 ppm (General rule 2211, 6301).

6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)
9. Aflatoxins
   (1) Aflatoxins (sum of B_1, B_2, G_1 and G_2): Not more than 10.0 ppb (General rule 6307).
   (2) Aflatoxin B_1: Not more than 5.0 ppb (General rule 6307).

Assay:
1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from insects.
Usage: Exterior-releasing medicinal (Pungent-warm exterior-releasing medicinal).
Property and flavor: Mild warm; pungent and sweet.
Meridian tropism: Bladder, liver, and spleen meridians.
Effects: Dispel wind to release exterior, eliminate dampness and relieve pain, arrest convulsions.
Administration and dosage: 4.5~11.5 g.

SAPPAN LIGNUM
蘇木
Su Mu / Su Mu
Sappan Wood

Sappan wood is the dried heart wood of *Caesalpinia sappan* L. (Fam. Leguminosae).
It contains not less than 3.0% of dilute ethanol-soluble extractives and not less than 1.0% of the total amount of protosappanin B and brazilin.

Description: Long-cylindrical, 10~100 cm in length, 3~12 cm in diameter. Externally reddish-yellow or brownish-yellow, with longitudinally brown striations and traces of knife cutting. Texture compact and hard, fracture reddish-yellow, rays slender and arranged densely, pale color, pith lax in the center. Odourless; taste slightly astringent.

Microscopic identification:
1. **Transverse section:**
   Heart wood of *Caesalpinia sappan*: Rays broad, 1~2 layers of cells wide. Vessels subrounded, about to 160 μm in diameter, usually containing yellowish-brown or reddish-brown contents. Xylem fibers polygonal, with extremely thickened walls. Xylem parenchymatous cells with walls thickened and lignified, some containing prisms of calcium oxalate. Parenchymatous cells of pith irregular polygonal, varying in size, walls slightly lignified, with pits.
2. **Powder:** Yellowish-red. Xylem fibers slender, 9~22 μm in diameter, walls thickened or slightly thickened, with sparse oblique pits, lumen linear or slightly wide. Some fiber bundles surrounded by cells containing prisms of calcium oxalate, forming crystal fibers; crystal-containing cells with unevenly thickened and lignified walls; prism crystals about to 17 μm in length. Xylem ray cells rectangular on the radial section, walls moniliform thickened and lignified, with single pits; rays 1~3 rows of cells wide on the tangentially longitudinal section, about to 62 cells high, pits distinct. Bordered-pitted vessels varying in size, large ones about to 160 μm in diameter, usually containing brown contents in clumps. Xylem parenchymatous cells normally longer and larger than ray cells, walls slightly thickened and lignified, pits distinct. Prisms of calcium oxalate and brown masses also visible.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add l.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of brazilin and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of dichloromethane, acetone, and formic acid (8:4:1) as the developing solvent. Apply 2 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Place the plate in a dryer for more than 12 hours. Examine under the ultraviolet light at 254 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 12.0% dry at 105°C for 5 hours (General rule 6015).
2. Total ash: Not more than 5.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251,

6301)

Assay:

1. Protosappanin B and brazilin:
   (1) Mobile phase: A solution of methanol and 0.1% formic acid (20:80). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of protosappanin B and brazilin and dissolve in 80% methanol to produce a solution containing 0.1 mg per mL of each.
   (3) Sample solution: Weigh accurately 1.0 g of powdered sample and place it in a round bottom flask, then add accurately 50 mL of 80% methanol, weigh, heat under reflux for 20 minutes, cool, weigh again, replenish the loss of the weight with 80% methanol, mix well, filter and use the filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (285 nm) and a column packing L1. The column temperature is maintained at 25℃. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of protosappanin B should not be less than 3,000.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   Protosappanin B or brazilin (%)=5 (r_U/r_S) (C_S) / (W)

   r_U: peak area of protosappanin B or brazilin of sample solution
   r_S: peak area of protosappanin B or brazilin of reference standard solution
   C_S: concentration of protosappanin B or brazilin of referenc standard solution (mg /mL)
   W: weight of test sample (g) calculated with dried sample.
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place.
Usage: Blood-regulating medicinal (Blood-activating and stasis-dispelling medicinal).
Property and flavor: Neutral; sweet and salty.
Meridian tropism: Heart, liver, and spleen meridians.
Effects: Activate blood to promoting menstruation, dissipate stasis to relieve pain.
Administration and dosage: 3~11.5 g.
Precaution and warning: Used with caution in blood deficiency without stasis and pregnancy.

SCAPHII SEMEN
胖大海
Pang Da Hai / Pang Da Ha
Boat Sterculia Seed

Boat sterculia seed is the dried mature seed of *Scaphium affine* (Mast.) Pierre (*Sterculia lychnophora* Hance) (Fam. Sterculiaceae).
It contains not less than 18.0% of dilute ethanol-soluble extractives and not less than 6.0% of water extractives.

Description: Spindle or elliptical, 2~3 cm in length, 1~1.5 cm in diameter. Apex obtuse, base slightly pointed and crooked, pale color rounded umbilicus, brown or dark brown, slightly shiny, irregular dry wrinkles. Outer layer of seed coat extremely thin, brittle, easy to fall off. Middle layer is thicker, dark brown, loose and brittle, immersed in water to expand into a sponge. Resin section is scattered in the cross section. Inner layer of seed coat reddish-brown, can be peeled off from the middle layer of seed coat. Micro-coriaceous, 2 pieces of thick endosperm, oval, 2 cotyledons. Close to the inside of the endosperm and the endosperm, endosperm and other big. Odor slight, taste light, chew sticky.

Microscopic identification:

1. **Transverse section:**
   Seed of *Scaphium affine*: Parenchyma cells of the seed coat expand irregular shape with water, single-grained hole, contain pale brown inclusions, large intercellular space. Inner seed coat has a layer of grid-like cells, wall lignified, bottom decadent cell. large intercellular space, endosperm cells contain starch granules and oil droplets, and the catheter is a ring-shaped catheter and a threaded catheter.
2. **Powder:** Pale brown, epidermal cells of the seed coat is square or pentagonal, pale brown, thickened by the vertical wall, wall holes, stomata on the surface, glandular hairs and non-glandular hairs, many epidermis glands, stalks are single cells, head Scalloped or obtusely elliptical, 45~95μm in diameter, containing brown inclusions; Non-glandular hair less, often grinding, star-shaped, several bifurcations, brown matter in the cell.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 5 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane, ethyl acetate, and formic acid (3:1:0.1) as the developing solvent. Apply 8 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots

become visible. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:

1. Loss on drying: Not more than 16.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 4.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).
9. Aflatoxins
   (1) Aflatoxins (sum of B_1, B_2, G_1 and G_2): Not more than 10.0 ppb (General rule 6307).
   (2) Aflatoxin B_1: Not more than 5.0 ppb (General rule 6307).

Storage: Store in a ventilated and dry place, and protect from mold and insects.
Usage: Phlegm-dispelling medicinal (Heat-phlegm clearing and resolving medicinal).
Property and flavor: Cold; sweet.
Meridian tropism: Lung and large intestine meridians.
Effects: Clear lung and resolve phlegm, soothe throat and restore voice, moisten the intestine and relax the bowel.
Administration and dosage: 2~5 pieces, soaked in boiling water or decocted for oral administration.

SCHISANDRAE FRUCTUS
五味子
Wu Wei Zih / Wu Wei Zi
Schisandra Fruit

Schisandra fruit is the dried ripe fruit of *Schisandra chinensis* (Turcz.) Baill. (Fam. Magnoliaceae). Commonly known as"Bai Wu Wei Zi".
It contains not less than 24.0% of dilute ethanol-soluble extractives, not less than 30.0% of water extractives and not less than 0.4% of schizandrin.

Description:
Irrgularly spheroidal or compressed-spheroidal, 5~8 mm in diameter. Externally red, purplish-red or dark red, shrunken, oily, sarcocarp soft, occasionally externally blackish-red or covered with white powder. Seeds 1~2, reniform, externally brownish-yellow, lustrous, testa thin and fragile. Odor of sarcocarp, slightly; taste of sarcocarp, sour. Odor of seeds, aromatic on crushing; taste of seeds, pungent and slighly bitter.

Microscopic identification:

1. **Transverse section:**
   Fruit of *Schisandra chinensis*: Exocarp composed of 1 layer of square or rectangular epidermal cells, walls slightly thickened, covered with cuticle, scattered with oil cells scattered. Mesocarp parenchymatous cells composed of more than 10 layers of cells, containing scattered starch granules, with small collateral vascular bundles. Endocarp composed of 1 layer of small, square parenchymatous cells. The outermost layer of testa composed of radially elongated stone cells, subrounded, thick-walled, with fine and dense pits and pit canals; inside showing several layers of stone cells, triangle or polygonal in shape, with slightly large pits. Oil cell layer composed of 1 layer of rectangular oil cells, containing brownish-yellow oil drops, further down 3~5 layers of small cells. Inner epidermal cells of testa composed of 1 layer of small cells, walls slightly thickened. Endosperm contains oil droplets and aleurone grains.
2. **Powder:** Dark purple. Epidermal cells of testa polygonal or elongated-polygonal in surface view, 18~50 μm in diameter, walls thickened with very fine and dense pit canals; lumen contains dark brown contents. Inner layer stone cells of testa polygonal to subrounded or irregular, up to 83 μm in diameter, with slightly thickened walls and distinct pits. Epidermal cells of exocarp polygonal in surface view, anticlinal walls slightly moniliform, with striated cuticle and scattered oil cells. Mesocarp cells shriveled, containing dark brown contents and starch granules.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of schisandrin and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane, ethyl acetate, and glacial acetic acid (10:5:1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 254 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and reference standard solution.

Impurities and other requirements:

1. Total ash: Not more than 8.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:

1. Schisandrin:
   (1) Mobile phase: A solution of water and acetonitrile (1:1). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of schisandrin, and dissolve in methanol to produce a solution containing 20 μg per mL.
   (3) Sample solution: Weigh accurately 0.5 g of powdered sample, add 70 mL of methanol, ultrasonicate for 30 minutes, centrifugal filtration and use the supernatant. The residue add 30 mL of methanol again and ultrasonicate for 15 minutes. Combine all supernatants and add methanol to 100 mL, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (252 nm) and a column (4.6 mm ×25 cm) packing L1 (5~10 μm). The column temperature is maintained at room temperature. The flow rate is about 1.0 mL/min. Inject reference standard solution into the liquid chromatography apparatus for 5 times, and record the peak areas. The relative standard deviation of the peak area of schisandrin should not be more than 1.5%.
   (5) Procedure: Inject accurately 20 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   Schisandrin : (%)=0.01 (r_U/r_S) (C_S) / (W)

   r_U: peak area of schisandrin of sample solution
   r_S: peak area of schisandrin of reference standard solution
   C_S: concentration of schisandrin of reference standard solution (μg/mL)
   W: weight of test sample (g) calculated with dried sample.
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from mold.
Usage: Astringent medicinal.
Property and flavor: Warm; sour and sweet.
Meridian tropism: Lung, heart and kidney meridians.
Effects: Costrain the lung and suppress cough, tonify kidney and astringe essence, antidiarrheal, calm the mind, tonify qi to engender fluid, relieve sweating.
Administration and dosage: 1.5~7.5 g.

SCHISANDRAE SPHENANTHERAE FRUCTUS
南五味子
Nan Wu Wei Zih/ Nan Wu Wei Zi
Orange Magnoliavine Fruit

Orange magnoliavine fruit is the dried ripe fruit of *Schisandra sphenanthera* Rehder & E.H.Wilson (Fam. Magnoliaceae).
It contains not less than 24.0% of dilute ethanol-soluble extractives, not less than 30.0% of water extractives and not less than 0.3% of schisandrin A.

Description: Irregularly spheroidal to compressed-spheroidal, 2-5 mm in diameter; Externally dark red to brown, pericarp fleshed thin, shrunken, shriveled, lusterless, containing kidney-shaped seeds 1-2. Kidney-shaped seeds, externally yellowish-brown, lustrous, testa thin and fragile, seeds are slightly smaller than seeds of Schisandrae Fructus, granular faintly. Odour of pulp slight, taste slightly sour. Odour of seeds fragrant when broken; taste slightly pungent and slightly bitter.

Microscopic identification:

1. **Transverse section:**
   Fruit of *Schisandra sphenanthera*: The outermost exocarp composed of 1 layer of epidermal cells, walls slightly thickened, covered with cuticle, some epidermal cells scattered with subrounded oil cells, 80 μm in diameter; Mesocarp inward, small collateral vascular bundle rings were visible, parenchymatous cells contain starch granules; endocarp consists of 1 layer of parenchymatous cells. One layer of testa consists of stone cells, oblong or subrounded, 50~120 μm long, 50~60 μm width, the outer wall is thicker than the inner wall, palisade, with fine and dense pit canals, lumen contains reddish-brown to blackish-brown contents; containing several layers of stone cells arranged slightly tangentially, thicker wall, larger pits; oil cell layering, subrectangular, radially elongated, contain brown volatile oil, have 3~4 rows of parenchymatous cells inside and outside, inner parenchyma contain rhaphe vascular bundles; inner epidermal cells of testa composed of 1 layer of small cells, walls slightly thickened. Endosperm contains oil droplets

and aleurone grains. Embryo cells contain aleurone grains.

2. **Powder:** Colour brown to dark purple. Stone cells of outer layer of testa, polygonal to elongated-polygonal in surface view, 18-32 mm in diameter, wall thickness 6~10 μm, with very fine and dense pit canals, lumen contains reddish brown dark brown contents. Rectangular in longitudinal section view; walls thickened with very fine and dense pit canals; lumen contains dark brown contents. Inner layer of testa vary in size, polygonal, subrounded, oval, oblong or irregular, 32-83 mm in diameter, 77-130 μm long, a small number of short-fibers-like can reach 160 μm, wall thickness approximately to 20 μm, the pit canals are slightly thicker or branched, lumen distinct. Epidermal cells of exocarp polygonal in surface view, anticlinal walls slightly beaded, with striated cuticle and scattered oil cells. Mesocarp cells shrivelled, containing brown contents and starch granules, starch granules are single round sphere, 3-18 μm in diameter; compound granules composed of 2-6 simple granules, Endosperm cells contain oil droplets and aleurone grains. A few fibers with annular striations and spiral vessels.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of schisandrin A and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F254 as the coating substance and a solution of *n*-hexane and ethyl acetate (2:1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 254 nm. The spots in the chromatogram obtained from the sample solution corresponding in Rf values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
2. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
3. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
4. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
5. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Schisandrin A:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and water as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of schisandrin A and dissolve in methanol to produce a solution containing 40 μg per mL.
   (3) Sample solution: Weigh accurately 0.4 g of the powdered sample, add accurately 25 mL of methanol, ultrasonicate for 30 minutes, centrifugal filtration, filter, use the filtrate, transfer to 50-mL volumetric flask, Repeat the extraction of the residue one more time. Combine the filtrate and make up to volume with methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (225 nm) and a column packing L1. The column temperature is maintained at 35℃. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of schisandrin A should not be less than 8,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~35	50	50
35~50	50→80	50→20
50~60	80	20

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   Schisandrin A (%)=0.005 (r_U/r_S) (C_S) / (W)

   r_U: peak area of schisandrin A of sample solution

   r_S: peak area of schisandrin A of reference standard solution

   C_S: concentration of schisandrin A of reference standard solution (μg/mL)

   W: weight of test sample (g) calculated with dried sample.
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011)
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from mold.

Usage: Astringent medicinal.

Property and flavor: Warm; sour and sweet.

Meridian tropism: Lung, heart, and kidney meridians.

Effects: Constrain the lung to suppress cough, tonify kidney and astringe essence, antidiarrheal, calm the mind, tonify qi to engender fluid, relieve sweating.

Administration and dosage: 1.5~7.5 g.

SCORPIO
全蠍
Cyuan Sie / Quan Xie
Scorpion

Scorpion is the dried body of *Buthus martensii* Karsch (Fam. Buthidae).
It contains not less than 18.0% of dilute ethanol-soluble extractives.

Description: The cephalothorax and preabdomen flattened long ellipsoidal, the postabdomen tail-like, shrunken and curved, the body of intact specimen about 6 cm in length. The cephalothorax greenish-brown, abdomen and appendage yellow, sting brown. The anterior part arising 1 pair of short and small chelicerae and 1 pair of long and large pedipalps in the shape of crab pincers, ventral part bearing 4 pairs of walking legs, composed of 7 segments, each of segments, with 2 claws on distal end. Abdomen consisted of preabdomen and postabdomen. The preabdomen broad, composed of 7 segments. The postabdomen slender, composed of 5 segments and one sting, with longitudinal furrows on each segment, the sting hooked, venomous. Texture light and fragile. Odour slightly stinking; taste salty.

Microscopic identification:
Powder: Yellowish-brown. Body walls yellowish- brown or yellowish-green, lustrous. Surface view of outer epidermis in polygonal reticulate striations, setae pits, circular holes and warty protuberance visible. Setae pits subrounded, sticking out from the outer epidermis, 15~40 μm in diameter. Setae yellowish-brown, body center 8~40 μm in diameter, with longitudinal striations, usually fallen off. Circular holes fine, 5~10 μm in diameter, existed under reticulate striations. Warty protuberance pale brown or colorless. The fibers of striated muscle many, colorless or pale yellow, light bands relatively broad in lateral view, dark bands with dense and short longitudinal striations. Fatty oil droplets spheroidal, colorless or pale yellow.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 1 mL of methanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-butanol, ethanol, glacial acetic acid, and water (4:1:1:2) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 0.5% ninhydrin hydrate and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:
1. Total ash: Not more than 20.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 3.0% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).
8. Aflatoxins
   (1) Aflatoxins (sum of B_1, B_2, G_1 and G_2): Not more than 10.0 ppb (General rule 6307).
   (2) Aflatoxin B_1: Not more than 5.0 ppb (General rule 6307).

Assay:
Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place, and protect from insects.
Usage: Liver-pacifying and wind-extinguishing medicinal.
Property and flavor: Neutral; pungent.
Meridian tropism: Liver meridians.
Effects: Extinguish wind to arrest convulsions, detoxify to dissipate binds, free the collateral vessels to relieve pain.
Administration and dosage: 2~6 g.

SCROPHULARIAE RADIX
玄參
Syuan Shen / Xuan Shen
Scrophularia Root

Scrophularia root is the dried root of *Scrophularia ningpoensis* Hemsl. (Fam. Scrophulariaceae).
It contains not less than 50.0% of dilute ethanol-soluble extractives, not less than 50.0% of water extractives and not less than 0.45% of the total amount of harpagide and harpagoside.

Description: Conical, slightly thick at the middle part or thick at the upper part and slender at the lower part, occasionally slightly curved as claw-like, 6~20 cm in length, 1~3 cm in diameter. Externally grayish-yellow or brown, with distinct longitudinal grooves and transverse lenticels. Texture compact, uneasily broken, fracture even, black, slightly lustrous. Odour characteristic resembling caramel; taste sweetish and slightly bitter. Gives a result of black water when soaked.

Microscopic identification:

1. **Transverse section:**
   Root of *Scrophularia ningpoensis*: Metaderm cells brownish-yellow, irregular rectangular in shape, slightly suberized. Cortex cells tangentially elongated, rectangular or subrounded; stone cells singly scattered or in groups of 3~5. Phloem rays with many fissures. Cambium present as a ring. Xylem presents as the majority proportion of section, xylem rays broad, mostly cleft-shaped, vessels arranged intermittently and radially, some vessels scattered in center. Parenchymatous cells contain nucleus-like contents.
2. **Powder:** Grayish-brown. Stone cells numerous, mostly singly scattered or 2~5 in groups; varying in shape, rectangular, subsquare, subrounded or irregular in shape, relatively large, 22~94 μm in diameter, walls 5~26 μm thick, with distinct striations. Fragments of parenchymatous cells numerous, containing nucleus-like contents. Xylem fibers slender, with walls slightly lignified. Reticulate and pitted vessels also exist.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of 50% ethanol, ultrasonicate for 10 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of harpagoside and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, methanol, and formic acid (4:1:0.1) as the developing solvent. Apply 3 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with vanillin/H_2SO_4 TS and heat at 105℃ until the spots become visible. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Total ash: Not more than 5.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 1.5% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)
8. Aflatoxins
   (1) Aflatoxins (sum of B_1, B_2, G_1 and G_2): Not more than 10.0 ppb (General rule 6307).
   (2) Aflatoxin B_1: Not more than 5.0 ppb (General rule 6307).

Assay:

1. Harpagide and harpagoside:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and 0.03% phosphoric acid as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of harpagide and harpagoside and dissolve in 30% methanol to produce a solution containing 60 μg and 20 μg per mL of each.
   (3) Sample solution: Weigh accurately 0.5 g of powdered sample and place it in a conical flask with stopper, accurately add 50 mL of 50% methanol, stopper tightly and weigh, soak for 1 hour, ultrasonicate for 45 minutes, cool, and weigh again, replenish the loss weight with 50% methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (210 nm) and a column packing L1. The column temperature is maintained at 23 ± 4℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of harpagide and harpagoside should not be less than 5,000 of each.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~10	3→10	97→90
10~20	10→33	90→67
20~25	33→50	67→50
25~30	50→80	50→20
30~35	80	20

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Harpagide or harpagoside: (%)= 0.005 (r_U/r_S) (C_S) / (W)
   r_U: peak area of harpagide or harpagoside of sample solution
   r_S: peak area of harpagide or harpagoside of reference standard solution
   C_S: concentration of harpagide or harpagoside of reference standard solution (μg/mL)

W: weight of test sample (g) calculated with dried sample.

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from mold and insects.
Usage: Heat-clearing medicinal (Heat-clearing and blood-cooling medicinal).
Property and flavor: Mild cold; sweet, bitter and salty.
Meridian tropism: Lung, stomach, and kidney meridians.
Effects: Clear heat to cool the blood, nourish yin and detoxicate.
Administration and dosage: 9~15 g

SCUTELLARIAE BARBATAE HERBA
半枝蓮
Ban Jhih Lian / Ban Zhi Lian
Skullcap Herb

Skullcap herb is the dried herb of *Scutellaria barbata* D. Don (Fam. Labiatae).
It contains not less than 12.0% of dilute ethanol-soluble extractives, not less than 14.0% of water extractives and not less than 0.2% of scutellarin.

Description: 15~35 cm in length. Stems quadrangular, 1~3 mm in diameter, externally brownish-green or dark purple, texture fragile and easily broken, fracture hollow. Leaves opposite, petioles short; lamina mostly crumpled, lanceolate or subtriangular as whole, the upper surface dark green, the lower surface grayish-green, 1.5~3 cm in length, 0.5~1 cm in width. Vertisillaster terminal, 2 flowers in one whorl, several whorls clustered to racemes. Corolla mostly fallen off, calyx persistent with 4 oblate nutlets inside. Odour slight; taste slightly bitter.

Microscopic identification:

1. **Transverse section:**
   Herb of *Scutellaria barbata*: Epidermal cells polygonal, anticlinal walls undulate; upper epidermis relatively large, 50~90 μm in length, 15~40 μm in width; lower epidermis 25~50 μm in length, 10~25 μm in width. Stomata usually exist in lower epidermis. Palisade cells composed of 1 row of cells, containing numerous chloroplasts; spongy cells composed of 2~3 rows of subrounded cells. Non-glandular hairs composed of 1~3 conical shaped cells, 50~140 μm in length. Glandular hairs exist in lower epidermis, the head composed of 4 cells, 28 μm in diameter, singular celled stalk. Glandular scales mostly present in lower epidermis, the heads spheroidal, 50~75 μm in diameter, singular celled stalk.
2. **Powder:**
   Leaf of Scutellariae barbatae herba: Pale brown. Epidermal cells polygonal; upper epidermal cells 50~90 μm in length, 15~40 μm in width; lower epidermal cells 25~50 μm in length, 10~25 μm in width. Palisade cells 40~80 μm in length, 10~35 μm in width, containing numerous chloroplasts. Most of spongy cells subrounded, occasionally spiral vessels. Non-glandular hairs conical, 50~140 μm in length.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 15 mL of methanol, ultrasonicate for 30 minutes then filter, use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of apigenin and dissolve in methanol to produce a solution containing 0.1 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of dichloromethane, methanol, and formic acid (10:0.5:0.5) as the developing solvent. Apply 10 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 5% $AlCl_3$/EtOH TS and heat at 105°C until the spots become visible. Examine under the ultraviolet light at 254 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 13.0% dry at 105°C for 5 hours (General rule 6015).
2. Total ash: Not more than 8.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 3.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:

1. Scutellarin:
   (1) Mobile phase: 1% acetic acid as the mobile phase A, and acetonitrile as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of scutellarin and

dissolve in methanol to produce a solution containing 25 μg per mL.

(3) Sample solution: Weigh accurately 0.2 g of powdered sample and place it in a 100-mL round bottom flask, add accurately 25 mL of 70% ethanol, heat under reflux for 15 minutes, cool, filter, transfer the solution to 50-mL volumetric flask, repeat the extraction of the residue one more time, combine the filtrate, make up to volume with 70% ethanol, mix well, filter and use the successive filtrate.

(4) Chromatographic system: The liquid chromatography is equipped with an UV detector (335 nm) and a column packing L1. The column temperature is maintained at 23 ± 4℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of scutellarin should not be less than 1,500.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~15	83→75	17→25
15~30	75	25

(5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Scutellarin: (%)= 0.005(r_U/r_S) (C_S) / (W)

r_U: peak area of scutellarin of sample solution

r_S: peak area of scutellarin of reference standard solution

C_S: concentration of scutellarin of reference standard solution (μg/mL)

W: weight of test sample (g) calculated with dried sample.

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place, and protect from moisture.

Usage: Heat-clearing medicinal (Heat-clearing and detoxcating medicinal).

Property and flavor: Cold; pungent and bitter.

Meridian tropism: Lung, liver, and kidney meridians.

Effects: Clear heat and detoxicate, induce diuresis to alleviate edema.

Administration and dosage: 15~30 g.

SCUTELLARIAE RADIX
黃芩
Huang Cin / Huang Qin
Scutellaria Root

Scutellaria root is the dried root of *Scutellaria baicalensis* Georgi (Fam. Labiatae).

It contains not less than 26.0% of dilute ethanol-soluble extractives, not less than 18.0% of water extractives and not less than 8.0% of baicalin.

Description: Conical, twisted, 8~30 cm in length, 1~4 cm in diameter. Externally brownish-yellow or dark yellow, bearing with sparse warty traces of rootlets, apex with scar of stem or remained stem base, the upper part rough, with twisted longitudinal striations and irregular reticulate wrinkles, the lower part with regular and fine wrinkles. Texture hard and fragile, easily broken, fracture yellow, reddish-brown in the center; the central part of an old root dark brown or brownish-black, withered or hollowed, commonly known as “Ku Cin”; the new root commonly known as “Zih Cin” or “Tiao Cin”. Odour slight; taste bitter.

Microscopic identification:

1. **Transverse section:**
   Root of *Scutellaria baicalensis*: The margins of cork mostly broken, cork cells flattened, scattered with stone cells. Narrow cortex and broad phloem with indistinct cell boundaries, scattered with numerous stone cells and phloem fibers, singly scattered or in groups, stone cells mostly presented at the outer margin, phloem fibers mostly presented at the inner side. Cambium in a ring. Xylem vessels in bundles, about 6~20, arranged into flatten layer-shaped, in the center of old roots, forming suberized cell ring, single ring or several in concentric circles. Parenchymatous cells contain starch granules.
2. **Powder:** Yellow. Phloem fibers extremely numerous, fusiform, 50~250 μm in length, 10~40 μm in diameter, wall extremely thickened, pit canals distinct. Xylem fibers relatively slender, mostly broken, wall slightly thickened, with oblique pits. Stone cells relatively numerous, subrounded, elongated-rounded, subsquare or irregular, 60~160 μm in length, wall up to 24 μm thick, pit canals occasionally branched. Reticulate vessels usually visible, bordered-pitted and annular vessels relatively few, fusiform xylem parenchymatous cells accompanied by vessels, with septa. Cork cells brownish-yellow, polygonal. Simple starch granules subspheroidal, 4~10 μm in diameter; compound granules rare, composed of 2~3 components.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 15 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference

drug and the method of preparation is the same as which is described above.

3. Reference standard solution: Weigh accurately a quantity of baicalin and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-butanol, glacial acetic acid, and water (7:1:2) as the developing solvent. Apply 10 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 254 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained with the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 14.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 6.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 5.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:

1. Baicalin:
   (1) Mobile phase: Methanol as the mobile phase A, and 0.1% phosphoric acid as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of baicalin, and dissolve in 70% methanol to produce a solution containing 20 μg per mL.
   (3) Sample solution: Weigh accurately 0.01 g of the powdered sample, add accurately 25 mL of 70% ethanol, ultrasonicate for 30 minutes, filter and transfer the filtrate to a 50-mL volumetric flask. Repeat the extraction of the residue one more time. Combine the filtrate, make up to volume with 70% methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (277 nm) and a column packing L1. The column temperature is maintained at 35℃. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of baicalin should not be less than 5,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~25	41	59
25~45	41→60	59→40

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Baicalin (%)=0.005 (r_U/r_S) (C_S) / (W)
   r_U: peak area of baicalin of sample solution
   r_S: peak area of baicalin of reference standard solution
   C_S: concentration of baicalin of reference standard solution (μg/mL)
   W: weight of test sample (g) calculated with dried sample.
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from insects.
Usage: Heat-clearing medicinal (Heat-clearing and dampness-drying medicinal).
Property and flavor: Cold; bitter.
Meridian tropism: Lung, gallbladder, spleen, heart, large intestine, and small intestine meridians.
Effects: Clear heat and dry dampness, purge fire and detoxicate, cool the blood and stop bleeding, eliminate heat and prevent miscarriage.
Administration and dosage: 3~10 g.

【Decoction pieces】

SCUTELLARIAE RADIX

It contains not less than 26.0% of dilute ethanol-soluble extractives, not less than 18.0% of water extractives and not less than 8.0% of baicalin.
Raw medicinal materials are processed to remove impurities, clean selection, soften thoroughly, cut into thin slices, and dry, or steam for half an hour, take out, then cut into thin slices and dry, mostly subrounded thin slices. Slices surface dark yellow to yellowish-brown, irregular and rough margin, yellow vascular bundles in the centre, occasionally withered or hollowed in the center of the flake, brown dots, Odour slight.

Thin layer chromatographic identification test: The method is the same as that for crude herb.
Impurities and other requirements: Methods and specifications are the same as those for crude herb.
Assay: The method is the same as that for crude herb.
Storage: The method is the same as that for crude herb.
Usage: Heat-clearing medicinal (Heat-clearing and dampness-drying medicinal).

Property and flavor: Cold; bitter.
Meridian tropism: Lung, gallbladder, spleen, heart, large intestine, and small intestine meridians.
Effects: Clear heat and dry dampness, purge fire and detoxicate, cool the blood to stop bleeding, eliminate heat to prevent abortion.
Administration and dosage: 3~10 g.

SELAGINELLAE HERBA
卷柏
Jyuan Bo / Juan Bo
Tamarishoid Spikemoss Herb

Tamarishoid spikemoss herb is the dried herb of *Selaginella tamariscina* (P.Beauv.) Spring or *Selaginella pulvinata* (Hook. & Grev.) Maxim. (Fam. Selaginellaceae).
It contains not less than 4.0% of dilute ethanol-soluble extractives, not less than 5.0% of water extractives and not less than 0.5% of amentoflavone.
Description: Crumpled into masses, fist-shaped or flattened spheroidal, varying in size, 3~10 cm in length. Branches fascicled, flat and branched, green or brownish-yellow, curved inwards, densely growing scaly leaflets at the apex. Central leaves (ventral leaves) ovate-oblong, arranged obliquely upward, margin membranous. Dorsal leaves (lateral leaves), membranous margin of dorsal surface frequently brownish-black or grayish-brown, margin irregular serrate or entire, glabrous. Texture fragile, easily broken. Base remained with fibrous roots. Odour slight; taste weak.

Microscopic identification:
1. **Transverse section:**
   Selaginellae Herba: Outermost layer composed of 1 row of epidermis, subrounded or suboblong, the outer walls slightly thickened; inside showing sclerenchyma, 12~15 layers, cells subrounded or suboblong, subisodiametric, cell diameter gradually increase from outside to inside. Parenchymatous cells of cortex 4~6 layers, subrounded or ovoid, leaf-trace vascular bundles occasionally found, every vascular bundle surrounded by aerenchyma. Endothelium is not obvious, vascular bundle is externally sieved, xylem inside is 2 prototypes, sieve cells are rectangular in shape and irregular in shape. Tracheid main is the scalariform, occasionally the thread, 4~30μm in diameter, cells subround, subpolygonal, middle diameter is the largest, gradually smaller toward both sides.
2. **Powder:** Grayish-green. Epidermal cells of leaf subrectangular or subpolygonal in surface view, with some oblong stomata. Tracheids mainly scalariform, spiral tracheids occasionally found, 4~30 μm in diameter. Epidermal cells of stem covered with cuticle, cells subrectangular or subpolygonal. Sclerenchyma cells subrounded or suboblong, with moniliform pits.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter, evaporate the filtrate to dryness, dissolve the residue in 1 mL of methanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of isopropanol, concentrated ammonia solution, and water (13:1:1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 2% $AlC1_3$/EtOH TS. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:
1. Loss on drying: Not more than 11.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 15.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 13.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).

Assay:
1. Amentoflavone:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and 0.1% phosphoric acid as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of amentoflavone, and dissolve in methanol to produce a solution containing 25 μg per mL.
   (3) Sample solution: Weigh accurately 0.2 g of the powdered sample and place it in a 100-mL round bottom flask, then add accurately 50 mL of methanol, heat under reflux for 2 hours, cool, filter with filter paper and transfer the filtrate to 50-mL volumetric flask, make up to volume with methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (330 nm) and a column packing L1. The column temperature is maintained at 25℃. The flow rate is about 1 mL/min. Program the chromatographic gradient

system as follows. The number of theoretical plates of the peak of amentoflavone should not be less than 8,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~15	20→50	80→50
15~18	50→100	50→0

(5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Amentoflavone (%)=0.005(r_U/r_S) (C_S) / (W)

r_U: peak area of amentoflavone of sample solution

r_S: peak area of amentoflavone of reference standard solution

C_S: concentration of amentoflavone of reference standard solution (μg/mL)

W: weight of test sample (g) calculated with dried sample.

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place.
Usage: Blood-regulating medicinal (Hemostatic medicinal).
Property and flavor: Neutral; pungent
Meridian tropism: Liver meridians.
Effects: Activate blood to promoting menstruation, stasis-dispelling and hemostatic.
Administration and dosage: 4.5~9 g.
Precaution and warning: Use cautiously during pregnancy.

SEMIAQUILEGIAE RADIX
天葵子
Tian Kuei Zih / Tian Kuei Zih
Semiaquilegia Root Tuber

Semiaquilegia root tuber is the dried root tuber of *Semiaquilegia adoxoides* (DC.) Makino (Fam. Ranunculaceae).
It contains not less than 51.0% of dilute ethanol-soluble extractives and not less than 54.0% of water extractives and not less than 0.02% of griffonilide.

Description: Irregular short column, spindle or block, slightly curved, 2~3 short branches, 1~3 cm in length,0.5~1 cm indiameter, externally dark brown to grayish black, with irregular wrinkles, fibrous roots or scars of fibrous roots, apex usually remained with stem base or leaves base, several layers of yellow-brown sheath scales, swollen in the center. Texture soft, easily broken, fracture bark almost white; wood yellowish-white or yellowish-brown, slightly radially arranged, odor slight; taste sweetish, slightly pungent and bitter.

Microscopic identification:
1. **Transverse section:**
Root tuber of *Semiaquilegia adoxoides*: Cork several layered, containing brown contents. Cortex relatively narrow. Phloem relatively broad. Cambium in a ring. Xylem rays broad to 20 layers of cells, vessel bundles arranged radially, some vessels scattered in the center, small pith distinct in the center.
2. **Powder:** Dark grayish-brown. Cork cells subsquare, subrectangular or polygonal, thick-walled, sometime containing yellowish-brown to dark reddish-brown contents. Parenchymatous cells of long ovate or irregular, wall thin. Vessels mainly reticulate.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 2.0 g of powdered sample to 20 mL of methanol, heat under reflux for 30 minutes, cool, filter, evaporate the filtrate to dryness, and dissolve the residue in 5 mL of methanol.
2. Reference drug solution: Take 2.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of griffonilide and dissolve in methanol to produce a solution containing 2.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and the lower layer of dichloromethane, methanol, and water (6:2:0.5) as the developing solvent. Apply 2 μL of each of the sample solution and reference drug solution and 5 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 254 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 18.0% dry at 105°C for 5 hours (General rule 6015).
2. Total ash: Not more than 7.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 4.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).

8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Griffonilide:
   (1) Mobile phase: A solution of acetonitrile and 0.5% formic acid (5:95). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of griffonilide, and dissolve in methanol to produce a solution containing 5 μg per mL.
   (3) Sample solution: Weigh accurately 0.5 g of powdered sample and place it in a 50-mL conical flask with a stopper, add 12.5 mL of methanol, ultrasonicate for 30 minutes, filter to 25-mL volumetric flask. Repeat the extraction of the residue one more time. Combine the filtrate and make up to volume with methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (258 nm) and a column packing L1. The column temperature is maintained at 25℃. The flow rate is about 0.7 mL/min. The number of theoretical plates of the peak of griffonilide should not be less than 1,000.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   Griffonilide : (%)=0. 0025 (r_U/r_S) (C_S) / (W)

   r_U: peak area of griffonilide of sample solution

   r_S: peak area of griffonilide of reference standard solution

   C_S: concentration of griffonilide of reference standard solution (μg/mL)

   W: weight of test sample (g) calculated with dried sample.

Storage: Store in a ventilated and dry place, and protect from insects.
Usage: Heat-clearing medicinal (Heat-clearing and detoxicating medicinal).
Property and flavor: Cold; bitter and sweet.
Meridian tropism: Liver and stomach meridians.
Effects: Clear heat and detoxicate, remove swelling and disperse stagnation.
Administration and dosage: 9~15 g.

SENNAE FOLIUM
番瀉葉
Fan Sie Ye / Fan Xie Ye
Senna Leaf

Senna leaf is the dried leaflet of *Senna alexandrina* Mill. (*Cassia acutifolia* Dehile；*Cassia angustifolia* Vahl) (Fam. Leguminosae).
It contains not less than 1.1% of the total amount of sennoside A and sennoside B.

Description: Lanceolate or narrowly lanceolate, 1.5~5 cm in length, 0.5~2 cm in width, pale grayish-yellow to pale yellowish-green, margin enter, apex acute, base slightly asymmetrical, with short petiole. Vein protuberant. Lower surface covered with sparse hairs. Odour slight; taste slightly bitter.

Microscopic identification:
Transverse section:
Leaflet of *Senna alexandrina*: Both upper and lower epidermis composed of 1 row of epidermal cells with stomata. Mesophyll isobilateral, composed of 2 rows of palisade cells, located at inner side of upper and lower epidermis respectively. The upper layer cells of palisade tissue relative long, up to 150 μm in length. The lower layer cells of palisade tissue 35~60 μm in length. Prisms and clusters of calcium oxalate scattered in parenchymatous cells. Several dozens fibers in bundles, surrounded by parenchymatous cells containing prisms of calcium oxalate, forming crystal fibers. Vascular bundles collateral. Collenchyma located at the inner side of the lower epidermis. Non-glandular hairs occasionally visible in lower epidermis.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 2.0 g of powdered sample to 25 mL of methanol, ultrasonicate for 30 minutes, stand, filter and use the filtrate.
2. Reference drug solution: Take 2.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately 1.0 mg of sennoside A and sennoside B in 1 mL of tetrahydrofuran and water (7:3) to produce a solution containing 1.0 mg per mL of each.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, *n*-propanol, glacial acetic acid, and water (3:3:0.2:2) as the developing solvent. Apply 10 μL of each of the sample solution and reference drug solution and 1 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 254 nm. The red spots in the chromatogram obtained with the sample solution correspondings in R_f values and color to the spots in the chromatogram obtained with the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Foreign matter: Petioles and fruits not more than 5.0% (General rule 6005).
2. Foreign matter: Not more than 1.0%, except for petioles and fruits (General rule 6005).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)
8. Pesticide residues:
   (1) The total DDT content: Not more than 0.2 ppm (General rule 6305).
   (2) The total BHC content: Not more than 0.9 ppm (General rule 6305).
   (3) The total PCNB content: Not more than 1.0 ppm (General rule 6305).

Assay:

1. Sennoside A and sennoside B:
   (1) Mobile phase: Add 2.45 g of tetraheptylammonium bromide in 1,000 mL solution of acetonitrile and 0.1M acetic acid-sodium acetate buffer solution (pH5.0) (35：65). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of sennoside A and sennoside B in a brown volumetric flask, dissolve in 0.1% sodium carbonate to produce a solution containing 50 μg and 0.1 mg per mL of each.
   (3) Sample solution: Weigh accurately 0.5 g of the powdered sample and place it in a conical flask with a stopper, accurately add 50 mL of 0.1% solution of sodium carbonate, weigh, ultrasonicate under 30~40℃ for 15 minutes, cool, weigh again and replenish the loss of the weight with 0.1% solution of sodium carbonate, mix well, filter and use the filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (340 nm) and a column packing L1. The column temperature is maintained at 40℃. The number of theoretical plates of the peak of sennoside B should not be less than 6,500.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   Sennoside A or sennoside B (%)=0.005 (r_U/r_S) (C_S) / (W)

   r_U: peak area of sennoside A or sennoside B of sample solution

   r_S: peak area of sennoside A or sennoside B of reference standard solution

   C_S: concentration of sennoside A or sennoside B of reference standard solution (μg/mL)

   W: weight of test sample (g) calculated with dried sample.

Storage: Store in a cool and dry place, and protect from light.
Usage: Purgative medicinal (Offensive purgative medicinal).
Property and flavor: Cold; sweet and bitter.
Meridian tropism: large intestine meridians.
Effects: Purging and remove food stagnation.
Administration and dosage: 2~6 g
Precaution and warning: Use cautiously during pregnancy.

SEPIAE ENDOCONCHA
海螵蛸
Hai Piao Siao / Hai Piao Xiao
Cuttlebone

Cuttlebone is the dried internal shell of *Sepiella inermis* (Van Hasselt) or *Sepia esculenta* Hoyle (Fam. Sepiidae).
Description:

1. Internal shell of *Sepiella inermis*: Flattened oblong, thick in the central part and thin at the edge, 9~14 cm in length, 2.5~3.5 cm in width, 1.2~1.5 cm thick. The dorsal surface bearing a porcelain white ridge-like protuberance, both sides slightly reddish, with indistinct minute tubercles arranged in semi-annular striations. The ventral surface white, with fine and dense undulate transverse striations from the caudal end to the middle portion. The caudal portion relatively wide and even, without bony spine. Texture light and fragile, fracture white, powdery, with slightly curved parallel striations. Odour slightly stinking; taste slightly salty.
2. Internal shell of *Sepia esculenta*: 13~23 cm in length, 5~7 cm in width, 0.8~1.2 cm thick, relatively thicker in the front part. The dorsal surface with distinct larger tubercles, slightly laminated arranged. The ventral surface mostly covered by the undulate transverse striations, with a distinct dark purple transverse striations in the front. The horny margin of the caudal portion gradually widen and curved ventrally, with a bony spine at the end, usually broken and fallen off.

Microscopic identification:
Powder: Off-white. Under the microscope identification, irregular transparent thin slices abundant, some with fine striations; some in irregular broken pieces, with reticulate or dotted striations on the surface.

Identification:
Take a quantity of powdered sample, add drops of dilute hydrochloric acid, bubble is produced.

Impurities and other requirements:
1. Loss on drying: Not more than 6.0% dry at 105℃ for 5 hours (General rule 6015).
2. Acid-insoluble ash: Not more than 16.0% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 5.0 ppm (General rule 2211, 6301).
5. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
6. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Storage: Store in a ventilated and dry place.
Usage: Astringent medicinal.
Property and flavor: Mild warm; salty and astringent.
Meridian tropism: Liver and kidney meridians.
Effects: Astringes and hemostatic, secure essence andstanch vaginal discharge, inhibit acidity to relieve pain, astringes moisture and wound healing.
Administration and dosage: 3~12 g, 1~4 g for powdering.

SESAMI SEMEN NIGRUM
胡麻仁
Hu Ma Ren / Hu Ma Ren
Black Sesame

Black sesame is the dried ripe seed of *Sesamum indicum* L. (Fam. Pedaliaceae). Commonly known as "Hei Zhi Ma".
It contains not less than 3.0% of dilute ethanol-soluble extractives and not less than 4.0% of water extractives.

Description: Flattened-ovate, one end acute, the other obtuse, 0.2~0.4 cm in length, 0.1~0.2 cm in width, about 0.1 cm thick. Externally black, with reticulate wrinkles or indistinct, apex with brown dotted hilum, testa membranous, endosperm thin membranous in longitudinal section, cotyledons 2, whitish, oily. Odour slight; taste slightly, oily aromatic after crushing.

Microscopic identification:
1. **Transverse section:**
   Seed of *Sesamum indicum*: layer of testa composed of 1 row of cylindrical cells arranged palisade-like, cells filled with black pigments, containing spherical crystals of calcium oxalate, aggregated by numerous cylinder prisms of calcium oxalate; inside showing 1 row of suboblong parenchymatous cells, cylinder prisms of calcium oxalate usually found; inside showing flat fragments of perisperm cells, endosperm composed of 3~4 rows of parenchymatous cells. Cotyledons 2, palisade cells existed under the upper epidermis. Cells of endosperm and embryo filled with aleurone grains and fatty oil.
2. **Powder:** Grayish-black. Testa cells polygonal in surface view, lumen filled with black pigments and spherical crystals of calcium oxalate, 25~48 μm in diameter. Cylinder prisms of calcium oxalate subcylindrical or subclavate, about 24 μm in length. Cells of cotyledons and embryo contain abundant aleurone grains and fatty oil droplets.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of sesamin and dissolve in absolute ethanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane, ethyl ether, and ethyl acetate (40:11:5) as the developing solvent. Apply 5 μL of the sample solution and reference drug solution and 2 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 7.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 8.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:
1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).

2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place, and protect from insects.
Usage: Tonifying and replenishing medicinal (Yin-tonifying medicinal).
Property and flavor: Neutral; sweet.
Meridian tropism: Liver, kidney, and large intestine meridians.
Effects: Tonify qi and essence blood, moisten dryness and lubricate intestines.
Administration and dosage: 9~15 g.

SIGESBECKIAE HERBA
豨莶草
Si Lian Cao / Xi Lian Cao
Glandularstalk St. Paulswort Herb

Glandularstalk St. Paulswort herb is the dried aerial part of *Sigesbeckia orientalis* L., *Sigesbeckia pubescens* (Makino) Makino or *Sigesbeckia glabrescens* (Makino) Makino (Fam. Compositae).
It contains not less than 13.0% of dilute ethanol-soluble extractives and not less than 4.0% of water extractives.

Description:
1. Aerial part of *Siegesbeckia orientalis*: Stems 30~120 cm in length, 3~12 mm in diameter, the lower part subcylindrical or flattened cylindrical, externally grayish-brown, occasionally with purplish-brown, with distinctly longitudinal furrows and fine wrinkles, covered with grayish-white pubescence; nodes distinct, slightly swollen; the upper part complex dichotomous branching, covered with dense grayish-white pubescence; texture light and fragile, easily broken, fracture yellowish-white or pale green, pith hollowed or whitish. Leaves opposite, lamina crumpled or rolled, ovate-lanceolate as whole, grayish green, 1.2~3.5 cm in length, 2.5~7 cm in width, margin shallow undulate or entire. Some bearing heads, peduncles with dense grayish-white piloses. Some bearing obovoid achenes, about 3~3.5 mm in length. Odour slight; taste slightly bitter.
2. Aerial part of *Siegesbeckia pubescens*: The upper part of stem with relatively more dichotomous branching. Leaves ovoid as whole, margin crenate with grayish-white pubescence. Peduncles with dark brown glandular-pubescence or long piloses. Achenes about 3.5 mm in length. Odour slight; taste slightly bitter.
3. Aerial part of *Siegesbeckia glabrescens*: Stem relatively slender, less than 80 cm in length. The upper part of stem with separate grayish-white pubescence. Leaves ovoid as whole, margin regularly serrate. Achenes about 2 mm in length. Odour slight; taste slightly bitter.

Microscopic identification:
1. **Transverse section:**
   (1) Stem of Sigesbeckiae Herba: Epidermis composed of 1 row of subrectangular to subpolygonal cells, covered with cuticle, containing non-glandular hairs. The outer part of cortex composed of 5~6 layers of subrounded or subpolygonal collenchyma tissue; inside showing several dozens rows of parenchymatous cells, containing yellowish-brown contents. Pericyclic fiber bundles arranged in an interrupted ring; vascular bundles arranged in a ring; cambium indistinct; xylem well developed. Vessels mainly bordered-pitted, reticulate and spiral
   (2) Leaf of Sigesbeckiae Herba: Upper epidermis with anticlinal walls slightly straight, lower epidermis with anticlinal walls sinuous, with stomata and hairs. Non-glandular hairs composed of 4~6 cells, glandular hairs composed of overlapped 4 cells. Palisade tissue 1 row, spongy tissue 2~3 rows. Outside the phloem scattered with a few of fibers, xylem cells lignified.
2. **Powder:** Grayish-white. Non-glandular hairs 1- to 6-celled, the apex relatively slender, the base relatively large. Glandular hairs subrounded in top view, composed of 4~6 cells, containing pale yellowish-brown contents. Parenchymatous cells subpolygonal, subsquare or subrounded, containing yellowish-brown contents. Vessels mainly bordered-pitted, reticulate and spiral, 12~88 μm in diameter. Xylem fibers scattered or in bundles, with pits cleft-shaped. Mesophyll contains clusters of calcium oxalate, 8~14 μm in diameter. Pollen grains occasionally found, subrounded, with spiny protuberance on the surface.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 15 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of kirenol and dissolve in methanol to produce a solution containing 0.1 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of chloroform and methanol (4:1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 5% vanillin/H_2SO_4 TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug

solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 13.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 13.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 4.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:
1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place.
Usage: Dampness-dispelling medicinal (Wind-dampness-dispelling medicinal).
Property and flavor: Cold; pungent and bitter.
Meridian tropism: Liver and kidney meridians.
Effects: Dispel wind dampness, unblock the meridian, clear heat and detoxicate.
Administration and dosage: 9~15 g.

SINAPIS ALBAE SEMEN
白芥子
Bai Jie Zih / Bai Jie Zi
White Mustard Seed

White mustard seed is the dried ripe seed of *Sinapis alba* L. (Fam. Cruciferae).
It contains not less than 12.0% of dilute ethanol-soluble extractives, not less than 11.0% of water extractives and not less than 0.5% of sinapine, calculated with sinapine cyanide sulfonate.

Description: Spheroidal, 1~2.5 mm in diameter. Externally grayish-white or yellowish-white, glossy, finely reticulated, with a dark colored and point-like hilum. Testa thin and fragile, after cutting, shows 2 cotyledons folded as saddle, radicle folded hidden in between the cotyledons. Odourless; taste slightly pungent.

Microscopic identification:
1. **Transverse section:**
   Seed of *Sinapis alba*: Epidermis composed of 1 layer of mucilage cells with mucilage striations; hypodermis composed of 2 layers of cells, approximately equal in size; palisade cells composed of 1 layer of sclerenchyma cells, approximately equal in height, with thickened inner and lateral walls and thin outer walls; pigment cells fallen off, without pigments. Endosperm composed of 1~2 layers of subrectangular cells, containing aleurone grains. Cotyledons and parenchymatous cells of radical contain fatty oil droplets and aleurone grains.
2. **Powder:** Pale brown. Palisade cells of testa pale yellow, composed of 1 layer of cells, approximately equal to height in sectional view, 14~26 μm in length, 7~17 μm in diameter, with thin outer and above the middle of lateral walls and thickened inner and lower lateral walls; subpolygonal or slightly extended in surface view, anticlinal walls straight or with curved undulation, 2~3 μm thick. Epidermal cells of testa subsquare or radially elongated in sectional view, swollen and mucification when moistened with water. Inner surface with indistinct longitudinal rod-shaped cellulose column formed by sedimentary cellulose; polygonal or subpolygonal in surface view, umbilical-shaped cellulose column surrounded by mucilage striations. Hypodermal cells of testa mostly shrunken, with indistinct intercellular spaces. Endosperm cells contain aleurone grains, oil droplets and gray granules; cotyledon cells contain aleurone grains and fatty oil droplets.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 50 mL of methanol, ultrasonicate for 1 hour, filter and evaporate the filtrate to dryness, and dissolve the residue in 5 mL of methanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of sinapine cyanide sulfonate and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, acetone, formic acid, and water (3.5:5:1:0.5) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 10.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 6.0% (General rule 6007).

3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:

1. Sinapine:
   (1) Mobile phase: A solution of acetonitrile and 0.08 M potassium dihydrogen phosphate solution (10:90). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of sinapine cyanide sulfonate and dissolve in mobile phase to produce a solution containing 0.2 mg per mL.
   (3) Sample solution: Weigh accurately 1.0 g of powdered sample and place it in a conical flask with a stopper, add 50 mL of methanol, ultrasonicate for 20 minutes, and filter. Repeat the extraction of the residue three more times. Combine the filtrates and evaporate the filtrates to dryness. Dissolve the residue with mobile phase, transfer to a 50-mL volumetric flask, make up to volume with mobile phase, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (326 nm) and a column packing L1. The column temperature is maintained at 23 ± 4°C. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of sinapine should not be less than 3,000.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Sinapine: (%)= 5(r_U/r_S) (C_S) / (W)
   r_U: peak area of sinapine of sample solution
   r_S: peak area of sinapine of reference standard solution
   C_S: concentration of sinapine of reference standard solution (mg/mL)
   W: weight of test sample (g) calculated with dried sample.
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from moisture.
Usage: Phlegm-dispelling medicinal (Cold-phlegm warming and resolving medicinal).
Property and flavor: Warm; pungent.
Meridian tropism: Lung meridians.
Effects: Warm and resolve cold phlegm, promote qi to dissipate stasis, disperse swelling to relieve pain.
Administration and dosage: 3~10 g; used an appropriate amount for external use.

SIPHONOSTEGIAE HERBA
北劉寄奴
Bei Liou Ji Nu / Bei Liou Ji Nu
Chinese Siphonostegia Herb

Chinese siphonostegia herb is the dried herb of *Siphonostegia chinensis* Benth. (Fam. Scrophulariaceae). It contains not less than 10.0% of dilute ethanol-soluble extractives and not less than 10.0% of water extractives and not less than 0.06% of luteolin.

Description: Whole length is 30~80 cm. Stems erect cylindrical, vary length. Externally brown or dark brown. Brittle, easy break. Yellow-white edge of the cross-section fibrillar, center loose. Leaves opposite, more detached broken, intact plume, black-green. Racemes terminal, flowers shortly stalked, calyx long tubular, yellowish brown to black-brown, with 10 longitudinal ribs, apex 5-lobed. Most of the calyx contains long elliptical and pointed fruits. Surface of the fruit black, longitudinal edges, 0.5~1 cm in length. Brittle and easy break, contains many small long-shaped seeds. Surface shrunk , brown. Odor slight, taste light.

Microscopic identification:

1. **Transverse section:**
   Stem of *Siphonostegia chinensis*: Partially contains yellow-brown material. Epidermis can be seen as non-glandular hairs, 2~4 cells of non-glandular hairs, Cortex consists of 2~4 cells. Middle column sheath fibers arranged in a ring. Phloem narrower, outside, epidermal cells linearly elongated, cell wall thickened, cork corked. Bottom surrounded by 4~6 layers of Parenchyma cells, The side is surrounded by a circle of 1~3 layers of fibers. Wall thick, cell small, lignification. Section polygonal and subelliptical. Formation layer not obvious. Xylem developed, consisting of 10 layers of catheters and xylem fibers. Catheter separated by the pith line, myelin line obvious and lignified, stepped lines, edged hole pattern, threaded catheter, 10~50 μm in diameter, lignification strong. Medulla large, soft cells of the medulla large, many large cell gaps.
2. **Powder:** Yellowish brown. Non-glandular hairs composed of several cells, sharp upper tip. Catheter stepped pattern, rim hole and threaded conduit, 10~50 μm in diameter, strongly lignified. Length of the fibers is different, most of them sharp at both

ends, some of them are slightly oblique at one end, wall thick, cell small, 9~27 μm in diameter, lignification strong.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 2.0 g of powdered sample to 20 mL of methanol, ultrasonicate for 30 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 1 mL of methanol.
2. Reference drug solution: Take 2.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of luteolin and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of dichloromethane, methanol, and formic acid (20:4:0.8) as the developing solvent. Apply 5 μL of each of the sample solution and reference drug solution and 2 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with $AlC1_3$/EtOH TS. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 11.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 8.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.5% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

Luteolin:

1. Mobile phase: A solution of acetonitrile and 0.3% phosphoric acid (30:70). The ratio may be adjusted, if necessary.
2. Reference standard solution: Weigh accurately a quantity of luteolin and dissolve in methanol to produce a solution containing 25 μg per mL.
3. Sample solution: Weigh accurately 0.5 g of the powdered sample and place it in a conical flask with a stopper, then add accurately 40 mL of ethanol, heat under reflux for 30 minutes, cool, transfer to 50-mL volumetric flask, make up to volume with ethanol, mix well, filter and use the filtrate.
4. Chromatographic system: The liquid chromatography is equipped with an UV detector (349 nm) and a column packing L1. The column temperature is maintained at 25℃. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of luteolin should not be less than 3,000.
5. Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   Luteolin: (%)= 0.005(r_U/r_S) (C_S) / (W)

   r_U: peak area of luteolin of sample solution

   r_S: peak area of luteolin of reference standard solution

   C_S: concentration of luteolin of reference standard solution (μg/mL)

   W: weight of test sample (g) calculated with dried sample

Storage: Store in a ventilated and dry place.
Usage: Blood-regulating medicinal (Blood-activating and stasis-dispelling medicinal).
Property and flavor: Cold; bitter.
Effects: Activate blood and eliminate stasis, free the collateral vessels to relieve pain, cool the blood to hemostatic, clear heatand drain dampness.
Administration and dosage: 6~12 g.

SIRAITIAE FRUCTUS
羅漢果
Luo Han Guo / Luo Han Guo
Grosvenor Shiratia Fruit

Grosvenor shiratia fruit is the dried ripe fruit of *Siraitia grosvenorii* (Swingle) C.Jeffrey ex A.M.Lu & Zhi.Y.Zhang (Fam. Cucurbitaceae).
It contains not less than 25.0% of dilute ethanol-soluble extractives, not less than 25.0% of water extractives and not less than 0.50% of mogroside V.

Description: Spheroidal or ellipsoidal, 4~7 cm in diameter. Externally yellowish-brown or brown, lustrous, pubescent, occasionally with dark longitudinal wrinkles. The center of apex with persistent stylopodium, base with fruit stalk. Texture light and fragile, easily broken, fracture yellowish-white, lax as spongy. Mesocarp and endocarp spongy, pale brown. Seeds numerous, flattened spheroidal, brownish-red, 1.5~2 cm in length, 0.7~1.5 cm in width, 3~4 mm thick, dented in the center, margin relatively thick, surround with radical furrows, containing 2 cotyledons. Odour slight; taste sweet.

Microscopic identification:

1. **Transverse section:**
   (1) Pericarp of *Siraitia grosvenorii*: Exocarp composed of 1 row of epidermal cells, covered with cuticle, 4~12 μm thick,

multicellular non-glandular hairs or its scars occasionally visible. On the outer side of mesocarp showing 4~6 rows of subrounded parenchymatous cells, inside mesocarp showing stone cell layer, composed of 6~9 rows of stone cells, subrounded, subsquare or polygonal. Vascular bundles bicollateral. Endocarp composed of 1 row of parenchymatous cells.

(2) Seed of *Siraitia grosvenorii*: Epidermis composed of 1 row of palisade tissue, 200~280 μm in length, 10~30 μm in width; inside showing several layers of sclerenchymatous fibers and large stone cell layer, arranged in a ring near seed. Endodermis composed of 1 row of flatten cells. Endosperm composed of 1~2 rows of cells. Cotyledon cells contain fatty oil droplets.

2. **Powder:** Yellowish-brown or brown. Palisade cells covered with cuticle, about 300 μm in length. Parenchymatous cells subrounded or irregular polygonal, with single pits. Stone cells abundant, stone cells of pericarp mostly in groups, yellow, square or ovate, 7~40 μm in diameter, wall thickened, with distinct pit canals; stone cells of testa subsquare, wall thin with pits. Fibers fusiform, 20~53 μm in length, 13~16 μm in diameter, lumen relatively large, with distinct wall pits. Vessels mainly spiral and scalariform. Non-glandular hairs composed of 6~10 cells, 150~450 μm in length, 30~40 μm in diameter, lumens contain brown contents.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of mogroside V and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, methanol, and water (5:2:1) as the developing solvent. Apply 2 μL of each of the sample solution and reference drug solution and 1 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 15.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 5.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Mogroside V:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and water as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of mogroside V, and dissolve in methanol to produce a solution containing 0.25 mg per mL.
   (3) Sample solution: Weigh accurately 1.0 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 25 mL of methanol, ultrasonicate for 30 minutes, filter with filter paper. Repeat the extraction of the residue two more times. Combine the filtrate, evaporate the filtrate to a small amount and transfer to 25-mL volumetric flask, make up to volume with methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (203 nm) and a column packing L1. The column temperature is maintained at 35℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of mogroside V should not be less than 10,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~40	10→45	90→55
40~60	45→95	55→5

   (5) Procedure: Inject accurately 20 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   Mogroside V (%)=2.5 (r_U/r_S) (C_S) / (W)

   r_U: peak area of mogroside V of sample solution

   r_S: peak area of mogroside V of reference standard solution

C_S: concentration of mogroside V reference standard solution (mg /mL)
W: weight of test sample (g) calculated with dried sample.

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place, and protect from moisture and insects.
Usage: Phlegm-dispelling medicinal (Cough-suppressing and panting-calming medicinal).
Property and flavor: Cool, sweett.
Meridian tropism: Lung and large intestine meridians.
Effects: Clear heat to moisten lung, suppress cough，soothe the throat, moisten the intestines.
Administration and dosage: 9~15 g.

SMILACIS GLABRAE RHIZOMA
土茯苓
Tu Fu Ling / Tu Fu Ling
Smooth Greenbrier Rhizome

Smooth greenbrier rhizome is the dried rhizome of *Smilax glabra* Roxb. (Fam. Liliaceae).
It contains not less than 5.0% of dilute ethanol-soluble extractives, not less than 5.0% of water extractives and not less than 0.45% of astilbin.
Description: Irregularly masses or subcylindrical, with knob-like protuberance, 5~22 cm in length. Externally yellowish-brown or grayish-brown, slightly lustrous, lumpy, remained with stiff fibrous roots, apex with scars of stem, some bark with irregularly fissured. Texture hard. Odour slight; taste slightly sweet and astringent.

Microscopic identification:
1. **Transverse section:**
Rhizome of *Smilax glabra*: Lower epidermis composed of 3~5 layers of cells, yellowish-brown, arranged densely, with thickened and lignified walls, some with pits. Cortex scattered with large mucilage cells, containing raphides of calcium oxalate. Pericycle scattered with collateral vascular bundles, relatively densely close to the center. Xylem usually contains 2 large vessels and numbers of small vessels; phloem contains some fibers. Parenchymatous cells contain numerous starch granules.
2. **Powder:** Pale brown. Simple starch granules subrounded, 8~48 μm in diameter, hilum slit-shaped, Y-shaped, cruciate or stellate, large granules with distinct striations; compound granules composed of 2~4 components. Raphides of calcium oxalate scattered or in bundles, 40~180 μm in length. Stone cells elongated-rounded, subsquare, subpolygonal, rectangular or subtriangular, 25~128 μm in diameter, walls 8~48 μm thick, some varying in thickness, pit canals mostly fine and branched. Fibers fusiform, short ones stone cell-shaped, mostly one end blunt-rounded and tapered at the other end, 22~72 μm in diameter, with walls extremely thickened, up to about 35 μm thick, some with walls varying in thickness or slightly thin at one side, pit canals short and dense, lumina vary in width. Bordered-pitted vessels up to about 48 μm in diameter, bordered pits mostly elongated laterally in scalariform; spiral and bordered-pitted tracheids occasionally found. Endodermal cells in fibrous roots occasionally visible, long strip-shaped or rectangular, up to about 50 μm in diameter, walls extremely thickened and lignified on three sides and thin on one side, pit canals long and branched irregularly.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 20 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of astilbin and dissolve in methanol to produce a solution containing 0.1 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of toluene, ethyl acetate, and formic acid (13:32:9) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air, spray with $AlC1_3$/EtOH TS and stand for 5 minutes. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 15.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 5.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:

1. Astilbin:
   (1) Mobile phase: A solution of methanol and 0.1% glacial acetic acid (39:61). The ratio of the solution varies as required.
   (2) Reference standard solution: Weigh accurately a quantity of astilbin and dissolve in 60% methanol to produce a solution containing 0.2 mg per mL.
   (3) Sample solution: Weigh accurately 0.8 g of powdered sample and place it in a round bottom flask, accurately add 100 mL of 60% methanol and weigh. Heat under reflux for 1 hour, cool and weigh again, replenish the loss of weight with 60% methanol, mix well. Filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (291 nm) and a column packing L1. The column temperature is maintained at 23 ± 4℃. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of astilbin should not be less than 5,000.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Astilbin (%)=10 (r_U/r_S) (C_S) / (W)
   r_U: peak area of astilbin of sample solution
   r_S: peak area of astilbin of reference standard solution
   C_S: concentration of astilbin of reference standard solution (mg/mL)
   W: weight of test sample (g) calculated with dried sample.
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place.
Usage: Heat-clearing medicinal (Heat-clearing and detoxcating medicinal).
Property and flavor: Neutral; sweet and bland.
Meridian tropism: Liver and stomach meridians.
Effects: Clear heat and detoxicate, eliminate dampness, promote urination benefit joint.
Administration and dosage: 15~60 g.

SOJAE SEMEN PREPARATUM
淡豆豉
Dan Dou Chih / Dan Dou Chi
Fermented Soybean

Fermented soybean is the fermented preparation obtained from the ripe seed of *Glycine max* (L.) Merr. (Fam. Leguminosae).

It contains not less than 12.0% of dilute ethanol-soluble extractives and not less than 12.0% of water extractives.

Description: Ellipsoidal, slightly flattened, 0.6~1 cm in length, 3~6 mm in width. Externally black, dull, with irregular wrinkles and a sallow membrane, one side with a strip-shape hilum, micropyle indistinct, testa mostly loose, some testa exfoliated to expose brown kernel, without endosperm. Texture soft, fracture brown-black, with tempeh odor.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of toluene, ethyl formate, and formic acid (5:4:1) as the developing solvent. Apply 8 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:

1. Loss on drying: Not more than 14.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 8.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:

1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from insects.
Usage: Exterior-releasing medicinal (Pungent-cold exterior-releasing medicinal).

Property and flavor: Cool, bitter and pungent.
Meridian tropism: Lung and stomach meridians.
Effects: Release exterior, eliminate vexation, promote sweating, invigorate stomach, disperse depressed heat.
Administration and dosage: 6~15 g.

SOPHORAE FLAVESCENTIS RADIX
苦參
Ku Shen / Ku Shen
Lightyellow Sophora Root

Lightyellow sophora root is the dried root of *Sophora flavescens* Aiton (Fam. Leguminosae).
It contains not less than 17.0% of dilute ethanol-soluble extractives, not less than 14.0% of water extractives and not less than 1.2% of the total amount of matrine and oxymatrine.

Description: Long cylindrical, apex swollen, irregular, remained with stem base, usually branched in lower part, 10~30 cm in length, 1~5 cm in diameter. Externally pale yellow or yellowish-brown, with distinct longitudinal wrinkles, lenticels protuberant and inward. Cork thin, texture hard, uneasily broken, fracture whitish-yellow, with distinct cambium ring. Odour sharp; taste extremely bitter. Sliced pieces oblique, varying in size and shape, 2~5 cm in length, 1~2 cm in width, 2~5 mm thick, fracture whitish-yellow, with annular cambium ring and radial striations.

Microscopic identification:
1. **Transverse section:**
   Root of *Sophora flavescens*: Cork composed of 6~12 rows of flat cells, occasionally fallen off. Cortex composed of about 20~30 rows of parenchymatous cell, vascular bundles scattered, containing prisms of calcium oxalate and starch granules. Phloem usually contains fibers in bundles, intrafascicular cambium indistinct. Xylem branches into 2~4 lines outwards, vessels 1~2 rows, 30~120 μm in diameter, reticulate and bordered-pitted vessels are visible, with 4~15 rows of rays. Pith in the center, scattered with a few of vessels and vascular bundles.
2. **Powder:** Pale yellow. Parenchymatous cells subrounded to subsquare or moniliform, containing crystals of calcium oxalate, rhombic or polygonal, starch granules also present, simple granules subrounded or ovate; compound granules numerous, composed of 2~10 components. Cork cells polygonal, pale brown to brown. Stone cells occasionally found, subrectangular, with thick walls. Vessels mainly bordered-pitted. Fibers and crystal fibers numerous, slender in a bundle, about 12~30 μm in diameter.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of ethanol, ultrasonicate for 30 minutes, cool, filter, and make up the filtrate to 10 mL.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and the lower layer of a solution of dichloromethane, methanol, and concentrated ammonia solution (5:0.6:0.3) below 10℃ as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with Dragendorff's reagent and $NaNO_2$/EtOH TS. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:
1. Loss on drying: Not more than 11.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 9.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 3.0% (General rule 6007).
5. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
6. Arsenic (As): Not more than 5.0 ppm (General rule 2211, 6301).
7. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
8. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
9. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:
1. Matrine and oxymatrine:
   (1) Mobile phase: A solution of acetonitrile, absolute ethanol, and 3% phosphoric acid (80:10:10). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of matrine and oxymatrine and dissolve in a solution of acetonitrile and absolute ethanol (80:20) to produce a solution containing 50 μg and 150 μg per mL of each.
   (3) Sample solution: Weigh accurately 0.3 g of powdered sample and place it in a conical flask with a stopper, add 0.5 mL of concentrated ammonia solution, add accurately 20 mL of chloroform, stopper tightly and weigh, ultrasonicate for 30 minutes, cool, weigh again, replenish the loss of the weight with chloroform, mix well. Filter and transfer 5 mL of successive filtrate,

accurately measured, to the pretreated neutral aluminium oxide column (100~200 mesh, 5.0 g, 1 cm in internal diameter). Elute with 20-mL quantities of chloroform, a solution of chloroform and methanol (7:3) successively, collect the eluates and evaporate to dryness. Dissolve the residue in a quantity of absolute ethanol, transfer to a 10-mL volumetric flask, make up to volume with absolute ethanol, mix well, filter and use the successive filtrate.

(4) Chromatographic system: The liquid chromatography is equipped with an UV detector (220 nm) and a column packing L18. The number of theoretical plates of the peak of matrine should not be less than 2,000.

(5) Procedure: Inject accurately 10 μL of the reference standard solution and sample solution into the liquid chromatography apparatus, and calculate the content.

Matrine or oxymatrine (%)=0.004(r_U/r_S) (C_S) / (W)

r_U: peak area of matrine or oxymatrine of sample solution

r_S: peak area of matrine or oxymatrine of reference standard solution

C_S: concentration of matrine or oxymatrine of reference standard solution (μg/mL)

W: weight of test sample (g) calculated with dried sample.

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place, and protect from moisture.
Usage: Heat-clearing medicinal (Heat-clearing and dampness-drying medicinal).
Property and flavor: Cold; bitter.
Meridian tropism: Heart, liver, stomach, large intestine, and bladder meridians.
Effects: Clear heat and dry dampness, dispel wind and kill worms, release heat and promote urination.
Administration and dosage: 4.5~9 g.

SOPHORAE FLOS ET FLOS IMMATURUS
槐花
Huai Hua / Huai Hua
Pagodatree Flower and Flower Bud

Pagodatree flower and flower bud is the dried flower and flower bud of *Styphnolobium japonicum* (L.) Schott (*Sophora japonica* L.) (Fam. Leguminosae). The former is called “Huai Hua”, and the latter is called “Huai Mi”.
It contains not less than 43.0% of dilute ethanol-soluble extractives and not less than 24.0% of water extractives and not less than 6.0% of rutin.

Description:
1. Huai Hua: Shrinking and curling, the petals are scattered. Calyx campanulate, yellowish green, about 1.5 cm in diameter, apex 5-lobed; petals 5, yellow or yellowish white, 1 piece is large, nearly round, apex dimple, and the remaining 4 are oblong. Stamens 10, 9 of them are joined together, filaments are slender. The pistil is cylindrical and curved. Light body. Odor slight , taste bitter.
2. Huai Mi: Oval or long oval, 2~8 mm in length, 2~3 mm in diameter. Calyx accounts for about 2/3 of the total length, a few are 1/2, calyx tube is yellowish green or grayish brown, with longitudinal veins, apex 5 lobes, The base is slightly pointed, sometimes with a short handle; not open corolla is oblate, exposed 2~4 mm, yellowish white or brownish yellow, with 10 stamens and 1 pistil. Odor slight, taste bitter.

Microscopic identification:
Transverse section:
Flower and flower bud of *Styphnolobium japonicum*: Round or oval. Corolla epidermal cells are polygonal or irregular, with a finely curved horny texture, microwave-like edge. Non-glandular hairs and stomata can be seen on the sepals, and many calcium oxalate crystals are stored in parenchyma cells. The pollen grains are subspherical, the outer wall is slightly thick, and the surface is smooth.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 15 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of rutin and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-butanol, acetic acid, and water (7:1:2) as the developing solvent. Apply 10 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% $AlC1_3$/EtOH TS. Examine under the ultraviolet light at 254 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 10.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 9.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 5.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General

rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
1. Rutin:
   (1) Mobile phase: A solution of methanol and 1.0% acetic acid (32:68). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of rutin and dissolve in methanol to produce a solution containing 30 μg per mL.
   (3) Sample solution: Weigh accurately 0.1 g of powdered sample and place it in a conical flask with a stopper, then add accurately 50 mL of methanol, weigh, ultrasonicate for 30 minutes, cool, weigh again, replenish the loss of the weight with methanol, mix well, filter. take accurately 2 mL of the filtrate to a 10-mL volumetric flask and make up to volume with methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (257 nm) and a column packing L1. The column temperature is maintained at 25℃. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of rutin should not be less than 2,000.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Rutin (%)=0.025(r_U/r_S) (C_S) / (W)
   r_U: peak area of rutin of sample solution
   r_S: peak area of rutin of reference standard solution
   C_S: concentration of rutin of reference standard solution (μg /mL)
   W: weight of test sample (g) calculated with dried sample.

Storage: Refrigerate or store in a cool and dry place, and protect from insects.
Usage: Blood-regulating medicinal (Hemostatic medicinal).
Property and flavor: Mild cold; bitter.
Meridian tropism: Liver and large intestine meridians.
Effects: Cool the blood to hemostatic, clear liver and purge fire.
Administration and dosage: 5~15 g.

SOPHORAE FLOS IMMATURUS
槐米
Huai Mi / Huai Mi
Pagodatree Flower Bud

Pagodatree flower bud is the dried flower bud of *Styphnolobium japonicum* (L.) Schott (*Sophora japonica* L.) (Fam. Leguminosae).
It contains not less than 25.0% of dilute ethanol-soluble extractives, not less than 20.0% of water extractives and not less than 15.0% of rutin.

Description: Slightly ovate and long-ovate, 2~8 mm in length, 2~3 mm in diameter. Calyx mostly about 2/3 or less 1/2 of all, calyx tube yellowish-green or grayish-brown, with longitudinal striations, apex 5-lobed, base slightly acute, occasionally with short pedicel. Corolla occurring above the calyx, flattened round, exposed 2~4 mm, yellowish-white or brownish-yellow. Stamens 10 and pistil 1. Odour slight; taste slightly bitter.

Microscopic identification:
Powder: Pale yellowish-brown. Non-glandular hairs 1- to 6-celled, complete ones up to 709 μm in length, 7~23 μm in diameter, multicellular ones with extremely long apical cells, the apex gradually acute or short acute, wall up to 9 μm thick, with irregularly cutinized spiral striations, separated from cell walls, occasionally with small warty protuberance; lumens of non-glandular hairs with thin walls containing yellow contents. Pollen grains spheroidal, 14~22 μm in diameter, with 3 germinal pores, pores round and large, surface smooth. Hesperidin crystals scattered in parenchymatous cells, yellow hesperidin crystals visible after treatment with chloral hydrate solution (no heating), minute raphides crystals aggregated into fan-shaped. Prisms of calcium oxalate present in parenchymatous cells of sepals, elongated-biconica, up to 29 μm in lengthl, 2~12 μm in diameter. Epidermal cells of sepals polygonal, walls straight or slightly curved, with non-glandular hairs or hair scars. Stomata anomocytic, with 4~8 subsidiary cells. Epidermal cells of petals and cells in inner walls of pollen sac are also visible.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 15 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of rutin and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-butanol, glacial acetic acid, and water (7:1:2) as the developing solvent. Apply 10 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10%

$AlC1_3$/EtOH TS. Examine under the ultraviolet light at 254 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Total ash: Not more than 10.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 4.0% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:
1. Rutin:
   (1) Mobile phase: A solution of methanol and 1% glacial acetic acid (32:68). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of rutin and dissolve in methanol to produce a solution containing 80 μg per mL.
   (3) Sample solution: Weigh accurately 0.1 g of the powdered sample and place it in a conical flask with a stopper, accurately add 50 mL of methanol, weigh, ultrasonicate for 30 minutes, cool, weigh again, replenish the loss of the weight with methanol, mix well, filter, take accurately 2 mL of the filtrate to a 10-mL volumetric flask and make up to volume with methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (257 nm) and a column packing L1. The column temperature is maintained at 25℃. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of rutin should not be less than 2,000.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Rutin (%)=0.025(r_U/r_S) (C_S) / (W)
   r_U: peak area of rutin of sample solution
   r_S: peak area of rutin of reference standard solution
   C_S: concentration of rutin of reference standard solution (μg /mL)
   W: weight of test sample (g) calculated with dried sample.
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from insects.
Usage: Blood-regulating medicinal (Hemostatic medicinal).
Property and flavor: Cold; bitter.
Meridian tropism: Liver and large intestine meridians.
Effects: Cool the blood to hemostatic, clear liver and purge fire.
Administration and dosage: 5~15 g.

SOPHORAE FRUCTUS
槐角
Huai Jiao / Huai Jiao
Sophora Fruit

Sophora fruit is the dried mature fruit of *Styphnolobium japonicum* (L.) Schott (*Sophora japonica* L.) (Fam. Leguminosae), commonly known as “Huai Shi”.
It contains not less than 54.0% of dilute ethanol-soluble extractives and not less than 42.0% of water extractives and not less than 5.0% of sophoricoside

Description: Cylindrical, sometimes curved, curled into a bead-like shape between seeds, easily broken at the contracture, epidermal yellowish green or yellowish brown, shiny, shrinking and rough, with yellow bands on one side. Residual column base with protrusions at the top, the base often has a petiole residue; the flesh is yellowish green, the meat is soft and sticky, and it is translucent and horny, and shrinks after drying. Each fruit has 1~6 seeds, the seeds are flat, elliptical, brown and black, and the surface is smooth. Hard, 2 cotyledons, yellowish green. Odour weak; taste slightly bitter, The seeds are chewed, bean flavor.

Microscopic identification:
Transverse section:
Fruit of *Styphnolobium japonicum*: The outer pericarp cells are arranged in 1 row, rectangular, and the outer wall is keratinized, and the pores are visible, and the surface is ring. The mesocarp is composed of multiple rows of parenchyma cells. The outer cells are arranged closely and the cavities are obvious. Most small stone cells are scattered at one end of the proximal umbilical cord. There are 1 column of endocarp cells, which are small and tangentially elongated. The outer side of the seed coat is a row of grid-like cells, arranged neatly, and the wall is lignified. There is one column of supporting cells underneath, which is in the shape of a sole. There are 2 cotyledons in the middle of the seed, and the periphery is endosperm cells.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of ethanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of sophoricoside and dissolve in ethanol to produce a solution containing 0.2 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, formic acid, and water (8:1:1) as the developing solvent. Apply 2 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 254 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 15.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 12.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Sophoricoside:
   (1) Mobile phase: Methanol as the mobile phase A, acetonitrile as the mobile phase B, and 0.1% phosphoric acid as the mobile phase C.
   (2) Reference standard solution: Weigh accurately a quantity of sophoricoside and dissolve in 50% ethanol to produce a solution containing 50 μg per mL.
   (3) Sample solution: Weigh accurately 0.1 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 40 mL of 50% ethanol, ultrasonicate for 30 minutes, centrifuge for 15 minutes. Take 1 mL of the supernatant and dilute to 2.5 mL, mix well, filter and use the filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (260 nm) and a column packing L1. The column temperature is maintained at room temperature. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of sophoricoside should not be less than 8,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)	Mobile phase C (%)
0~30	22→32	6	72→62
30~30.1	32→84	6	62→10
30.1~33	84	6	10

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Sophoricoside (%)=0.01(r_U/r_S) (C_S) / (W)

r_U: peak area of sophoricoside of sample solution

r_S: peak area of sophoricoside of reference standard solution

C_S: concentration of sophoricoside of reference standard solution (μg /mL)

W: weight of test sample (g) calculated with dried sample.

Storage: Store in a ventilated and dry place, and protect from insects.

Usage: Blood-regulating medicinal (Hemostatic medicinal).

Property and flavor: Cold; bitter.

Meridian tropism: Liver and large intestine meridians.

Effects: Cool the blood to hemostatic, clear liver and purge fire.

Administration and dosage: 6~15 g.

SOPHORAE TONKINENSIS RADIX ET RHIZOMA
山豆根
Shan Dou Gen / Shan Dou Gen
Vietnamese Sophora Root

Vietnamese sophora root is the dried root and rhizome of *Sophora tonkinensis* Gagnep. (Fam. Leguminosae).

It contains not less than 15.0% of dilute ethanol-soluble extractives, not less than 16.0% of water extractives and not less than 0.7% of the total amount of matrine and oxymatrine.

Description: Slender or stout cylindrical, often curved, 30~50 cm in length, 1~5 cm in diameter, with some sparse rootlets, its scars or bud scars, apex remained with stem base, with longitudinal wrinkles, lenticels less, externally yellow to blackish-brown, cork easily exfoliated, with longitudinal wrinkles, fracture even, fibrous, wood dark yellow, xylem bundle arranged in ring, Odour bean-like; taste very bitter.

Microscopic identification:

1. **Transverse section:**
   Root and rhizome of *Sophora tonkinensis*: Cork polygonal, composed of 6~12 layers of cells, pale brown or yellowish-brown in color, with thin or slightly thickened walls. The outer rows of cells in cortex containing prisms of calcium oxalate, scattered with lignified and thickened walls. Fiber bundles scattered in cortex and phloem, with lignified and thickened walls. Phloem undeveloped. Cambium arranged in a ring or indistinctly. Stele composed of vessels, xylem fibers and pith. Rays 1~8 layers wide, arranged radially. Bordered-pitted and reticulated vessels are found, mostly singly scattered or in groups. Starch granules occurred in parenchymatous cells, simple granules spheroidal or subspheroidal.
2. **Powder:** Pale yellow. Odourless but tastes extremely bitter. Cork cells polygonal, pale brown or yellow in color. Fibers and crystal fibers present in bundles or distributed singly, 10~40 μm in diameter, with endings obtusely rounded, irregular striations seen on the surface view. The fiber surrounded by prisms of calcium oxalate, some forming crystal fibers. The crystal fibers subrounded, subrectangular or irregular in shape, with irregular lignified and thickened walls, 20~40 μm long, 15~35 μm in diameter. Vessels mainly reticulate and bordered-pitted, 150~360 μm long. Starch granules with indistinct striation and hilum, 4~30 μm in diameter.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 0.5 g of powdered sample to 10 mL of dichloromethane and 0.2 mL of concentrated ammonia solution, shake for 15 minutes, filter, evaporate to dryness; dissolve the residue in 0.5 mL of dichloromethane.
2. Reference drug solution: Take 0.5 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of matrine and oxymatrine and dissolve in dichloromethane to produce a solution containing 1.0 mg per mL of each.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of dichloromethane, methanol, and concentrated ammonia solution (9:1:1) as the developing solvent. Apply 2~4 μL of each of the sample solution and reference drug solution and 4~6 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with modified Dragendorff's reagent. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 13.0% dry at 105°C for 5 hours (General rule 6015).
2. Total ash: Not more than 5.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:

1. Matrine and oxymatrine:
   (1) Mobile phase: A solution of acetonitrile, isopropanol, and 3.0% phosphoric acid (80:5:15). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of matrine and oxymatrine and dissolve in mobile phase to produce a solution containing 20 μg and 150 μg per mL of each.
   (3) Sample solution: Weigh accurately 0.5 g of powdered sample and place it in a conical flask with a stopper, accurately add 50 mL of a solution of chloroform, methanol and concentrated ammonia solution (40:10:1), stopper tightly and weigh, stand for 30 minutes and weigh again, ultrasonicate for 30 minutes, and weigh again, replenish the loss of a solution of weight with a mixture of chloroform, methanol and concentrated ammonia solution (40:10:1), shake well, filter it. Measure accurately 10 mL of the filtrate, recover the solvent in vacuum to dryness at 40°C, dissolve the residue in a small quantity of methanol, transfer to 10-mL volumetric flask, make up to volume with methanol, mix well, filter, and use the filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (210 nm) and a column packing L18. The number of theoretical plates of the peak of matrine should not be less than 4,000.
   (5) Procedure: Inject accurately 5 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Matrine and oxymatrine (%)=0.005 (r_U/r_S) (C_S) / (W)
   r_U: peak area of matrine and oxymatrine of sample solution
   r_S: peak area of matrine and oxymatrine of reference standard solution

Cs: concentration of matrine and oxymatrine of reference standard solution (μg/mL)
W: weight of test sample (g) calculated with dried sample.

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place, and protect from insects.
Usage: Heat-clearing medicinal (Heat-clearing and detoxcating medicinal).
Property and flavor: Cold; bitter.
Meridian tropism: Heart, lung, and stomach meridians.
Effects: Clear heat and detoxicate, promote throat, disperse swelling to relieve pain.
Administration and dosage: 3~11.5 g.
Precaution and warning: Contraindicated in spleen-stomach deficiency cold and sloppy.

SPARGANII RHIZOMA
三稜
San Ling / San Ling
Common Burreed Rhizome

Common burreed rhizome is the dried tuber of *Sparganium stoloniferum* (Graebn.) Buch.-Ham ex Juz. (Fam. Sparganiaceae).
It contains not less than 4.0% of dilute ethanol-soluble extractives and not less than 7.0% of water extractives.
Description: Conical, slightly compressed, few fusiform, apex round and base acute, with marks pared with a knife, 3~6 cm in length, 2~4 cm in diameter. Externally yellowish-white or grayish-yellow, with numerous scars of fibrous root arranged in ring, the upper part with stem scars, the lateral with 3~5 symmetrical protrusions (bud scars). Texture heavy, compact, fracture yellowish-white, starchy. Odour slight; taste weak, slightly numb on chewing.

Microscopic identification:
1. **Transverse section:**
Tuber of *Sparganium stoloniferum*: Epidermal cells yellowish- brown or reddish-brown, cell boundaries faintly visible, epidermal cells occasionally abraded. Cortex cells irregular in shape, containing aerenchyma, with large intercellular spaces, scattered with secretory cells, containing yellowish-brown secretions. Endodermis composed of 1 layer of rectangular cells, arranged densely. Vascular bundles scattered in amphivasal concentric type. Phloem with thin walls, cells irregular in shape. Xylem vessels slightly lignified, 5~20 μm in diameter, mainly scalariform, pitted and reticulate. Fibers of vascular bundle sheath existed outside xylem. Parenchymatous cells of stele subrounded, 20~50 μm in diameter, scattered with secretory cells, containing yellowish-brown secretions and abundant starch granules.
2. **Powder:** Yellowish-white. Odour slight; taste slightly bitter, astringent and numb. Epidermal cells yellowish-brown or reddish-brown, intercellular spaces faintly visible. Cortex cells irregular in shape. Vessels slightly lignified, 5~20 μm in diameter, mainly pitted and reticulate. Fibers mostly in bundles, fusiform, slightly lignified. Parenchymatous cells of stele subrounded, 20~50 μm in diameter. Secretory cells subrounded, containing yellowish-brown secretions, 15~35 μm in diameter. Starch granules extremely small, subrounded or elliptical, with indistinct striations, simple granules mostly aggregated into masses; compound granules rare.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of petroleum ether (30~60℃) and ethyl acetate (4:1) as the developing solvent. Apply 8 μL of each of the above solutions to the plate. Once the top of solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:
1. Loss on drying: Not more than 13.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 5.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:
1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).

2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from insects.
Usage: Blood-regulating medicinal (Blood-activating and stasis-dispelling medicinal).
Property and flavor: Neutral; pungent and bitter.
Meridian tropism: Liver and spleen meridians.
Effects: Break blood and move qi, resolve accumulation and relieve pain.
Administration and dosage: 4.5~11.5 g.
Precaution and warning: Avoid to use during pregnancy.

SPATHOLOBI CAULIS
雞血藤
Ji Sie Teng / Ji Xie Teng
Suberect Spatholobus Stem

Suberect spatholobus stem is the dried lianoid stem of *Spatholobus suberectus* Dunn (Fam. Leguminosae).
It contains not less than 6.0% of dilute ethanol-soluble extractives and not less than 5.0% of water extractives.
Description: Slightly flattened cylindrical, slightly curved, 1.5~7 cm in diameter, with three broad longitudinal furrows. Sliced pieces usually cut into oblong lump, 15~30 cm in length, or irregular slices, 0.3~1.5 cm thick. Cork grayish-brown or reddish-brown when the cork exfoliated. Texture compact and hard, uneasily broken. In the transversely cut surface, xylem reddish-brown or brown, showing distinctly numerous pores of vessels; phloem with blackish-brown resinous secretion, arranged alternately with xylem, forming 3~10 eccentric semi-circular or circular rings; pith small, inclined to one side. Odour slight; taste bitter and astringent.

Microscopic identification:
1. **Transverse section:**
Lianoid stem of *Spatholobus suberectus*: Cork composed of several layers of cork cells, containing brownish-red contents. Cortex relatively narrow, scattered with stone cell groups, lumen filled with brownish-red contents; parenchymatous cells contain prisms of calcium oxalate. Phloem arranged alternately with xylem in several whorls forming abnormal vascular bundles. Sclerenchymatous cell layer present at the outer side of phloem, composed of stone cell groups and fiber bundles; rays mostly compressed; secretory cells extremely numerous, filled with brownish-red contents, usually several to dozens arranged tangentially into layers; fiber bundles relatively numerous, unlignified to slightly lignified, surrounded by cells containing prisms of calcium oxalate, forming crystal fibers, walls of crystal-containing cells lignified and thickened; stone cell groups scattered. Xylem rays occasionally contain brownish-red contents; vessels singly scattered, subrounded, up to about 400 μm in diameter; xylem fiber bundles also form crystal fibers; few xylem parenchymatous cells contain brownish-red contents.
2. **Powder:** Brownish-red. Stone cells rectangular, subrounded, subtriangular or subsquare, 14~109 μm in diameter, wall 3~26 μm thick, striations and pit canals distinct, some lumens contain reddish-brown contents or prisms of calcium oxalate. Fibers slender, 6~25 μm in diameter, wall 3~8 μm thick, unlignified or lignified, mostly broken, the sectional ends truncate or slit to several strips, primary walls easily separated, with clefts on the surface, some slit longitudinally, few partially swollen into lacerate shape, pit canals and lumens indistinct. Some fiber bundles surrounded by cells containing prisms of calcium oxalate, forming crystal fibers, walls of crystal-containing cells unevenly lignified and thickened. Secretory cells and phloem rays usually arranged vertically, cell boundaries indistinct, lumens contain yellowish-brown or reddish-brown contents. Bordered-pitted vessels huge, mostly broken, intact ones 20~450 μm in diameter, bordered pits arranged densely, some pits with indistinct margins, pit apertures slit-shaped or elongated-oblong, few elongated and several linked; some vessel lumens contain brown contents. Cork cells singly scattered or several in groups, polygonal in surface view, anticlinal walls unevenly thickened and lignified, with slit-shaped pits on the surface, some lumens contain brown contents; subrectangular in sectional view, walls unevenly thickened or thickened on three sides and thin on one side. Xylem ray cells, brown masses and prisms of calcium oxalate also visible.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 2.0 g of powdered sample to 40 mL of methanol, ultrasonicate for 30 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 10 mL of water, extract by shaking with 10 mL of ethyl acetate, and discard the water solutions. Evaporate the ethyl acetate extract to dryness, dissolve the residue in 1 mL of methanol.
2. Reference drug solution: Take 2.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of formononetin and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of dichloromethane and methanol (15:1) as the developing solvent. Apply 2 μL of each of the sample solution and reference drug solution and 1 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in

the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Total ash: Not more than 4.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 3.0% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:
1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place, and protect from moisture and insects.
Usage: Blood-regulating medicinal (Blood-activating and stasis-dispelling medicinal).
Property and flavor: Warm; bitter and sweet.
Meridian tropism: Liver and kidney meridians.
Effects: Move blood and tonify blood, relax sinews and activate collateral.
Administration and dosage: 9~15 g.

SPIRODELAE HERBA
浮萍
Fu Ping / Fu Ping
Spirodela Herb

Spirodela herb is the dried herb of *Spirodela polyrrhiza* (L.) Schleid. (Fam. Lemnaceae).
It contains not less than 12.0% of dilute ethanol-soluble extractives and not less than 12.0% of water extractives and not less than 0.1% of luteolin-7-*O*-glucoside.

Description: Flat, suboval, diameter of about 2~5 mm. Upper epidermis pale brownish green, small depression on the lateral side, neat or slightly curled edge. Lower epidermis dark brownish green, several fibrous root. Light weight, fragile, Odor slight, taste light.

Microscopic identification:
Transverse section:
Leaf of *Spirodela polyrrhiza*: 1 epidermal cell, inner parenchyma cells subround or subelliptical, cells contain calcium oxalate clusters or needle crystals. Epithelial cells are wavy and have infinitive vent. The pericellular wall of the epidermis is nearly straight and has no stomata.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 0.2 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 0.2 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of luteolin-7-*O*-glucoside and dissolve in methanol to produce a solution containing 0.2 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, formic acid, and water (8:1:1) as the developing solvent. Apply 2 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 10.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 25.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 11.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:
1. Luteolin-7-*O*-glucoside:
   (1) Mobile phase: A solution of acetonitrile (contain 0.1% formic acid and 2 mM ammonium formate) as the mobile phase A, and 0.1% formic acid as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of luteolin-7-*O*-glucoside, and dissolve in methanol to produce a solution containing 25 μg per mL.
   (3) Sample solution: Weigh accurately 0.5 g of the powdered sample and place it in a 50-mL conical flask with a stopper, then add accurately 25 mL of methanol, ultrasonicate for 30 minutes, filter, transfer the filtrate to a 25-mL volumetric flask and make up to

volume with methanol, mix well, filter and use the successive filtrate.

(4) Chromatographic system: The liquid chromatography is equipped with an UV detector (254 nm) and a column packing L1. The column temperature is maintained at 35℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of luteolin-7-*O*-glucoside should not be less than 4,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~10	5→20	95→80
10~20	20	80
20~30	20→21	80→79
30~40	21→50	79→50

(5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Luteolin-7-*O*-glucoside (%)=0.0025(r_U/r_S) (C_S) / (W)

r_U: peak area of luteolin-7-*O*-glucoside of sample solution

r_S: peak area of luteolin-7-*O*-glucoside of reference standard solution

C_S: concentration of luteolin-7-*O*-glucoside of reference standard solution (μg/mL)

W: weight of test sample (g) calculated with dried sample.

Storage: Store in a ventilated and dry place, and protect from moisture.
Usage: Exterior-releasing medicinal (Pungent-cold exterior-releasing medicinal).
Property and flavor: Cold; pungent.
Meridian tropism: Lung and bladder meridians.
Effects: Dispel wind to release exterior, outthrust rashes, promote urination, dispel dampness and relieve itching.
Administration and dosage: 3~12 g; used an appropriate amount for external use.

STEMONAE RADIX
百部
Bai Bu / Bai Bu
Stemona Root

Stemona root is the dried root tuber of *Stemona sessilifolia* (Miq.) Miq., *Stemona japonica* (Blume) Miq. or *Stemona tuberosa* Lour. (Fam. Stemonaceae).
It contains not less than 55.0% of dilute ethanol-soluble extractives and not less than 55.0% of water extractives.

Description:

1. Root tuber of *Stemona sessilifolia*: Single or many in cluster, fusiform, the upper end relatively slender, shrunken and curved, 5~12 cm in length, 0.5~1 cm in diameter. Externally yellowish-white or pale brownish-yellow, with irregular longitudinal deep furrows and occasionally transverse wrinkles. Texture fragile, easily broken, softened when hygroscopic, fracture horny, pale yellowish-brown or yellowish-white, bark broad, stele compressed. Odour slight; taste sweet then bitter.
2. Root tuber of *Stemona japonica*: Two ends slightly thinned. Externally mostly with irregular folds and transverse wrinkles.
3. Root tuber of *Stemona tuberosa*: Stout, long spindle or long strip, 8~24 cm in length, 0.8~2 cm in diameter. Externally pale yellowish-brown to grayish-brown, with shallow longitudinal wrinkles or irregular longitudinal grooves, with shallow wrinkles. Texture compact, fracture yellowish-white to blackish-brown, stele large, pith whitish.

Microscopic identification:

1. **Transverse section:**
   (1) Root tuber of *Stemona sessilifolia*: Velamen composed of 3~4 layers of cells, walls lignified and thickened with dense and fine striations. Cortex broad, the outer layer cells arranged in order, the endothelium distinct. In stele, phloem bundles and xylem bundles arranged alternately; unlignified fibers singly scattered or 2~3 in bundles, locating in the inner side of phloem bundles; xylem vessels subpolygonal, up to 48 μm in radial diameter, up to 88 μm in tangential diameter, occasionally vessels singly scattered or 2~3 in groups, distributing near the margin of pith, arranged in 2 whorls. Pith scattered with small fibers, singly scattered or 2~3 in bundles.
   (2) Root tuber of *Stemona japonica*: Velamen composed of 3~6 layers of cells. Phloem fibers lignified. Vessels relatively large, up to 184 μm in radial diameter, usually penetrating into pith, mostly arranged in 3 whorls.
   (3) Root tuber of *Stemona tuberosa*: Velamen composed of 3 layers of cells, walls extremely lignified and without fine striations, the inner walls of the inner layers extremely thickened. Cortex scattered with fibers in the outer part, with slightly lignified walls. In stele, phloem bundles 36~40; xylem vessels rounded-polygonal, up to 107 μm in diameter, each xylem bundle composed of xylem fibers and slightly lignified xylem parenchymatous cells linking into a ring. Pith with few fibers, usually scattered singly. Parenchymatous cells contain gelatinized starch granules.
2. **Powder:**
   (1) Root tuber of *Stemona sessilifolia*: Pale yellow to yellowish-brown. In surface view, velamen cells rectangular or polygonal, walls lignified, with distinct, dense and fine striations. Vessels with simple oblique pits or

pit borders. Parenchymatous cells adjacent vessels rectangular in shape, containing large simple pits. Raphides of calcium oxalate rare, up to 60 μm in length.

(2) Root tuber of *Stemona japonica*: Yellowish-brown. Vessels relatively large, mostly up to 64 μm in diameter. Xylem fibers up to 32 μm in diameter.

(3) Root tuber of *Stemona tuberosa*: Yellowish-brown. In surface view, velamen cells subpolygonal or subsquare, walls slightly lignified and thickened, without dense striations; the inner walls extremely thickened in sectional view. Bordered-pitted vessels with relatively large pits, a few elongatively arranged in reticulate or scalariform. Xylem fibers 16~60 μm in diameter, occasionally containing transverse septa. Parenchymatous cells contain starch granules.

Identification:
Check alkaloid: Take 5.0 g of powdered sample, add 50 mL of 80% ethanol, heat under reflux for 1 hour, filter and evaporate the filtrate to remove ethanol, the residue add ammonia solution and adjust pH value to 10~11 (General rule 1009), extract by shaking with 5 mL of chloroform, evaporate the chloroform layer to dryness, dissolve the residue in 5 mL of 1% hydrochloric acid, filter. Divided the filtrate into two parts, one filtrate add modified Dragendorff's reagent, an orange-red precipitate is produced; the other one add silicotungstic acid in water, a milky precipitate is produced.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 2.0 g of powdered sample to 15 mL of methanol, heat under reflux for 20 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 10 mL of methanol.
2. Reference drug solution: Take 2.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane, dichloromethane, and acetone (5:2:2) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 0.5% ninhydrin/ EtOH TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:
1. Loss on drying: Not more than 15.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 8.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.5% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:
1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from moisture and insects.
Usage: Phlegm-dispelling medicinal (Cough-suppressing and panting-calming medicinal).
Property and flavor: Mild warm; sweet and bitter.
Meridian tropism: Lung meridians.
Effects: Suppress cough, kill worms and lice.
Administration and dosage: 3~10 g.

STEPHANIAE TETRANDRAE RADIX
防己
Fang Ji / Fang Ji
Stephania Tetrandra Root

Stephania tetrandra root is the dried root of *Stephania tetrandra* S.Moore (Fam. Menispermaceae), commonly known as “Fen Fang Ji” and “Han Fang Ji”.
It contains not less than 6.0% of dilute ethanol-soluble extractives and not less than 5.0% of water extractives and not less than 0.9 % of the total amount of tetrandrine and fangchinoline.

Description: Irregular cylindrical, semi-cylindrical or block-shaped, multi-curved, 5~10 cm in length, 1~5 cm in diameter. Epidermis pale grayish yellow, often nodular tumor in the curved part. Weight, solid, flat section, grayish white, rich powder, sparsely arranged radial texture. Odor slight, taste bitter.

Microscopic identification:
1. **Transverse section:**
Root of *Stephania tetrandra*: Cork layer often removed, sometimes remains. Cortex narrow, stone cells scattered or 2~5 groups, arranged tangentially. Phloem narrower. Layer ring. Xylem wide, Catheter intermittently arranged radially, with wood fibers next to them. Marrow line distinct and wide.

Parenchyma cells filled with starch granules, fine rod-shaped calcium oxalate crystal seen.

2. **Powder:** Grayish-white or pale yellowish-white. Many starch granules, single spheres spherical, helmet-shaped or polygonal, umbilical points punctate, crack-like, herringbone or stellate, layering not obvious; compound composed of 2~4 granules, under polarized light microscope black cross. Most of the catheters round pits. Many stone cells, which are subround, subsquare or oblong, thick walls, large cells, pitted vessel and distinct pit canals. A few fibers, long fusiform, lignified. Cork cells are pale yellow, polygonal.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 3.0 g of powdered sample to 15 mL of 70% ethanol in an 50-mL erlenmeyer flask, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 3.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of tetrandrine and fangchinoline in ethanol to produce a solution containing 1.0 mg per mL of each.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of dichloromethane, acetone, methanol, and concentrated ammonia solution (6:1:1:0.1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with modified Dragendorff's reagent. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 13.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 5.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Tetrandrine and fangchinoline:

(1) Mobile phase: Acetonitrile as the mobile phase A, and 0.03% triethylamine in water as the mobile phase B.

(2) Reference standard solution: Weigh accurately a quantity of tetrandrine and fangchinoline and dissolve in methanol to produce a solution containing 30 μg per mL of each.

(3) Sample solution: Weigh accurately 0.2 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 20 mL of methanol, ultrasonicate for 30 minutes. Centrifuge for 10 minutes, transfer the supernatant to a 50-mL volumetric flask. Repeat the extraction of the residue one more time. Combine the supernatant and make up to volume with methanol, mix well, filter and use the filtrate.

(4) Chromatographic system: The liquid chromatography is equipped with an UV detector (280 nm) and a column packing L1. The column temperature is maintained at 25℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of tetrandrine and fangchinoline should not be less than 10,000 of each.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~2	30	70
2~25	30→85	70→15

(5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Tetrandrine and fangchinoline (%) = 0.005 (r_U/r_S) (C_S) / (W)

r_U: peak area of tetrandrine and fangchinoline of sample solution

r_S: peak area of tetrandrine and fangchinoline of reference standard solution

C_S: concentration of tetrandrine and fangchinoline of reference standard solution (μg/mL)

W: weight of test sample (g) calculated with dried sample.

Storage: Store in a ventilated and dry place, and protect from mold and insects.

Usage: Dampness-dispelling medicinal (Wind-dampness-dispelling medicinal).

Property and flavor: Cold; bitter.

Meridian tropism: Bladder and lung meridians.

Effects: Dispel wind dampness, relieve pain, induce diuresis.

Administration and dosage: 5~12 g.

STROBILANTHII CUSIAE RHIZOMA ET RADIX
南板藍根
Nan Ban Lan Gen / Nan Ban Lan Gen
Strobilanthes Root

Strobilanthes root is the dried rhizome and root of *Strobilanthes cusia* (Nees) Kuntze (Fam. Acanthaceae).
It contains not less than 6.0% of dilute ethanol-soluble extractives and not less than 8.0% of water extractives.

Description: Rhizome cylindrical and slightly square, branched, 2~6 mm in diameter. Externally grayish-brown, nodes swollen, with numerous curved and slender roots, about 1 mm in diameter, with terrestrial stem at the upper part, occasionally with branches arranged opposite. Texture hard and fragile, fracture uneven, with broad pith in the center. Odour slight; taste week.

Microscopic identification:

1. **Transverse section:**
   Rhizome of *Strobilanthes cusia*: Epidermis composed of 1 layer of cells. Cortex relatively broad, cells elongated tangentially; cystoliths relatively numerous, subrounded or oblong, 17~33 μm in diameter; fibers singly scattered or in a bundle; endodermis distinct. Phloem relatively narrow; fibers singly scattered or in a bundle, wall slightly lignified or unlignified. Xylem vessels singly scattered or several in a group; xylem fibers relatively developed, wall lignified. Xylem rays broad, 2~8 layers of cells. Pith with distinct pits; cystoliths rare.
2. **Powder:** Yellowish-brown. Odourless, taste slightly bitter. Epidermal cells subrounded, subsquare or subrectangular, arranged tangentially. Cortex composed of parenchymatous cells, oval, oblong, long-oblong, subsquare, subrectangular or long-polygonal, containing cystoliths and sta rch granules. Cambium with cells rectangular or flat-rectangular, elongated tangentially. Xylem parenchymatous cells subrounded or subisodiametric-angular, membrane thick and strongly lignified. Xylem rays with cells oblong, long-oblong, square or long-polygonal, arranged radially. Xylem fibers with septum, subrounded, oblong or subisodiametric-angular, septum wall thickened and strongly lignified. Vessels extremely lignified, mainly bordered-pitted and reticulate. Fiber-like and tube-like tracheids are visible. Pith cells subrounded, isodiametric-polygonal or long-polygonal, with intercellular spaces, containing cystoliths and starch granules.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 2.0 g of powdered sample to 20 mL of dichloromethane, heat under reflux for 1 hour, filter, evaporate the filtrate to dryness, and dissolve the residue in 2 mL of dichloromethane.
2. Reference drug solution: Take 2.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of indigo and indirubin and dissolve in dichloromethane to produce a solution containing 1.0 mg and 0.5 mg per mL of each.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of toluene, dichloromethane, and acetone (5:4:1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 15.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 11.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place., and protect from mold and insects.
Usage: Heat-clearing medicinal (Heat-clearing and detoxcating medicinal).
Property and flavor: Cold; bitter.
Meridian tropism: Heart and stomach meridians.
Effects: Clear heat and detoxicate, cool the blood to soothe throat.
Administration and dosage: 9~15 g.

STRYCHNI SEMEN
馬錢子
Ma Cian Zih / Ma Qian Zi
Nux Vomica

Nux vomica is the dried ripe seed of *Strychnos nux-vomica* L. (Fam. Loganiaceae).

It contains not less than 8.0% of dilute ethanol-soluble extractives, not less than 13.0% of water extractives, among 1.2~2.2% of strychnine and not less than 0.8% of brucine.

Description: Flattened button-shaped, edge protuberant, one side slightly dented, the other side slightly protuberant, 1~3 cm in diameter, 0.3~0.6 cm thick. Externally grayish-brown or grayish-green, densely covered with silver-gray hairs, arranged radially, silky-lustrous. The center of dented surface with a protuberant dot-like hilum, edge with a protuberant rib and slightly protuberant micropyle. Texture hard, uneasily broken. Kernel pale yellow, 2 cotyledons, cordate, with 5~7 veins. Odourless; taste extremely bitter, with hypertoxicity.

Microscopic identification:

1. **Transverse section:**
   Seed of *Strychnos nux-vomica*: Epidermal cells differentiated into unicellular non-glandular hairs, extended obliquely, 500~1,000 μm in length, 25 μm in width, wall thick and strongly lignified, with longitudinal striations, the apex obtuse-rounded, the base enlarged, with pits and pit canals, lumen subrounded in sectional view. Brown parenchymatous cells existed in the inner layer of testa. Endosperm cells polygonal, wall about 25 μm thick, containing aleurone grains and fatty oil, aleurone grains 15~40 μm in diameter.
2. **Powder:** Grayish-yellow. Non-glandular hairs of testa mostly broken, about 1,100 μm in length, 25~75 μm in diameter, wall thick and strongly lignified, the base stone cell like. Unicellular non-glandular hairs cylindrical, lumen containing brown contents. Endosperm cells subrounded or polygonal, pale yellow, wall thick with dense pit canals, intercellular layer undulately curved, containing aleurone grains, fatty oil and pigments.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of toluene, acetone, ethanol, and concentrated ammonia solution (4:5:0.6:0.4) as the developing solvent. Apply 10 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with Dragendorff's spray reagent and $NaNO_2$ TS and heat at 105°C until the spots become visible, and examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:

1. Loss on drying: Not more than 13.0% dry at 105°C for 5 hours (General rule 6015).
2. Total ash: Not more than 3.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:

1. Strychnine and brucine:
   (1) Mobile phase: A solution of acetonitrile and a solution of equal quantities of 0.01 M sodium 1-heptanesulfonate solution and 0.02 mol/L potassium dihydrogen phosphate solution (adjusted pH value to 2.8 with 10% phosphoric acid) (21:79). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of strychnine and brucine and dissolve in chloroform to produce a solution containing 0.12 mg and 0.1 mg per mL of each.
   (3) Sample solution: Weigh accurately 0.6 g of powdered sample and place it in a conical flask with a stopper, add 3 mL of Sodium Hydroxide TS, mix well, and stand for 30 minutes. Add accurately 20 mL of chloroform, stopper tightly and weigh, heat under reflux for 2 hours, cool, weigh again, replenish the loss of the weight with chloroform, and mix well. Filter with filter paper sprayed with a small quantity of anhydrous sodium sulfate. Accurately measure 3 mL of the successive filtrate in a 10-mL volumetric flask, make up to volume with methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (260 nm) and a column packing L1. The number of theoretical plates of the peak of strychnine should not be less than 5,000
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Strychnine or brucine (%)=6.67(r_U/r_S) (C_S) / (W)
   r_U: peak area of strychnine or brucine of sample solution
   r_S: peak area of strychnine or brucine of reference standard solution

Cs: concentration of strychnine or brucine of reference standard solution (mg/mL)
W: weight of test sample (g) calculated with dried sample.

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place, and protect from moisture.
Usage: Dampness-dispelling medicinal (Wind-dampness-dispelling medicinal).
Property and flavor: Warm; bitter; highly toxic.
Meridian tropism: Liver and spleen meridians.
Effects: Free collateral vessels and disperses binds, disperse swelling and relieve pain.
Administration and dosage: 0.3~0.6 g, used in pills or powder after processed.
Precaution and warning: Unprocessed one highly toxic, avoid using unprocessed one, should be used cautiously for oral admininistration. Forbit to use during pregnancy.

TALCUM
KAOLINUM
滑石
Hua Shih / Hua Shi
Talc

Talc is a mineral of silicates of talcum group, containing mainly hydrated magnesium silicate [$Mg_3(Si_4O_{10})(OH)_2$]. It is formed from ultrabasic rocks via metapepsis； or natural clay minerals, mainly [$Al_2SiO_5(HO)_4$ and Al_2O_3•$2SiO_2$•$2H_2O$], produced from natural clay minerals.
Description: Aggregates of dense or scaly masses, irregular or flattened cuboid, white, yellowish-white or pale bluish-gray. Externally with pearl-like luster, translucent or opaque. Texture soft and fine, smooth and unctuous on touching, nonhygroscopic and nondisintegrated in water. White powder can be scraped off with a finger nail. Odourless; tasteless, with a cooling sensation.

Microscopic identification:
Powder: White or almost white. Fine and sandless powder, unctuous on touching.

Identification:
Weigh accurately 0.5 g of powdered sample, add accurately 200 mg of anhydrous sodium carbonate and 2 g of anhydrous potassium carbonate, grind and transfer to a platinum crucible, heat until completely melted, cool. Apply 50 mL of hot water to transfer the melt to an evaporating dish or a beaker, add a quantity of hydrochloric acid until not bubble up, and add extra 10 mL of hydrochloric acid, heat in a water bath until dryness, cool. Add 20 mL of water, boil and filter, the residue is insoluble silicon dioxide. Use the filtrate and add about 2.0 g ammonium chloride and 5 mL of ammonium. If precipitate is produced, filter, and add sodium tertiary phosphate solution to the filtrate, and the white crystals precipitate of ammonium magnesium phosphate are produced.

Impurities and other requirements:
1. Absence of asbestos [NOTE—Suppliers of Talc may use one of the following methods to determine the absence of asbestos.] Proceed as directed for test A or test B. If either test is positive, perform test C.
   A: The infrared spectrophotometry (General rule 1197) of a potassium bromide dispersion of it at the absorption band at 758 ± 1 cm^{-1}, using scale expansion, may indicate the presence of tremolite or chlorite. If the absorption band remains after ignition of the substance at 850° for at least 30 minutes, it indicates the presence of tremolite. In the range 600~ 650 cm^{-1} using scale expansion, any absorption band or shoulder may indicate the presence of serpentines.
   B: X-ray diffraction employing the following conditions: Cu Kα monochromatic 40 kV radiation, 24~30 mA; the incident slit is set at 1°; the detection slit is set at 0.2°; the goniometer speed is 1/10° 2θ/min; the scanning range is 10°~13° 2θ and 24°~26°2 θ; the sample is not oriented. Prepare a random sample, and place on the sample holder. Pack and smooth its surface with a polished glass microscope slide. Record the diffractograms: the presence of amphiboles is detected by a diffraction peak at 10.5 ± 0.1° 2θ, and the presence of serpentines is detected by diffraction peaks at 24.3 ± 0.1° 2θ to 12.1 ± 0.1° 2θ.
   C: The presence of asbestos (see optical microscopy) is shown if there is a range of length to width ratios of 20:1 to 100:1, or higher for fibers longer than 5μm, if there is a capability of splitting into very thin fibrils; and if there are two or more of the following four criteria: (1) parallel fibers occurring in bundles, (2) fiber bundles displaying frayed ends, (3) fibers in the form of thin needles, and (4) matted masses of individual fibers and/or fibers showing curvature.
2. Loss on drying: Not more than 0.5% dry at 105℃ for 5 hours (General rule 6015).
3. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
4. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
5. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
6. Lead (Pb): Not more than 15.0 ppm (General rule 2251, 6301)

Storage: Store in a ventilated and dry place.

Usage: Dampness-dispelling medicinal (Dampness-draining diuretic medicinal).
Property and flavor: Cold; sweet and bland.
Meridian tropism: Stomach and bladder meridians.
Effects: Induce diuresis and relieve strangury, resolve summerheat-heat, dispel dampness and wound healing.
Administration and dosage: 10~24 g, used an appropriate amount for external use.

TARAXACI HERBA
蒲公英
Pu Gong Ying / Pu Gong Ying
Mongolian Dandelion Herb

Mongolian dandelion herb is the dried herb of *Taraxacum mongolicum* Hand.-Mazz. or *Taraxacum formosanum* Kitam. or similar species (Fam. Compositae).
It contains not less than 13.0% of dilute ethanol-soluble extractives, not less than 15.0% of water extractives and not less than 0.02% of caffeic acid.

Description: Crumpled and rolled masses. Main root conical, frequently curved, 3~10 cm in length, with lateral roots and fibrous roots; externally grayish-brown, with deeply longitudinal furrows and wrinkles; root stock with brown or yellowish-white hairs, some fallen off. Leaves greenish-brown or dark gray, crumpled in a mass or rolled into strips, apex acute or obtuse, margin lobate or pinnatifid; base becoming narrow downwards to petiole-shape; midrib of lower surface distinct. Scapes relatively slender; heads terminal; corolla yellowish-brown; achenes numerous with yellowish-white pappi. Odour slight; taste slightly bitter.

Microscopic identification:
1. **Transverse section:**
   Taraxaci herba: 1 layered epidermis covered with cuticle, cells rectangular or square. Cork composed of several rows of yellowish-brown cells, subrectangular or subpolygonal. Phloem broad, composed of parenchymatous cells, sieve laticiferous tube groups and laticiferous tube groups; parenchymatous cells subrounded, suboblong, subrectangular or subpolygonal, with distinct intercellular spaces, containing inulin; laticiferous tube groups surrounded by small cells, scattered, arranged in several interrupted whorls. Cambium in a ring, about 4~7 rows of cells. Xylem composed of vessels, ray cells and parenchymatous cells; vessels relatively large, scattered; rays indistinct; xylem parenchymatous cells subrectangular, subpolygonal or suboblong, with distinct intercellular spaces, containing inulin. Pith composed of parenchymatous cells in the center. The side walls (radial walls) of leaf epidermal cells are mostly wavy, and the outer wall is covered with cuticle. Both surfaces bearing nonglandular hairs (about 3~9 cells), 17~34 μm in diameter, apical crumpled to whip-shape or fallen off. Most of stomata on the lower surface are anomocytic or anisocytic, with 3~6 subsidiary cells; mesophyll containing fine crystals of calcium oxalate. Laticiferous tubes occurring alongside the veins.
2. **Powder:** Grayish-brown. Both upper and lower epidermal cells of leaf contain non-glandular hairs in surface view, composed of 3~9 cells, lower epidermis with relatively numerous stomata, with 3~6 subsidiary cells. Laticiferous tube groups of roots contain pale yellow secretions in longitudinal view, cells subrectangular or suboblong. Vessels mainly annular and scalariform, about 10~70 μm in diameter. Inulin varying in size, subfan-shaped or subrounded.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 20 mL of methanol, ultrasonicate for 30 minutes, filter, evaporate the filtrate to dryness, dissolve the residue in 10 mL of water, extract shaking for two times, each time with 10 mL of ethyl acetate, combine the ethyl acetate extracts and evaporate to dryness, dissolve the residue in 1 mL of methanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of caffeic acid and dissolve in methanol to produce a solution containing 0.5 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of dichloromethane, ethyl acetate, and formic acid (5:4:1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 254 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 13.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 20.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 8.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:

1. Caffeic acid:
   (1) Mobile phase: Methanol as the mobile phase A, and 0.1% phosphoric acid as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of caffeic acid, and dissolve in methanol (contain 5% formic acid) to produce a solution containing 5 μg per mL.
   (3) Sample solution: Weigh accurately 0.5 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 20 mL of methanol (contain 5% formic acid), ultrasonicate for 30 minutes. Centrifuge for 10 minutes, transfer the supernatant to a 50-mL volumetric flask. Repeat the extraction of the residue one more time. Combine the supernatant and make up to volume with methanol (contain 5% formic acid), mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (323 nm) and a column packing L1. The column temperature is maintained at 25℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of caffeic acid should not be less than 3,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~10	5→23	95→77
10~25	23	77

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   Caffeic acid (%)=0.005(r_U/r_S) (C_S) / (W)

   r_U: peak area of caffeic acid of sample solution
   r_S: peak area of caffeic acid of reference standard solution
   C_S: concentration of caffeic acid of reference standard solution (μg /mL)
   W: weight of test sample (g) calculated with dried sample.
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from mold and insects.
Usage: Heat-clearing medicinal (Heat-clearing and detoxcating medicinal).
Property and flavor: Cold; bitter and sweet.
Meridian tropism: Liver and stomach meridians.
Effects: Clear heat and detoxicate, remove swelling and disperse stagnation, induce diuresis and relieve strangury.
Administration and dosage: 9~15 g.

TAXILLI HERBA
桑寄生
Sang Ji Sheng / Sang Ji Sheng
Chinese Taxillus Twig

Chinese taxillus twig is the dried stem and branch with leaf of *Taxillus chinensis* (DC.) Danser (Fam. Loranthaceae).
It contains not less than 7.0% of dilute ethanol-soluble extractives, not less than 7.0% of water extractives and not less than 0.02% of quercitrin.

Description: Stems cylindrical, 3~15 mm in diameter. Externally gray or purplish-brown, with branches and scars of branches or leaves, with numerous fine lenticels, young branches with brown-red pubescences. Texture hard, easily broken, fracture of wood split-shaped. Occasionally with leaves, leaves frequently crumpled, oval as whole, margin entire, brown, coriaceous, young leaves covered with fine pubescences. Odour slight; taste astringent.

Microscopic identification:

1. **Transverse section:**
   Stem and branch with leaf of *Taxillus chinensis*: Cork composed of about 10 layers of cork cells, usually containing brown contents, occasionally with lenticels. Cortex with cells tangentially elongated; scattered with subsquare or rectangular stone cells, walls mostly three-side thickened, 1 side relatively thin, containing prisms of calcium oxalate; fiber bundles arranged in a ring in pericycle and in the inner side of cortex. Phloem narrow. Cambium indistinct. Xylem occupied the most parts of the stem, vessels singly scattered or 2~3 in groups, surrounded by xylem fibers and xylem parenchymatous cell; xylem rays 1~4 layers of cells wide, occasionally forming stone cells, containing prisms. Pith with cell walls slightly thickened, with distinct pits; stone cells scattered in groups, also containing prisms. Parenchymatous cells contain starch granules.
2. **Powder:** Pale yellow. Stone cells subsquare, subrectangular, subtriangular or conchoidal, 14~76 μm in diameter, walls of cells mostly three-side thickened, lumen near one side, containing prisms of calcium oxalate and yellowish-brown or reddish-brown masses, some prisms embedded in brown masses. Prisms of calcium oxalate square, rectangular, short-cylindrical or polyhedral, 3~30 μm in diameter and up to 38 μm in length. Clusters of calcium oxalate scattered in leaf parenchymatous cells, 8~25 μm in diameter. Stellate hairs overlapped, pale yellow or yellow, intact one 3~5 overlapped, trifurcately or tetrafurcately branched, branches

mostly curved, with walls slightly thickened. Epidermal cells of leaf yellowish-brown in surface view; mesophyll cells yellowish-brown, occasionally containing prisms and clusters of calcium oxalate or its symbionts. Pericycle fibers 14~35 μm in diameter, with walls extremely thickened, primary walls broken, usually with longitudinal slits on the surface. Xylem fibers 10~27 μm in diameter, wall 3~7 μm thick, with pit canals sparsely. Bordered-pitted vessels 25~50 μm in diameter, bordered pits polygonal, arranged densely, occasionally with reticular three-side thickened; reticulate, scalariform or reticular-spiral vessels occasionally visible. Xylem parenchymatous cells, pith cells, cork cells and starch granules also present.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 2.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 2.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of quercitrin and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, 2-butanone, formic acid, and water (24:3.6:1.5:0.9) as the developing solvent. Apply 5 μL of the sample solution and reference drug solution and 2 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 2.5% $AlC1_3$/EtOH TS, examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 13.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 10.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:

1. Quercitrin:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and 0.5% acetic acid as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of quercitrin, and dissolve in methanol to produce a solution containing 25 μg per mL.
   (3) Sample solution: Weigh accurately 0.5 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 10 mL of 50% methanol, ultrasonicate for 30 minutes. Centrifuge for 10 minutes, filter the supernatant. Repeat the extraction of the residue one more time. Combine the filtrate, transfer to 20-mL volumetric flask and make up to volume with 50% methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (254 nm) and a column packing L1. The column temperature is maintained at room temperature. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of quercitrin should not be less than 10,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~3	10	90
3~5	10→13	90→87
5~20	13→20	87→80
20~21	20→100	80→0

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Quercitrin (%)=0.002(r_U/r_S) (C_S) / (W)
   r_U: peak area of quercitrin of sample solution
   r_S: peak area of quercitrin of reference standard solution
   C_S: concentration of quercitrin of reference standard solution (μg/mL)
   W: weight of test sample (g) calculated with dried sample.
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place, and protect from mold and insects.
Usage: Dampness-dispelling medicinal (Wind-dampness-dispelling medicinal).

Property and flavor: Neutral; sweet and bitter.
Meridian tropism: Liver and kidney meridians.
Effects: Tonify liver and kidney, strengthen sinew and bone, dispel wind dampness, prevent abortion.
Administration and dosage: 9~15 g.

【Decoction pieces】

TAXILLI HERBA

It contains not less than 7.0% of dilute ethanol-soluble extractives, not less than 7.0% of water extractives and not less than 0.02% of quercitrin.
Raw medicinal material are processed to remove impurities, clean selection, soften thoroughly, cut into thin slices, and dry, mostly appearing thick pieces or irregular small sections. Externally reddish-brown or greyish-brown, with fine longitudinal wrinkles and numerous fine prominent brown lenticels, some young branches with dark brown pubescences; bard reddish-brown, wood pale in dolour. Leaves frequently rolled or broken, when whole, ovate or elliptical, externally yellowish-brown, apex obtusely rounded, base rounded or broadly cuneate, margin entire; texture leathery. Odour slight; taste astringent.

Thin layer chromatographic identification test: The method is the same as that for crude herb.
Impurities and other requirements: Methods and specifications are the same as those for crude herb.
Assay: The method is the same as that for crude herb.
Storage: The method is the same as that for crude herb.
Usage: Dampness-dispelling medicinal (Wind-dampness-dispelling medicinal).
Property and flavor: Neutral; sweet and bitter.
Meridian tropism: Liver and kidney meridians.
Effects: Tonify liver and kidney, strengthen sinew and bone, dispel wind dampness, prevent abortion.
Administration and dosage: 9~15 g.

TETRAPANACIS MEDULLA
通草
Tong Cao / Tong Cao
Ricepaperplant Pith

Ricepaperplant pith is the dried pith in the stem of *Tetrapanax papyrifer* (Hook.) K.Koch (Fam. Araliaceae).

Description: Cylindrical, 20~40 cm in length, 1~2.5 cm in diameter. Externally white or pale yellow, with shallow longitudinal furrows. Texture light, soft and loose, slightly elastic, easily broken, fracture even, with silvery luster, with a hollow of 0.3~1.5 cm in diameter or translucent membrane in the middle part, arranged in scalariform in longitudinally cut surface, solid ones visible occasionally (only a tiny small pieces of stem pith). Odourless and tasteless.

Microscopic identification:
1. **Transverse section:**
   Pith in the stem of *Tetrapanax papyrifer*: All cells are parenchymatous cells, elliptical, subrounded or subpolygonal, wall thin, occasionally with pits, the outer cells smaller, some cells contain clusters of calcium oxalate, 15~64 μm in diameter.

Impurities and other requirements:
1. Loss on drying: Not more than 12.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 8.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Storage: Store in a ventilated and dry place.
Usage: Dampness-dispelling medicinal (Dampness-draining diuretic medicinal).
Property and flavor: Mild cold; sweet and bland.
Meridian tropism: Lung and stomach meridians.
Effects: Clear heat and promote urination，unblock qi and promote lactation.
Administration and dosage: 3~5 g.
Precaution and warning: Use cautiously during pregnancy.

THLASPI HERBA
荠蒾
Si Ming / Xi Ming
Thlaspi Herb

Thlaspi herb is the dried aerial part of *Thlaspi arvense* L. (Fam. Cruciferae).
It contains not less than 11.0% of dilute ethanol-soluble extractives and not less than 12.0% of water extractives and not less than 0.1% of isovitexin.

Description:
This product is the aerial-part with fruit.
1. Stem of *Thlaspi arvense*: Cylindrical, grayish-yellow with fine longitudinal edges. It is brittle and easy to fold, with a hollow section or a loose white pith in the center. The leaves have fallen off, and a few residuals are curled and broken, showing a dark yellowish-green color. There is a infructescence in the top of the stem and the leaf axils.
2. Fruit of *Thlaspi arvense*: Flat oval, grayish-yellow, slightly bulging in the middle, winged at the edges, each with a longitudinal ridgeline in between, apex

recessed, slender fruit stalk at base. 2 chambers in the fruit, separated by a longitudinal membrane, and each chamber has several seeds. The seeds are ovoid, brownish-black, with several concentric rings on both sides. Odor slight and the taste is light.

Icroscopic identification:

Transverse section:

Stem of *Thlaspi arvense*: Parenchyma cells of the epidermis are in a square shape of 1 column, peripheral wall is thickened. The cortex is a series of parenchyma cells. The phloem is narrow. Xylem vessels are several groups in a polygonal shape. The vascular bundle is about 10 to 25 cells of lignified fiber. The pith is broad, lignified, and is a circular or elliptical single-grained pit.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of isovitexin and dissolve in methanol to produce a solution containing 0.1 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, formic acid, and water (5:1:1) as the developing solvent. Apply 2 μL of each of the sample solution and reference drug solution and 1 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 11.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 8.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

Isovitexin:

1. Mobile phase: Acetonitrile as the mobile phase A, and 0.1% acetic acid as the mobile phase B.
2. Reference standard solution: Weigh accurately a quantity of isovitexin and dissolve in water to produce a solution containing 50 μg per mL.
3. Sample solution: Weigh accurately 1.0 g of the powdered sample and place it in a 50-mL conical flask with a stopper, then add accurately 25 mL of 50% ethanol, ultrasonicate for 30 minutes, filter. Repeat the extraction of the residue one more time, combine the filtrate, evaporate the filtrate to a small amount and transfer to 25-mL volumetric flask, make up to volume with 50% ethanol, mix well, filter and use the successive filtrate.
4. Chromatographic system: The liquid chromatography is equipped with an UV detector (270 nm) and a column packing L1. The column temperature is maintained at room temperature. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of isovitexin should not be less than 10,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~20	12→20	88→80
20~23	20→100	80→0
23~28	100	0

5. Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Isovitexin (%)=0.0025(r_U/r_S) (C_S) / (W)

r_U: peak area of isovitexin of sample solution

r_S: peak area of isovitexin of reference standard solution

C_S: concentration of isovitexin of reference standard solution (μg/mL)

W: weight of test sample (g) calculated with dried sample.

Storage: Store in a ventilated and dry place, and protect from mold and insects.

Usage: Heat-clearing medicinal (Heat-clearing and detoxicating medicinal).

Property and flavor: Mild cold; pungent.

Meridian tropism: Liver, stomach, and large intestine meridians.

Administration and dosage: 9~15 g.

TRACHELOSPERMI CAULIS CUM FOLIUM
絡石藤
Luo Shih Teng / Luo Shi Teng
Chinese Starjasmine Stem

Chinese starjasmine stem and leaf is the dried stem with leaf of *Trachelospermum jasminoides* (Lindl.) Lem. (Fam. Apocynaceae).
It contains not less than 4.0% of dilute ethanol-soluble extractives and not less than 6.0% of water extractives.

Description: Stem cylindrical, curved, much-branched, varying in length, 0.2~0.7 cm in diameter; externally reddish-brown, with longitudinal wrinkles or small protuberances; nodes swollen, bearing with branchlets, occasionally with adventitious roots and opposite root scars; texture hard, fracture pale yellow, center hollowed. Leaves opposite, short petioled, elliptical or ovate-lanceolate, 1~8 cm in length, 0.7~3.5 cm in width, margin entire, apex obtuse or nearly acute, occasionally rolled; upper surface dark green, lower surface yellowish-green, with densely hairs; main vein 1, lateral veins obvious; texture coriaceous. Odour slight; taste slightly bitter.

Microscopic identification:

1. **Transverse section:**
   Stem of *Trachelospermum jasminoides*: The outermost layer was cork, composed of 3~6 rows of reddish-brown cork cells, occasionally cortex cells and epidermis remained outside the cork. Cortex narrow, stone cells presented at the outside, arranged in an interrupted ring, subrounded, lumen distinct, scattered with prisms of calcium oxalate. Phloem fibers in bundles, arranging in an interrupted ring, stone cells occasionally found. Cambium in a ring. Xylem composed of xylem fibers, vessels and rays, vessels mostly singly scattered. On the inner part of the xylem, cambium and internal phloem situated. Pith usually broken, cells subrounded, scattered with fiber bundles and prisms of calcium oxalate.
2. **Powder:** Greenish-gray. Epidermis covered with protuberance of adventitious roots or root scars. Cork cells reddish-brown, arranged neatly, subrectangular or suboblong. Cortex cells thin, subrectangular, about 10~40 μm in diameter, lumen distinct, scattered with prisms of calcium oxalate and stone cells. Xylem composed of xylem fibers, vessels and rays, xylem fibers about 30~105 μm in diameter. Vessels mainly bordered-pitted, about 10~75 μm in diameter, pitted and annular vessels are also found. Pith cells small, subrounded, scattered with fiber bundles and prisms of calcium oxalate.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes and filter, evaporate the filtrate to dryness, and dissolve the residue in 1 mL of methanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of tracheloside and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of dichloromethane, methanol, and glacial acetic acid (8:1:0.2) as the developing solvent. Apply 2 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 8.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 13.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 6.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:

1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place.
Usage: Dampness-dispelling medicinal (Wind-dampness-dispelling medicinal).
Property and flavor: Mild cold; bitter.
Meridian tropism: Heart, liver, and kidney meridians.
Effects: Dispel wind to free collateral vessels, cool the blood and disperse swelling.
Administration and dosage: 6~12 g.

TRIBULI FRUCTUS
蒺藜
Ji Li / Ji Li
Tribulus Fruit

Tribulus fruit is the dried ripe fruit of *Tribulus terrestris* L. (Fam. Zygophyllaceae).
It contains not less than 8.0% of dilute ethanol-soluble extractives and not less than 8.0% of water extractives.

Description: Fruit consist of 5 mericarps, arranged radially, 0.7~0.12 cm in diameter, occasionally split into single mericarp. Mericarp hatchet-shaped, 0.3~0.6 cm in length; dorsal surface yellowish-green, protuberant, with longitudinal ribs and numerous spinlets; lateral surfaces both with a pair of long spines and short spines and reticular striations, with remained spine scars and reticular striations when spine removed. Texture hard. Odour slight; taste bitter and pungent.

Microscopic identification:

1. **Transverse section:**
   Fruit of *Tribulus terrestris*: Exocarp composed of 1 row of cells. Mesocarp composed of parenchymatous cells, scattered with small vascular bundles; conical fiber bundles located at the spine part, with group of stone cells at the base; several prisms of calcium oxalate located near the endocarp, forming crystal layer. Endocarp composed of fibers arranged criss-cross. Testa composed of 1 layer of arranged neatly cells, with walls thickened. Cotyledons with thin wall, containing oil droplets.
2. **Powder:** Yellowish-green or grayish-yellow. Fibers pale yellow, long strip-shaped, varying in length, arranged criss-cross or in bundles, about 35~95 μm in length, 4~15 μm in diameter. Stone cells singly scattered or in bundles, yellow, subovate, lone strip-shaped or irregular, about 4~15 μm in diameter; thick wall ones with lumens extremely narrow, thin wall ones with relatively dense pits. Vessels mainly spiral, reticulate occasionally found, 7~15 μm in diameter. Prisms of calcium oxalate numerous, 10~40 μm in diameter. Epidermal cells of testa mostly flaky, pale brown, subsquare or subpolygonal, 10~18 μm in diameter, walls thickened and lignified.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 2.0 g of powdered sample to 25 mL of *n*-hexane, ultrasonicate for 30 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 20 mL of methanol, ultrasonicate for 30 minutes. Evaporate the the filtrate to dryness, dissolve the residue in 5 mL of methanol.
2. Reference drug solution: Take 2.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and the lower layer of dichloromethane, methanol, and water (13:7:2) at 10 ℃ as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with *p*-anisaldehyde/H_2SO_4 TS and heat at 105℃ until the spots become visible. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:

1. Loss on drying: Not more than 11.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 12.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 4.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:

1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from mold and insects.
Usage: Liver-pacifying and wind-extinguishing medicinal.
Property and flavor: Mild warm; pungent and bitter.
Meridian tropism: Liver meridians.
Effects: Pacify the liver to subdue yang, soothe the liver and release depression, dispel wind to brightens eyes, relieve itching.
Administration and dosage: 6~12 g.

TRICHOSANTHIS RADIX
栝楼根
Gua Lou Gen / Gua Lou Gen
Trichosanthes Root

Trichosanthes root is the dried root of *Trichosanthes kirilowii* Maxim. or *Trichosanthes rosthornii* Harms (Fam. Cucurbitaceae), commonly known as ”Tian Hua Fen”.
It contains not less than 6.0% of dilute ethanol-soluble extractives and not less than 15.0% of water extractives.

Description: Irregular cylindrical, longitudinal semi-cylindrical lobes or in pieces, 8~16 cm in length, 1.5~5.5 cm in diameter. Externally yellowish-white or pale brownish-yellow, with longitudinal wrinkles, rootlet scars and slightly concave transverse lenticel. Some remained with yellowish-brown outer bark. Texture compact, fracture white or pale yellow, starchy, wood yellow, slightly radially arranged in transversely cut section and striated in longitudinally cut section. Odourless; taste slightly bitter.

Microscopic identification:

1. **Transverse section:**
   Trichosanthis radix: Inside cork showing a ring of stone cells arranged interruptedly. Phloem relatively narrow. Xylem extremely broad, vessels singly scattered or 3~10 in a group, near primary xylem vessels usually showing small pieces of inter xylary phloem. Parenchymatous cells filled with starch granules.
2. **Powder:** Off-white. Starch granules extremely numerous, simple granules subspheroid, semicircular or helmet-shaped, 6~48 μm in diameter, hilum dotted, shortly cleft or V-shaped, striations faintly visible; compound granules composed of 2~8 components. Bordered-pitted vessels huge, mostly broken, some bordered pits hexagonal or square, arranged densely. Stone cells yellowish-green, rectangular, elliptical, subsquare, polygonal or fusiform, 27~72 μm in diameter, with relatively thickened walls and densely fine pits. Xylem parenchymatous cells contain starch granules.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, shake for 5 minutes, stand, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-butanol, glacial acetic acid, and water (4:1:1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with ninhydrin TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:

1. Loss on drying: Not more than 15.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 4.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 400 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 5.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:

1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from insects.
Usage: Heat-clearing medicinal (Heat-clearing and fire-purging medicinal).
Property and flavor: Mild cold; sweet and mild bitter.
Meridian tropism: Lung and stomach meridians.
Effects: Clear heat and purge fire, disperse swelling and expel pus.
Administration and dosage: 10~15 g.
Precaution and warning: Incompatible with *Aconitum* spp.

TRICHOSANTHIS SEMEN
栝樓仁
Gua Lou Ren / Gua Lou Ren
Trichosanthes Seed

Trichosanthes seed is the dried ripe seed of *Trichosanthes kirilowii* Maxim. or *Trichosanthes rosthornii* Harms (Fam. Cucurbitaceae).
It contains not less than 2.0% of dilute ethanol-soluble extractives and not less than 3.0% of water extractives.

Description:

1. Seed of *Trichosanthes kirilowii*: Ovate and elliptical, flattened, 11~15 mm in length, 6~7 mm in width, about 3.5 mm thick. Externally pale brown to brown, with fine dots and an indistinct circle of furrow along the edge. Apex relatively narrow, with a pale and slit-shaped hilum, base obtuse or slightly oblique. Testa hard; tegmen pale green, cotyledons 2, hypertrophy and oily. Odour slight; taste weak and oily.
2. Seed of *Trichosanthes rosthornii*: Relatively large and flattened, 1.5~1.9 cm in length, 0.8~1 cm in width, about 2.5 mm thick. Externally brown, with a distinct and wider rim circle of furrow. Apex relatively wider and truncate.

Microscopic identification:

1. **Transverse section:**
   Trichosanthis semen: Seed coat cortex1 row of small tangentially elongated cells. Wall thickness, lignifications, with fine cuticle striations. Stone cell layer is a number of different types of stone cells, wall thickness, lignifications, with wall holes and colporate. The reticular cells are 2 to 3 layers of slightly round cells. Micro-lignifications, with obvious reticular wall holes, Seed cells contain a lot of fatty oil.
2. **Powder:** Dark reddish-brown. Epidermal cells of testa subpolygonal or irregular in surface view, periclinal walls with slightly curved or straight cuticle striations; cells vary in shape in sectional view, some elongated radially into palisade-shaped, some elongated tangentially covered with cuticle. Sclerenchymatous cells relatively large, brown, irregularly rectangular, elongated-rounded or subtriangular, walls sinuous, occasionally showing short-branched, 32~78 μm in diameter, up to 152 μm in length, wall 6~16 μm thick, occasionally vary in thickness, lignified, with reticulated clefts, pit canals relatively dense. Stone cells irregular in shape or elongated strip-shaped, walls sinuous or showing short-branched, 12~68 μm in diameter, up to 170 μm in length, wall 7~14 μm thick, a few with striations, pit canals relatively sparse, occasionally with indistinct pit canals at one side, some lumens contain yellowish-brown or brown contents. The stellate cells are irregularly long or oblong, curved wall, with several short branches or protrusions, the branches are obtuse, cells grow to 175 μm, 12 to 29 μm in diameter, and 3 to 9 μm in wall thickness. Lignifications, pits are obvious and the colporate are dense, some cells contain brown matter, and the stellate cells are larger and wall thinner, protrusions are many and blunt, The size of the pits is different. In addition, cotyledon cells are filled with aleurone grain, and contains fatty oil droplets and lipid substances; endosperm cells are filled with fine aleurone grain; inlaid arranged aril cells, pigmented masses, and the like.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of petroleum ether (30~60℃), ultrasonicate for 10 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of 3,29-dibenzoyl rarounitriol and dissolve in dichloromethane to produce a solution containing 0.1 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane and ethyl acetate (5:1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained with the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 12.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 3.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:

1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from mold and insects.
Usage: Phlegm-dispelling medicinal (Heat-phlegm clearing and resolving medicinal).
Property and flavor: Cold; sweet.
Meridian tropism: Lung, stomach, and large intestine meridians.
Effects: Clear heat to resolve phlegm, soothe chest to dissipate binds, moisten the intestine and relax the bowel.
Administration and dosage: 9~30 g.
Precaution and warning: Incompatible with *Aconitum* sp.

TRIGONELLAE SEMEN
胡蘆巴
Hu Lu Ba / Hu Lu Pa
Common Fenugreek Seed

Common fenugreek seed is the dried mature seed of *Trigonella foenum-graecum* L. (Fam. Leguminosae).
It contains not less than 16.0% of dilute ethanol-soluble extractives and not less than 11.0% of water extractives and not less than 0.36% of trigonelline.

Description: Triangular, 2~3 mm in length, 1.5 mm in wide. Epidermis grayish brown to taupe, dark spots, one end slightly wider, truncated, other end is tapered and blunt. Intersection bit of a kind of umbilical, hard, hard to break, skin thin, cotyledons white, rich oil. Odor slight, taste bitter.

Microscopic identification:

1. **Transverse section:**
   Seed of *Trigonella foenum-graecum*: Outermost part of the seed coat is 1 column of cells, outer layer is cuticle, grating cell is tip pointed, wall thick, layer obvious, micro-lignification, outer side has a brilliance band, cell cavity often has yellowish brown inclusions. Inwardly, there are 1 column of supporting cells, flat ladder-shaped, large cell gaps, lateral flat wall thickening, lateral strips with radial strips thickening texture, followed by 3~4 rows of parenchyma cells. Outermost part of the endosperm 1 row of aleurone layers. Cells subsquare, contain brown material. Rest of the endosperm cells are large, subround, thin primary wall, thick secondary wall, mucinization, large number of mucous cells in the endosperm. Cotyledon cells small, cells contain confusing powder and fatty oil droplets.
2. **Powder:** Brownish yellow. 1 column of epidermal grid cells, upper part of lateral wall and outer wall thicker, fine vertical groove pattern, lower cell cavity larger, brilliance band; epidermis view polygonal, wall thicker, cell cavity smaller. Supporting cell 1 column, slightly dumbbell-shaped, slightly narrow at the upper end, wider at the lower end, strip-like texture on the vertical wall; the bottom view subround or hexagonal, dense radial stripes thickening, like a chrysanthemum pattern, cavity obvious. Cotyledon cells contain aleurone and fatty oil droplets.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 25 mL of ethanol, heat under reflux for 30 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 2 mL of ethanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of trigonelline and dissolve in ethanol to produce a solution containing 2.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of acetone and water (1:1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 254 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 12.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 5.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Trigonelline:
   (1) Mobile phase: Acetonitrile mixing with a solution, containing 0.03% sodium dodecyl sulfonate and 0.1% acetic acid in water at the ratio of 10:90, is prepared to be mobile phase. The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of trigonelline and dissolve in methanol to produce a solution containing 30 μg per mL.
   (3) Sample solution: Weigh accurately 0.2 g of the powdered sample and place it in a 15-mL centrifuge tube, then add accurately 10 mL of methanol, ultrasonicate for 30 minutes. Centrifuge for 10 minutes, transfer the supernatant to a 25-mL volumetric flask. Repeat the extraction of the residue one more time. Combine the supernatant and make up to volume with methanol, mix well, filter and use the filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (265 nm) and a column packing L1. The column temperature is maintained at 25°C. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of trigonelline should not be less than 8,000.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   Trigonelline (%)=0.0025(r_U/r_S) (C_S) / (W)

   r_U: peak area of trigonelline of sample solution

   r_S: peak area of trigonelline of reference standard solution

   C_S: concentration of trigonelline of reference standard solution (μg/mL)

   W: weight of test sample (g) calculated with dried sample.

Storage: Store in a ventilated and dry place.
Usage: Tonifying and replenishing medicinal (Yang-tonifying medicinal).
Property and flavor: Warm; bitter.
Meridian tropism: Kidney meridians.
Effects: Warm kidney yang, expel cold dampness.
Administration and dosage: 3~12 g

TRITICI FRUCTUS LEVIS
淨小麥
Fu Siao Mai / Fu Xiao Ma
Blighted Wheat

Blighted wheat is the light and shriveled fruit of the dried caryopsis of *Triticum aestivum* L. (Fam. Gramineae).
It contains not less than 5.0% of dilute ethanol-soluble extractives and not less than 5.0% of water extractives.

Description: Elliptical, both sides slightly acute, up to 6 mm in length, 1.5~2.5 mm in diameter. Externally pale yellowish-brown or yellow, slightly crumpled, the lateral side with a longitudinal deep furrow in the center, apex with yellowish-white pilose hairs. Texture hard, fracture white, starchy. Odour slight; taste weak. Caryopsis occasionally covered with glumes, lemma and palea, glumes coriaceous with a ridge, apex acute; lemma membranous, apex with an awn; palea chartaceous, apex without an awn. Odour slight; taste weak.

Microscopic identification:
Transverse section:
Caryopsis of *Triticum aestivum*: Pericarp fused with testa, the epidermal cells of the pericarp composed of 1 layer, with relatively thickened wall. Transverse cell 1 layer, oblong, arranged regularly, located inside the pericarp, with a relatively thickened wall. Aleurone layer located in the outermost side of endosperm, the cells square, filled with aleurone grains. Vascular tissue small, located deeply in the crease. The embryo composed of parenchymatous cells. The endosperm embraces the embryo, filled with starch granules.

Impurities and other requirements:
1. Loss on drying: Not more than 15.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 3.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 3.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:
1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place, and protect from insects.
Usage: Astringent medicinal.
Property and flavor: Cool, sweet.
Meridian tropism: Heart meridians.
Effects: Tonify qi, eliminate heat, antihidrotics.
Administration and dosage: 15~30 g.

TSAOKO FRUCTUS
草果
Cao Guo / Cao Guo
Tsaoko Amomum Fruit

Tsaoko amomum fruit is the dried ripe fruit of *Amomum tsao-ko* Crevost & Lemarié (Fam. Zingiberaceae).
It contains not less than 8.0% of dilute ethanol-soluble extractives and not less than 8.0% of water extractives. Masses of seeds contain not less than 1.4% (v/w) of volatile oil.

Description: Oblong, with 3 obtuse ribs, 2~4 cm in length, 1~2.5 cm in diameter. Externally grayish-brown, with distinct longitudinal furrows and ribs, apex with a rounded and protuberant stylopodium, base with a short fruit stalk or its scar. Pericarp thick and tenacious, the central part showing brown septa dividing the masses of seeds into 3 groups, each containing mostly 8~11 seeds. Seed irregular polyhedral, 3~5 mm in diameter, externally reddish-brown, covered with grayish-white membranous aril, oily. Odour slight; taste slightly pungent and bitter.
Tsaoko fructus

Microscopic identification:
Transverse section:
Fruit of *Amomum tsao-ko*: Exocarp composed of 1 row of square cells, covered with cuticle. Mesocarp broad, cells containing clusters or prisms of calcium oxalate and oil cells, scattered with collateral vascular bundles, with fiber bundles on the outer side. Endocarp composed of 1 row of parenchymatous cells. Aril composed of several rows of cells. Epidermis of testa composed of 1 row of suboblong cells, 35~40 μm in length, 20~30 μm in width, wall thick and covered with cuticle; inside showing parenchymatous cells, containing yellowish-brown contents. Oil cells 1~2 rows, square, elongated radially, 40~80 μm in length, 35~60 μm in width. Endotesta composed of 1 row of sclerenchymatous cells, arranged in palisade- shaped, reddish-brown. Perisperm cells polygonal or subrounded, containing clusters or prisms of calcium oxalate and abundant starch granules. Endosperm cells contain aleurone grains and starch granules.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 1 mL of methanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of 1,8-cineole and dissolve in methanol to produce a solution containing 5.0 μL per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane, ethyl acetate, and acetone (30:0.5:1) as the developing solvent. Apply 8 μL of each of the sample solution and reference drug solution and 1 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray *p*-anisaldehyde/H_2SO_4 TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 14.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 10.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 3.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:
1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).
3. Volatile oil: Carry out the method for determination of volatile oil (General rule 6013).

Storage: Store in a cool and dry place, and protect from moisture.
Usage: Dampness-dispelling medicinal (Dampness-resolving with aroma medicinal).
Property and flavor: Warm; pungent.
Meridian tropism: Spleen and stomach meridians.
Effects: Dry dampness to fortify spleen, eliminate phlegm and interrupt malaria.
Administration and dosage: 3~6 g.

TYPHAE POLLEN
蒲黃
Pu Huang / Pu Huang
Cattail Pollen

Cattail pollen is the dried pollen of *Typha angustifolia* L. or *Typha orientalis* C.Presl and similar species (Fam. Typhaceae).
It contains not less than 9.0% of dilute ethanol-soluble extractives and not less than 11.0% of water extractives.

Description: Yellow and fine powder. Texture light, with satiny feeling and easily adsorbed on fingers, capable of floating on water. Odourless; taste weak.

Microscopic identification:
Powder: Yellow. Starch granules solitary, subrounded or oblong, 17~29 μm in diameter, with reticulate glyph on the surface, containing indistinct single pits.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 30 mL of methanol, ultrasonicate for 30 minutes, cool, filter, and make up the filtrate to 10 mL.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of toluene, ethyl acetate, and formic acid (5:2:1) as the developing solvent. Apply 10 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 254 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:
1. Loss on drying: Not more than 13.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 10.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 4.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251,

6301)

Assay:
1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place, and protect from moisture and insects.
Usage: Blood-regulating medicinal (Hemostatic medicinal).
Property and flavor: Neutral; sweet.
Meridian tropism: Liver and pericardium meridians.
Effects: Hemostatic, dissipate stasis, induce diuresis and relieve strangury.
Administration and dosage: 5~10 g, wrap-decocted; used an appropriate amount for external use.
Precaution and warning: Use cautiously during pregnancy.

UNCARIAE RAMULUS CUM UNCIS
鉤藤
Gou Teng / Gou Teng
Uncaria Stem with Hooks

Uncaria stem with hooks is the dried stem with hooks of *Uncaria rhynchophylla* (Miq.) Miq., *Uncaria macrophylla* Wall., *Uncaria hirsuta* Havil., *Uncaria lanosa* Wall. var. *appendiculata* (Benth.) Ridsale or *Uncaria sinensis* (Oliv.) Havil. (Fam. Rubiaceae).
It contains not less than 8.0% of dilute ethanol-soluble extractives and not less than 8.0% of water extractives.

Description: Stem cylindrical or subsquare, 2~3 cm in length, 2~5 mm in diameter. Externally reddish-brown to purplish-red, with fine longitudinal striations and glabrous. Most nodes bearing with two opposite downward curved hooks, some ones with a hook at one side and a protuberant scar at another side; hooks slightly flattened or rounded, base relatively broad, apex acute; dotted scars of falling petiole and ring-shaped scars of stipule visible on the branch connected with the hook base. Texture light and tenacious, fracture yellowish-brown, bark fibrous, pith yellowish-white, lax as sponge or hollowed. Odourless; taste weak.

(1) Stem with hooks of *Uncaria hirsuta*: Stem subcylindrical or subsquare, 3~6 cm in length, 3~4 mm in diameter, externally yellowish-brown or yellowish-green, Most nodes bearing with two opposite or one downward curved hooks, hook shag, 1.4~1.8 cm in length, 2 mm in base width, flat or slightly flat, stipules remaining on the nodes, the leaves are deep and split. Texture light and tenacious, fracture yellowish-brown, bark fibrous, pith yellowish white or hollowed, Odor slight ; taste Weak.

Microscopic identification:
1. **Transverse section:**
   (1) Branch of *Uncaria hirsuta* stem with hooks: Epidermis covered with thickened cuticle. Cortex contains brown contents and a few of starch granules. Pericyclic fiber bundles linked into an interrupted ring. Phloem fibers of 2 types: one type is sclerenchyma, the other type is parenchyma, usually singly scattered or 2~3 in bundles. Phloem parenchymatous cells contain sandy crystals of calcium oxalate. Phloem rays 1 layer wide. Cambium distinct. Xylem vessels subrounded, mostly singly scattered, occasionally 2~4 parallelly arranged; xylem fibers with thin wall, uneasily distinguished with xylem parenchymatous cells. Pith broad, occupied about half portion of sectional diameter, surrounded by 1~2 layers of sclerenchymatous cells, with distinct single pits, containing brown contents.
   (2) Hook of *Uncaria* stem with hooks: The basic characters same as branch, but the tissue arranged densely, xylem relatively broad at the hook apex, pith narrow.
   (3) Branch of *Uncaria hirsute*: Large outer wall has distinct non-glandular hair, Epidermis cell 1~2 row, epidermis covered with thickened cuticle, composed of subrectangular and Square cells, 37~56 μm in length, 22~28 μm in width. Cortex composed of 6~12 layers of cells, square and subsquare , subpolygonal, with intercellular spaces, contain sandy crystals of calcium oxalate. Phloem occupied about 12~18 layers, cells small and shrinking, subsquare and irregular, bast fibers single or 3~16 bundles, arranged in a strip shape, 18~36 μm in diameter. Cambium in a ring, shrinkage is not obvious. Wood occupying one half, lignified distinct; composition of rimmed catheter, threaded catheter, xylem fibers, xylem parenchyma cells; catheter closely aligned with the xylem fibers, catheter distinct, oblong, subround, subsquare, irregular, 26~58 μm in diameter; rays distinct, subsquare, subpolygonal, 20~38 μm in diameter. Center pith, about one third, wide, subround, subpolygonal, hollow, obvious cell gap.
2. **Powder:** Pale reddish-brown. Phloem fibers mostly in bundles, 16~42 μm in diameter, unlignified to slightly lignified, pit canals indistinct. Vessels spiral, reticulate, scalariform and bordered-pitted, bordered-pitted vessels up to 68 μm in diameter. Phloem parenchymatous cells contain sandy crystals of calcium oxalate. Slightly lignified parenchyma fragments abundant (including xylem rays, pith and xylem parenchymatous cells), cells subsquare, subrounded, irregular or fine-rectangular. 17~72 μm in diameter, walls slightly thickened,

with numerous oblong or round single pits. Epidermal cells brownish-yellow, subsquare, polygonal or slightly elongated, up to 32 μm in diameter, walls slightly thickened, cells containing oil droplets, relatively thickened cuticle layer are found in sectional view. Fiber-shaped tracheids rare, mostly in bundles with phloem fibers.

(1) Stem with hooks of *Uncaria hirsuta*: Pale yellowish brown to reddish brown. Epidermis cell yellowish brown, subsquare, polygonal, 22~28 μm in diameter, wall slightly thicker, oil droplets in the cells, thicker cuticles can be seen in the cross section. Phloem fiber bundles abundant, 18~36 μm in diameter, lignified, pit canals distinct. Catheter main thread, steps, network and edges, 26~58 μm in diameter, long. Phloem, parenchymatous cells containing sandy crystals. parenchymatous cells, containing xylem myeloid, xylem parenchyma and medullary cells, subround, subsquare, irregular, fine rectangle, wall slightly thicker, many oval or round single holes, 20~38 μm in diameter. Occasionally fiber-optic pseudo-catheter, mostly in bundles with phloem fibers.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 2.0 g of powdered sample to 2 mL of concentrated ammonia solution, macerate for 30 minutes, add 50 mL of dichloromethane, heat under reflux for 2 hours, cool, filter and evaporate the filtrate to dryness, dissolve the residue in 1 mL methanol.
2. Reference drug solution: Take 2.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of isorhynchophylline and dissolve in methanol to produce a solution containing 0.5 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of petroleum ether (30~60℃) and acetone (6:4) as the developing solvent. Apply 15 μL of each of the sample solution and reference drug solution and 5 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with modified Dragendorff's reagent spray reagent. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained with the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 10.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 3.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:

1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place, and protect from moisture.
Usage: Liver-pacifying and wind-extinguishing medicinal.
Property and flavor: Mild cold; sweet.
Meridian tropism: Liver, heart, and pericardium meridians.
Effects: Extinguish wind to arrest convulsions，clear heat and pacify liver.
Administration and dosage: 3~15 g, added when the decoction is nearly done.

VACCARIAE SEMEN
王不留行
Wang Bu Liou Sing / Wang Bu Liu Xing
Cowherb Seed

Cowherb seed is the dried ripe seed of *Vaccaria hispanica* (Mill.) Rauschert (Fam. Caryophyllaceae).
It contains not less than 6.0% of dilute ethanol-soluble extractives, not less than 8.0% of water extractives and not less than 0.4% of vaccarin.

Description: Spheroidal, 1.5~2 mm in diameter. Externally black, slightly lustrous, with dense fine and granular protuberances under the magnifier, with pale dot-like hilum and a concave furrow. Texture hard, fracture grayish-white, horny. Odour slight; taste weak.

Microscopic identification:

1. **Transverse section**:
   Seed of *Vaccaria hispanica*: Embryo bended, the major portion of embryo is occupied by endosperm. Epidermal cells of testa brownish-black, undulating bend. Inner epidermis of testa reddish-brown. Endosperm cells polygonal or sub-elliptical, lumen contains starch granules.
2. **Powder:** Grayish-brown. Odourless, taste slightly bitter. Fragments of testa reddish-brown, lumen

distinct, sub-elliptical in shape, with striations. Endosperm cells relatively large, polygonal or sub-elliptical, lumen walls relatively thin, containing starch granules and aleurone granules.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 0.5 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 0.5 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of vaccarin and dissolve in methanol to produce a solution containing 0.1 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, methanol, and water (6:2:1) as the developing solvent. Apply 2 μL of each of the sample solution and reference drug solution and 1 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 13.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 4.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:

1. Vaccarin:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and water as the mobile phase B
   (2) Reference standard solution: Weigh accurately a quantity of vaccarin, and dissolve in 50% methanol to produce a solution containing 0.1 mg per mL.
   (3) Sample solution: Weigh accurately 0.6 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 10 mL of 50% methanol, ultrasonicate for 30 minutes. Centrifuge for 10 minutes. Repeat the extraction of the residue one more time. Combine the extracts and transfer the solution to 25-mL volumetric flask, make up to volume with 50% methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (270 nm) and a column packing L1. The column temperature is maintained at 35℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of vaccarin should not be less than 3,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~15	10→15	90→85
15~20	15→100	85→0

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   Vaccarin: (%)= 2.5 (r_U/r_S) (C_S) / (W)

   r_U: peak area of vaccarin of sample solution
   r_S: peak area of vaccarin of reference standard solution
   C_S: concentration of vaccarin of reference standard solution (mg/mL)
   W: weight of test sample (g) calculated with dried sample.
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from insects.
Usage: Blood-regulating medicinal (Blood-activating and stasis-dispelling medicinal).
Property and flavor: Neutral; bitter.
Meridian tropism: Liver and stomach meridians.
Effects: Activate blood to promoting menstruation, promote lactation, disperse swelling.
Administration and dosage: 4.5~11.5 g.
Precaution and warning: Use cautiously during pregnancy.

VERBENAE HERBA
馬鞭草
Ma Bian Tsao / Ma Bian Cao
European Verbena

European Verbena is the dried aerial part of *Verbena officinalis* L. (Fam. Verbenaceae).

It contains not less than 15.0% of dilute ethanol-soluble extractives and not less than 13.0% of water extractives and not less than 0.5% of verbenalin.

Description: Slightly square-shaped, multi-branched, with longitudinal grooves on all sides. Epidermis grayish green to yellowish green and rough. Hard and brittle, marrow or hollow. Leaves opposite, shrunken, broken, greenish brown, intact, flattened, 3 lobed, with serrate edges. Spikes are slender and have a small number of small flowers. Odor slight, taste bitter.

Microscopic identification:

1. **Transverse section:**
   (1) Stem of *Verbena officinalis*: Epidermis consists of 1 column of subsquare or rectangular cells, the outer wall is slightly thicker; collenchyma underneath, collenchyma at the four corners is wider, consisting of about 4~7 rows of collenchymatous cell. Cortical fibers are bundled and arranged intermittently into a ring, fiber bundle at the corner is large. Cortex is composed of 5~7 columns of cells, subround, elliptical or irregular. Phloem narrow, cells irregular; layer loop is formed; xylem is relatively wide, arranged in a ring, duct is arranged radially in a broad section, consisting of subround parenchyma cells, large intercellular spaces, occasionally broken or hollow.
   (2) Leaf of *Verbena officinalis*: Upper epidermis consists of 1 column of cells. Collenchyma visible on the main vein and inside the epidermis. Grid structure consists of 1 row of oblong cells; cavernous tissue composed of irregularly shaped cells, loosely arranged. Vascular bundle vertical, xylem in the middle of the veins, surrounded by the phloem. Lower epidermis consists of 1 column of irregular cells, vertical wall is wavy. Epidermis occasionally saw single cells non-glandular hairs and glandular scales.
2. **Powder:** Greenish-brown. Non-glandular hair is a single cell, apex acuminate, slightly enlarged base. Pollen grains are subround or subround triangle, with a smooth surface, 3 germination holes. Epidermal cells of the stem are long polygonal or subrectangular, vertical wall is flat, outer wall is slightly thick, irregular pores. Epidermal cells of the leaves have undulating curvature, stomata infinitive or inequalities, sometimes glandular scales; glandular scales consist of a multicellular head and a single cell stem. Fibers are bundled, large and closely arranged; colorful under a polarizing microscope. Conduits are primarily spiral, reticulate and bordered pit conduits.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, heat under reflux for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of verbenalin and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of ethyl acetate, methanol, and water (9:2:1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 11.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 10.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 3.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. Verbenalin:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and 0.05% phosphoric acid as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of verbenalin and dissolve in 75% methanol to produce a solution containing 20 μg per mL.
   (3) Sample solution: Weigh accurately 0.1 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 20 mL of 75% methanol, ultrasonicate for 30 minutes and centrifuge for 10 minutes. Transfer the supernatant to a 50-mL volumetric flask. Repeat the extraction of the residue one more time. Combine the supernatant and make up to volume with 75% methanol, mix well, filter

and use the filtrate.

(4) Chromatographic system: The liquid chromatography is equipped with an UV detector (238 nm) and a column packing L1. The column temperature is maintained at 30℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of verbenalin should not be less than 9,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~10	10	90
10~30	10→20	90→80

(5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Verbenalin (%)=0.005(r_U/r_S) (C_S) / (W)

r_U: peak area of verbenalin of sample solution

r_S: peak area of verbenalin of reference standard solution

C_S: concentration of verbenalin of reference standard solution (μg/mL)

W: weight of test sample (g) calculated with dried sample.

Storage: Store in a ventilated and dry place.
Usage: Heat-clearing medicinal (Heat-clearing and detoxicating medicinal).
Property and flavor: Cool, bitter.
Meridian tropism: Liver and spleen meridians.
Effects: Clear heat and detoxicate, activate blood and dissipate stasis, cool the blood and break blood, induce diuresis to alleviate edema.
Administration and dosage: 5~30 g; used an appropriate amount for external use.

VIGNAE SEMEN
赤小豆
Chih Siao Dou / Chi Xiao Dou
Rice Bean

Rice bean is the dried ripe seed of *Vigna umbellata* (Thunb.) Ohwi & H.Ohashi (Fam. Leguminosae).
It contains not less than 8.0% of dilute ethanol-soluble extractives and not less than 10.0% of water extractives.

Description: Cylindrical and slightly flattened, both ends slightly truncate or obtusely rounded, 5~8 mm in length, 2~4 mm in diameter. Externally purplish-red or dark reddish-brown, occasionally brownish-yellow, smooth, slightly lustrous or dull. Hilum white, slightly protuberant at one side, dented and forming a longitudinal furrow in the middle, 2~4 mm in length, with an indistinct ridge at the other side. Texture hard, uneasily broken, cotyledons 2, milky-white, thick, radicle slender, curved. Odour slight; taste slightly sweet, bean-like on chewing.

Microscopic identification:
Transverse section:
Seed of *Vigna umbellata*: Epidermal cells of testa composed of 1 layer of palisade cells and 2 layers at hilum, 37~75 μm in radial direction, 7~12 μm in tangential direction, lumina contain pale reddish-brown contents, near the upper part with a light line; brace cells 1 row, dumbbell-shaped, 13~17 μm in radial direction, 10~20 μm in tangential direction, constrict parts 7~12 μm in tangential direction; underneath ranged about 10 layers of parenchymatous cells. Cotyledon cells contain starch granules, fine prisms of calcium oxalate, 3~13 μm in diameter, and clusters of calcium oxalate, 6~16 μm in diameter. A caruncle occurring at outside the palisade cells in hilum, cells containing starch granules; inner with tracheid, cells walls reticulate thickened, with asteroidal cells in both sides, with intercellular spaces.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter then evaporate the filtrate to dryness, dissolve the residue in 1 mL of methanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-propanol and water (7:3) as the developing solvent. Apply 10 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 1% ninhydrin/EtOH TS and heat at 105℃ until the spots become visible. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:
1. Loss on drying: Not more than 14.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 8.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:
1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from insects.
Usage: Dampness-dispelling medicinal (Dampness-draining diuretic medicinal).
Property and flavor: Neutral; sweet and sour.
Meridian tropism: Heart and small intestine meridians.
Effects: Induce diuresis to alleviate edema, detoxicate to expel pus.
Administration and dosage: 10~30 g.

VIOLAE HERBA
紫花地丁
Zih Hua Di Ding / Zi Hua Di Ding
Philippine Violet Herb

Philippine violet herb is the dried herb of *Viola philippica* Cav. (Fam. Violaceae).
It contains not less than 9.0% of dilute ethanol-soluble extractives, not less than 10.0% of water extractives and not less than 0.2% of esculetin.

Description: Frequently crumpled into masses. The main roots long-conical, pale yellowish-brown, 0.1~0.3 cm in diameter, with fine longitudinal wrinkles; texture hard, easily broken, fracture even, starchy. Leaves grayish-green, lanceolate or ovate-lanceolate as whole, 1.5~6 cm in length, 1~2 cm in width; apex obtuse, base truncate or slightly cordate, margin obtusely serrate, both surfaces pubescent; petioles with distinct narrow wings. Pedicels slender; corolla pale purple, petal 5, spur tubular. Capsules elliptical or 3-split; seeds numerous. Odour slight; taste slightly bitter and sticky.

Microscopic identification:
1. **Transverse section:**
   (1) Root of *Viola philippica*: The outermost layer was 4~6 layers of cork cells, cell wall slightly lignified; cortex broad, parenchymatous cells subrounded. Phloem scattered with sieve tube groups, rays indistinct. Cambium in a ring, cells flat. Xylem composed of vessels, fiber tracheids, xylem fibers and xylem parenchymatous cells; vessels scattered or 2~4 arranged in groups, polygonal or subrounded, walls lignified; xylem fibers well developed, arranging around vessels. Parenchymatous cells filled with starch granules and clusters of calcium oxalate; starch granules mostly simple, subspheroidal, 2~8 μm in diameter; clusters of calcium oxalate 20~30 μm in diameter.
   (2) Leaf of *Viola philippica*: In surface view, upper epidermis with anticlinal walls slightly straight, moniliform thickened, with distinct cutinized striations on the surface, stomata relatively few, anisocytic; lower epidermis with anticlinal walls slightly curved, indistinct thickness, with cutinized striations on the surface. Both upper and lower epidermis contain unicellular non-glandular hairs of 2 types: one type is slightly short, conical, wall thick with distinct warty protuberance, 50~85 μm in length, 20~30 μm in diameter; the other type is long, slightly curved, walls with short linear striations, 160~360 μm in length, 20~30 μm in diameter. Mesophyll contains clusters of calcium oxalate, 15~40 μm in diameter.
2. **Powder:** Yellowish-brown. Containing clusters of calcium oxalate. Parenchymatous cells contain starch granules. Vessels mainly scalariform and reticulate.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, cool and filter and make up the filtrate to 10 mL.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of esculetin and dissolve in methanol to produce a solution containing 0.2 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of toluene, ethyl acetate, and formic acid (5:3:1) as the developing solvent. Apply 2 μL of each of the sample solution and reference drug solution and 1 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 12.0% dry at 105°C for 5 hours (General rule 6015).
2. Total ash: Not more than 25.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 11.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).

7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:

1. Esculetin:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and 0.1% glacial acetic acid as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of esculetin, and dissolve in ethanol to produce a solution containing 10 μg per mL.
   (3) Sample solution: Weigh accurately 0.2 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 20 mL of 50% ethanol, ultrasonicate for 30 minutes. Centrifuge for 15 minutes, filter the supernatant. Repeat the extraction of the residue one more time. Combine the filtrate and transfer to 50-mL volumetric flask and make up to volume with 50% ethanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (340 nm) and a column packing L1. The column temperature is maintained at room temperature. The flow rate is about 1 mL/min.Program the chromatographic gradient system as follows. The number of theoretical plates of the peak of esculetin should not be less than 10,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~5	5→15	95→85
5~15	15→26	85→74
15~20	26→95	74→5
20~25	95	5

   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
   Esculetin (%)=0.005(r_U/r_S) (C_S) / (W)
   r_U: peak area of esculetin of sample solution
   r_S: peak area of esculetin of reference standard solution
   C_S: concentration of esculetin of reference standard solution (μg/mL)
   W: weight of test sample (g) calculated with dried sample.
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place.
Usage: Heat-clearing medicinal (Heat-clearing and detoxicating medicinal).
Property and flavor: Cold; bitter and pungent.
Meridian tropism: Heart and liver meridians.
Effects: Clear heat and detoxicate, disperse abscesses and nodule.
Administration and dosage: 15~30 g, used an appropriate amount for external use.

VISCI HERBA
槲寄生
Hu Ji Sheng / Hu Ji Sheng
Coloed Mistletoe Herb

Coloed mistletoe herb is the dried stem and branch with leaf of *Viscum coloratum* (Kom.) Nakai (Fam. Loranthaceae).
It contains not less than 0.04% of syringoside.

Description: Stems cylindrical, 2~5 branched in fork shape, about 30 cm in length, 0.3~1 cm in diameter; externally yellowish-green, golden-yellow or yellowish-brown, with longitudinal wrinkles; nodes swollen, with branches or scars of branches; texture light and fragile, easily broken; fracture uneven, bark yellow, wood pale yellow, pith rays radial, pith often inclined to one side. Leaves opposite on the tips of branches, easily fallen off, sessile; lamina oblong-lanceolate, 2~7 cm in length, 0.5~1.5 cm in width; apex obtusely rounded, base cuneate, margin entire; externally yellowish-green, with five wrinkles, quinque-veined, the middle 3 distinct; texture coriaceous. Odourless; taste slightly bitter, sticky on chewing.

Microscopic identification:

1. **Transverse section:**
   Stem of *Viscum coloratum*: Epidermal cells rectangular, covered with yellowish-green cuticle, 19~80 μm thick. Cortex relatively broad, fibers arranged in bundles of several dozens of cells, slightly lignified; stone cells extremely numerous in old stem, singly scattered or in bundles. Phloem relatively narrow, scattered with stone cells in old stem; cambium indistinct. Xylem rays scattered with fiber bundles; vessels surrounded by numerous fibers. Pith distinct. Parenchymatous cells contain clusters of calcium oxalate and a few of prism crystals.
2. **Powder:** Pale yellow. Fragments of epidermis yellowish-green, cells subsquare with stomata. Fibers in bundles, 10~34 μm in diameter, wall relatively thickened, slightly sinuous and lignified. Clusters of calcium oxalate 17~45 μm in diameter; prism crystals relatively few, 8~30 μm in diameter. Stone cells subsquare, subpolygonal or irregular, 42~102 μm in diameter.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.5 g of powdered sample to 30 mL of ethanol, heat under reflux for 30 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 1 mL of absolute ethanol.
2. Reference drug solution: Take 1.5 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of oleanolic acid and dissolve in absolute ethanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of cyclohexane, ethyl acetate, and glacial acetic acid (20:6:1) as the developing solvent. Apply 4 μL of each of the sample solution and reference drug solution and 2 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with 10% H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under visible light and ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
2. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
3. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
4. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
5. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:

Syringoside:

1. Mobile phase: A solution of methanol and 0.1% phosphoric acid (15:85). The ratio may be adjusted, if necessary.
2. Reference standard solution: Weigh accurately a quantity of syringoside and dissolve in methanol to produce a solution containing 50 μg per mL.
3. Sample solution: Weigh accurately 2.0 g of the powdered sample and place it in a conical flask with a stopper, accurately add 25 mL of 70% methanol, stopper tightly and weigh, ultrasonicate for 30 minutes, cool, weigh again, replenish the loss of the weight with 70% methanol, mix well, filter and use the filtrate.
4. Chromatographic system: The liquid chromatography is equipped with an UV detector (264 nm) and a column packing L1. The number of theoretical plates of the peak of syringoside should not be less than 5,000.
5. Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Syringoside (%)=0.0025(r_U/r_S) (C_S) / (W)

r_U: peak area of syringoside of sample solution

r_S: peak area of syringoside of reference standard solution

C_S: concentration of syringoside of reference standard solution (μg /mL)

W: weight of test sample (g) calculated with dried sample.

Storage: Store in a cool and dry place, and protect from insects.

Usage: Dampness-dispelling medicinal (Wind-dampness-dispelling medicinal).

Property and flavor: Neutral; bitter and sweet.

Meridian tropism: Liver and kidney meridians.

Effects: Tonify liver and kidney, strengthen sinew and bone, dispel wind dampness, prevent abortion.

Administration and dosage: 9~15 g.

VITICIS FRUCTUS
蔓荊子
Man Jing Zih / Man Jing Zi
Shrub Chastetree Fruit

Shrub chastetree fruit is the dried ripe fruit of *Vitex trifolia* L. subsp.*litoralis* Steenis or *Vitex trifolia* L. (Fam. Verbenaceae).

It contains not less than 4.0% of dilute ethanol-soluble extractives, not less than 4.0% of water extractives and not less than 0.03% of vitexicarpin.

Description: Spheroidal, 4~6 mm in diameter. Externally grayish-black or blackish-brown, covered with grayish-white frost-like hairs, bearing with 4 longitudinal shallow furrows. Apex slightly concave, base with grayish-white persistent calyx and short fruit stalk. Persistent calyx 1/3~2/3 length of the fruit, apex 5-toothed, with 1~2 deep lobes, grayish-white, covered with dense pubescences. Texture hard, uneasily broken. In transverse section, pericarp thick, pale grayish-yellow; Exocarp with brown oil spots (oil cavity); endocarp showing 4 locules (4 nutlets), each locule containing 1 seed. Kernel containing abundant fatty oil. Odour aromatic; taste weak and slightly pungent.

Microscopic identification:

1. **Transverse section:**

Viticis fructus: Exocarp composed of 1 layer of subsquare epidermal cells, covered with cuticle, with glandular hairs and non-glandular hairs. Mesocarp broad, occupied the most portion of the pericarp, the outer part of 2~3 rows of cells contain pigments, the remaining with cell walls slightly thickened and

lignified; vascular bundles small. Endocarp composed of several layers of stone cells, wall thickened, pit canals distinct.

2. **Powder:** Dark grayish-brown. Stone cells of endocarp subsquare, subrounded, subpolygonal, fusiform or long strip-shaped, 9~65 μm in diameter, up to 171 μm in length, walls 5~22 μm thick, striations mostly distinct, pit canals relatively dense, lumen narrow, mostly containing 1 to several fine prisms of calcium oxalate. Parenchymatous cells of pericarp subrounded, subpolygonal, subrectangular or suboblong, 19~70 μm in diameter, walls slightly thickened, occasionally moniliform lignified, some lumens contain yellowish-brown contents. Epidermal cells of exocarp rectangular in sectional view, covered with cuticle, the margins denticulate-shaped; subpolygonal in surface view, with dense cutinized striations, hairs or round hair scars visible. Non-glandular hairs 1- to 5-celled, straight, a few curved or down-prostrate, complete ones 36~191 μm in length, 9~23 μm in diameter, wall slightly thickened with warty protuberance, the apical cells relatively dense, the basal cells slightly shrunken. Glandular scales with head 4-celled, 36~63 μm in diameter, the stalk extremely short, unicellular. A few of small glandular hairs visible, the head 1- to 4-celled; the stalk 1- to 3-celled. Reticular epidermal cells of testa with periclinal walls reticular thickened, slightly lignified, pits strip-shaped, arranged in order.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 15 mL of methanol, ultrasonicate for 30 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 1 mL of methanol.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of vitexicarpin and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-butanol, ethanol, and 4N ammonia water (5:1:2) as the developing solvent. Apply 2 μL of each of the sample solution and reference drug solution and 1 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 254 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 15.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 9.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 3.5% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:

1. Vitexicarpin:
   (1) Mobile phase: A solution of methanol and 0.4% phosphoric acid (60:40). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of vitexicarpin and dissolve in methanol to produce a solution containing 30 μg per mL.
   (3) Sample solution: Weigh accurately 2 g of the powdered sample and place it in a conical flask with a stopper, accurately add 50 mL of methanol, weigh, heat under reflux for 1 hour, cool, weigh again, replenish the loss of the weight with methanol, mix well, filter and use the filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (258 nm) and a column packing L1. The number of theoretical plates of the peak of vitexicarpin should not be less than 2,000.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   Vitexicarpin (%)=0.005(r_U/r_S) (C_S) / (W)

   r_U: peak area of vitexicarpin of sample solution

   r_S: peak area of vitexicarpin of reference standard solution

   C_S: concentration of vitexicarpin of reference standard solution (μg /mL)

   W: weight of test sample (g) calculated with dried sample.
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place.

Usage: Exterior-releasing medicinal (Pungent-cold exterior-releasing medicinal).

Property and flavor: Mild cold; pungent and bitter.

Meridian tropism: Bladder, liver, and stomach meridians.

Effects: Disperse wind-heat, clear head and eyes.
Administration and dosage: 5~12 g.

XANTHII FRUCTUS
蒼耳子
Cang Er Zih / Cang Er Zi
Cocklebur Fruit

Cocklebur fruit is the dried ripe fruit with involucres of *Xanthium sibiricum* Patrin ex Widder. (Fam. Compositae). It contains not less than 3.0% of dilute ethanol-soluble extractives and not less than 5.0% of water extractives.

Description: Fusiform or oval, 1~1.5 cm in length, 0.4~0.7 cm in diameter. Involucresyellowish-brown or yellowish-green, with hooked bristles, apex with 2 relatively thick spines, separated or linked up, base with a fruit stalk scar; texture hard and tenacious, the center of transverse section showing a septum and 2 locules, each loculus containing an achene. Achene slightly fusiform, relatively even at one side, apex with a protruding stylopodium; pericarp thin, grayish-black, with longitudinal wrinkles; testa membranous, pale gray; cotyledons 2, oily. Odour slight; taste slightly bitter.

Microscopic identification:
1. **Transverse section:**
   Fruit with involucres of *Xanthium sibiricum*: Outside and inside the involucre showing 1 layer epidermal cells. Between the outer and inner epidermis mainly composed of fiber layers, arranged criss-cross, the outer several rows of fibers arranged longitudinally in the lengthwise direction of the fruit, cells polygonal in sectional view; the inner fibers arranged vertically into long strip-shaped, occasionally with hook-like protuberance, fibers scattered with 1 layer of vascular bundles; the remaining all composed of parenchymatous cells. Outside pericarp showing epidermal cells and 1 layer brown pigment layer, inside showing parenchyma tissue, scattered with vascular bundles. Cotyledons contain oil droplets and aleurone grains.
2. **Powder:** Grayish-yellow. Fibers abundant, singly scattered or in bundles of 2 types: one type is slender and fusiform, numerous, wall relatively thin, 425 μm in length, 17 μm in width; the other type few, wall relatively thickened with distinct pits, 255 μm in length, 15 μm in width. Xylem parenchymatous cells rectangular, with single pits, 96~120 μm in length, 19~24 μm in width. Vessels few, reticulate vessels 210 μm in length, 34 μm in width; spiral vessels 96 μm in length, 12 μm in width. Cotyledon cells contain aleurone grains and oil droplets. Parenchymatous cells of testa subrounded or elongated-rounded, pale yellow.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 15 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of chlorogenic acid and dissolve in methanol to produce a solution containing 0.5 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-butyl acetate, formic acid, and water (7:2.5:2.5) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 13.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 8.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:
1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a ventilated and dry place.
Usage: Exterior-releasing medicinal (Pungent-warm exterior-releasing medicinal).
Property and flavor: Warm; pungent and bitter.
Meridian tropism: Lung meridians.
Effects: Promote sweating to resolve heat, calms convulsion, relieve pain, relieve stuffy nose.
Administration and dosage: 3~12 g.

ZANTHOXYLI PERICARPIUM
花椒
Hua Jiao / Hua Jiao
Pricklyash Peel

Pricklyash peel is the dried ripe pericarp of *Zanthoxylum schinifolium* Siebold & Zucc. or *Zanthoxylum bungeanum* Maxim. (Fam. Rutaceae).
It contains not less than 10.0% of dilute ethanol-soluble extractives, not less than 8.0% of water extractives and not less than 1.0% (v/w) of volatile oil.

Description:
1. Pericarp of *Zanthoxylum schinifolium* (Shiang Jiao Tz): 1~3 follicles (mostly 3), slightly spheroidal, 3~4 mm in diameter, splitting along dorsal and ventral suture. Exocarp brown-green or yellowish-green, with reticulated wrinkles, scattered with numerous dark and dented oil dots, curved inwards. Endocarp grayish-white or pale yellow, commonly separated from exocarp at the base, curved inwards. Most of the seeds have Fallen off, occasionally retained, oval, 3~4 mm in diameter, black and bright, Hilum line shape, light brown. Taste slightly sweet and pungent.
2. Pericarp of *Zanthoxylum bungeanu*m (Hung Jiao): Most follicles singly (occasionally 2, rarely 3), 4~5 mm in diameter, pericarp splitting along ventral suture, slightly splitting along dorsal. Exocarp reddish-purple or reddish-brown, crumpled extremely, scattered with numerous protuberant oil dots, 0.5~1 mm in diameter. Endocarp pale yellow, commonly separated from exocarp at the base, curved inwards, with a small fruit stalk and 1~2 undeveloped carpel, small and granular Odour strongly aromatic; taste lastingly pungent and numb.

Microscopic identification:
1. **Transverse section:**
   Pericarp of *Zanthoxylum bungeanum*: 1 layered epidermis covered with cuticle, cells containing brown contents, stomata occasionally found in surface view, 32~42 μm in diameter. Vascular bundles and large oil cavities distributed in mesocarp, oil cavities oblong, 500~900 μm in length, 300~700 μm in diameter, containing pale yellow oil. Parenchymatous cells contain numerous clusters of calcium oxalate, mostly distributed near endocarp, 15~45 μm in diameter. Endocarp composed of several layers of lignified fiber cells, varying in length, arranged alternately, cells strip-shaped near mesocarp, the others long-rounded, subrounded or polygonal, 12~22 μm in diameter.
2. **Powder:**
   (1) Pericarp of *Zanthoxylum schinifolium*: Dark brown. Endocarp cells fusiform, varying in length, arranged alternately or overlapped vertically, subrectangular or subpolygonal, 10~27 μm in diameter, walls slightly thickened and lignified. Epidermal cells of pericarp subpolygonal in surface view, walls thin, with dense and horny-like striations on the surface, containing hesperidin crystals. Stomata rare. Epidermal cells of testa reddish-brown or brownish-black; reddish-brown ones with anticlinal walls thin or slightly moniliform thickened; brownish-black ones with indistinct cell boundaries. Clusters of calcium oxalate 8~35 μm in diameter. Slightly lignified hypodermal cells of pericarp, fine vessels, xylem fibers and hesperidin crystals also present.
   (2) Pericarp of *Zanthoxylum bungeanum*: Dark brown, exocarp epidermal cells with anticlinal walls moniliform thickened, calcium oxalate clusters are more common, 10 ~ 40μm in diameter.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 2.0 g of powdered sample to 10 mL of ethyl ether, shake well, macerate for all night, filter, evaporate the filtrate to 1 mL, and use the filtrate.
2. Reference drug solution: Take 2.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane and ethyl acetate (4:1) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution.

Impurities and other requirements:
1. Loss on drying: Not more than 16.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 9.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 2.0% (General rule 6007).
4. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
8. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:
1. Water extractives: Carry out the method for determination of water extractives (General rule 6011).

2. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).
3. Volatile oil: Carry out the method for determination of volatile oil (General rule 6013).

Storage: Refrigerate or store in a cool and dry place, preserve in a well-closed container, and protect from insects.
Usage: Interior-warming medicinal.
Property and flavor: Hot; pungent.
Meridian tropism: Spleen, stomach, and kidney meridians.
Effects: Warm the middle to relieve pain, kill worms, relieve itching.
Administration and dosage: 1~5 g.

ZINGIBERIS RHIZOMA
乾薑
Gan Jiang / Gan Jiang
Dry Ginger Rhizome

Dry ginger rhizome is the dried rhizome of *Zingiber officinale* Roscoe. (Fam. Zingiberaceae).
It contains not less than 10.0% of dilute ethanol-soluble extractives, not less than 15.0% of water extractives and not less than 0.3% of 6-gingerol.

Description: In flattened pieces with fingered branches, branched parts usually with remains of scale leaves, apex with stem scars or buds, 3~7 cm in length, 1~2 cm thick. Externally grayish-yellow or grayish-brown. Texture compact, rough, with longitudinal wrinkles and distinct annulated-nodes, fracture yellowish-white or grayish-yellow, scattered with yellow oil drops. Odour aromatic; taste pungent.

Microscopic identification:
1. **Transverse section:**
   Rhizome of *Zingiber officinale*: The outermost layer was cork composed of several rows of flattened cork cells. Cortex scattered with leaf-trace vascular bundles. Endodermis distinct, with Casparian strip. Collateral vascular bundles scattered in stele, small vascular bundles arranged densely in pericycle, the stele occupied the most part of the rhizome. Xylem scattered with unlignified fiber bundles. Parenchyma tissue contains oil cells and ovate starch granules.
2. **Powder:** Pale yellowish-brown. Oil cells scattered in parenchymatous cells, containing yellow oil droplets or dark red contents. Starch granules numerous, ovate or elliptical, dotted hilum located at the small end, with distinct striations. Vessels mostly spiral, reticular, scalariform or annular, 15~80 μm in diameter. Fibers scattered or in bundles, unlignified, with fine oblique pits and septa, 15~40 μm in diameter.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of 6-gingerol and dissolve in methanol to produce a solution containing 0.5 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane, ethyl acetate, and acetone (10∶1∶5) as the developing solvent. Apply 5 μL of each of the sample solution and reference drug solution and 2 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with vanillin/H_2SO_4 TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Total ash: Not more than 6.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 5.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)

Assay:
1. 6-Gingerol:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and water as the mobile phase B.
   (2) Reference standard solution: Weigh accurately a quantity of 6-gingerol and dissolve in methanol to produce a solution containing 20 μg per mL
   (3) Sample solution: Weigh accurately 0.25 g of the powdered sample and place it in a 50-mL centrifuge tube, add 20 mL of 75% methanol, ultrasonicate for 30 minutes, centrifuge for 15 minutes, use the supernatant. Repeat the extraction of the residue one more time. Combine the supernatant, transfer to 50-mL volumetric flask, make up to volume with 75% methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid

chromatography is equipped with an UV detector (280 nm) and a column packing L1. The column temperature is maintained at room temperature. The flow rate is about 1 mL/min. The number of theoretical plates of the peak of 6-gingerol should not be less than 5,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~10	45	56
10~20	45→100	56→0
20~30	100	0

(5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

6-Gingerol (%)=0.005(r_U/r_S) (C_S) / (W)

r_U: peak area of 6-gingerol of sample solution

r_S: peak area of 6-gingerol of reference standard solution

C_S: concentration of 6-gingerol of reference standard solution (μg /mL)

W: weight of test sample (g) calculated with dried sample.

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Store in a cool and dry place, and protect from moisture and insects.
Usage: Interior-warming medicinal.
Property and flavor: Hot; pungent.
Meridian tropism: Spleen, stomach, kidney, heart, and lung meridians.
Effects: Warm the middle to dissipate cold, returns yang and frees the vessels, warm the lung and resolve fluid retention.
Administration and dosage: 3~9 g.

【Decoction pieces】

ZINGIBERIS RHIZOMA

It contains not less than 10.0% of dilute ethanol-soluble extractives, not less than 15.0% of water extractives and not less than 0.3% of 6-gingerol.

Raw medicinal materials are processed to remove impurities, clean selection, soften thoroughly, cut into thin slices, and dry, mostly appearing irregular longitudinal section or oblique slices, cut surface yellowish-grey or pale yellowish-brown, slightly starchy and fibrous, with fine wrinkle and annular nodes, endodermis with obvious cambium ring, scattered with yellow oil dots. Odour aromatic and characteristic, taste pungent and hot.

Thin layer chromatographic identification test: The method is the same as that for crude herb.
Impurities and other requirements: Methods and specifications are the same as those for crude herb.
Assay: The method is the same as that for crude herb.
Storage: The method is the same as that for crude herb.
Usage: Interior-warming medicinal.
Property and flavor: Hot; pungent.
Meridian tropism: Spleen, stomach, kidney, heart, and lung meridians.
Effects: Warm the middle to dissipate cold, returns yang and frees the vessels, warm the lung and resolve fluid retention.
Administration and dosage: 3~9 g.

ZINGIBERIS RHIZOMA RECENS
生薑
Sheng Jiang / Sheng Jiang
Fresh Ginger Rhizome

Fresh ginger rhizome is the fresh rhizome of *Zingiber officinale* Roscoe (Fam. Zingiberaceae).
It contains not less than 2.0% of dilute ethanol-soluble extractives and not less than 2.0% of water extractives and not less than 0.05% of 6-gingerol.

Description: Irregular lumpy, slightly flattened, with fingered branches, 4~18 cm in length, 1~3 cm thick. Externally yellowish-brown or grayish-brown, rough, with longitudinal wrinkles and distinct annulated-nodes, branched parts usually with remains of scale leaves, apex with stem scars or buds. Texture fragile, easily broken, fracture yellowish-white or grayish-yellow, endodermis ring obvious, scattered with vessels. Odour characteristic; taste pungent.

Microscopic identification:
1. **Transverse section:**
Rhizome of *Zingiber officinale*: Epidermis composed of 3~6 rows of cells. Cork composed of several rows of flattened cork cells. Cortex composed of parenchymatous cells, scattered with leaf-trace collateral vascular bundles, some surrounded with fiber bundles. Endodermis distinct. Stele composed of parenchymatous cells, occupied the most part of the rhizome, scattered with several collateral vascular bundles, those near the pericycle relatively small and tightly arranged. Unlignified fiber bundles present inside or surrounded xylem. Parenchymatous cells contains numerous starch granules and oil droplets.
2. **Powder:** Pale yellowish-brown. Oil cells scattered in parenchymatous cells, oblong or subrounded, 32~96 μm in diameter, with walls relatively thin, containing pale greenish-yellow oil droplets. Fiber scattered or in bundles, apex blunt, few branches, 15~40 μm in diameter, walls slightly thickened, unlignified, oblique pits and septa visible, some with one side undulate or serrate. Resin subrounded

or oblong, containing reddish-brown contents. Starch granules numerous, long-ovate, triangular-ovoid, elliptical, subrounded or irregular, slightly flattened, clavate in lateral view, slightly acute or beak-shape at the small end, 5~32 μm in length, 8~48 μm in diameter, dotted hilum located at the small end, some cleft-shaped, striations distinct, black and cruciate-shaped under the polarized microscope. Vessels mostly scalariform, spiral and reticular, annular vessels few, 15~70 μm in diameter.

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 20 mL of ethyl acetate, ultrasonicate for 10 minutes, filter, evaporate the filtrate to dryness, and dissolve the residue in 1 mL of ethyl acetate.
2. Reference drug solution: Take 1.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of 6-gingerol and dissolve in methanol to produce a solution containing 0.5 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and a solution of *n*-hexane, ethyl acetate, and acetone (10:1:7) as the developing solvent. Apply 5 μL of each of the sample solution and reference drug solution and 2 μL of the reference standard solution to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with vanillin/H_2SO_4 MeOH TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Total ash: Not more than 1.0% (General rule 6007).
2. Acid-insoluble ash: Not more than 0.3% (General rule 6007).
3. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
4. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
5. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
6. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
7. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301).

Assay:

1. 6-Gingerol:
   (1) Mobile phase: A solution of methanol and water (65:35). The ratio may be adjusted, if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of 6-gingerol and dissolve in methanol to produce a solution containing 15 μg per mL.
   (3) Sample solution: Weigh accurately 0.5 g of powdered sample and place it in a 50-mL conical flask with a stopper, then add 10 mL of methanol, ultrasonicate for 30 minutes, Transfer the filtrate to a 20-mL volumetric flask. Repeat the extraction of the residue one more time, combine the filtrate, and make up to volume with methanol, mix well, filter and use the filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (230 nm) and a column packing L1. The column temperature is maintained at 25℃. The flow rate is about 1 mL/min.The number of theoretical plates of the peak of 6-gingerol should not be less than 2,500.
   (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

   6-Gingerol (%)=0.002(r_U/r_S) (C_S) / (W)

   r_U: peak area of 6-gingerol of sample solution
   r_S: peak area of 6-gingerol of reference standard solution
   C_S: concentration of 6-gingerol of reference standard solution (μg /mL)
   W: weight of test sample (g) calculated with dried sample.

Storage: Store in a cool and moist place.
Usage: Exterior-releasing medicinal (Pungent-warm exterior-releasing medicinal).
Property and flavor: Warm; pungent.
Meridian tropism: Lung, spleen, and stomach meridians.
Effects: Promote sweating to release the flesh, warm the middle to stop vomiting, warm the lung and suppress cough and resolve fluid retention.
Administration and dosage: 3~15 g.

ZIZIPHI SPINOSAE SEMEN
酸棗仁
Suan Zao Ren / Suan Zao Ren
Jujube Seed

Jujube seed is the dried ripe seed of *Ziziphus jujuba* Mill. var. *spinosa* (Bunge) Hu ex H. F. Chow (Fam. Rhamnaceae).
It contains not less than 6.0% of dilute ethanol-soluble extractives, not less than 7.0% of water extractives and not less than 0.03% of jujuboside A.

Description: Oblate or flattened ellipsoidal, 5~9 mm in length, 5~7 mm in width, about 3 mm thick. Externally purplish-red or purplish-brown, smooth and lustrous, some with fissures. One surface relatively even, with a protuberant longitudinal rib, the other surface slightly protuberant. One end dented, with a linear hilum; the other

end scattered with a finely raised chalaza. Testa relatively fragile; endosperm white; cotyledons 2, pale yellow, oily. Odour slight; taste weak.

Microscopic identification:
Powder: Brownish-red. Palisade cells of testa brownish-red, with polygonal surface, about 15 μm in diameter, walls thickened and lignified, lumen small. Endotesta cells brownish-yellow, with rectangular or subsquare surface, wall moniliform thickened and lignified. Epidermal cells of cotyledons contain fine clusters of calcium oxalate and prism crystals.

Thin layer chromatographic identification test (General rule 1621.3):
1. Sample solution: Add 5.0 g of powdered sample to 15 mL of methanol, ultrasonicate for 30 minutes, filter, evaporate the filtrate to dryness, dissolve the residue in 1 mL of methanol.
2. Reference drug solution: Take 5.0 g of the reference drug and the method of preparation is the same as which is described above.
3. Reference standard solution: Weigh accurately a quantity of jujuboside A and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Use silica gel F_{254} as the coating substance and the upper layer of *n*-butanol, glacial acetic acid, and water (20:6:25) as the developing solvent. Apply 5 μL of each of the above solutions to the plate. Once the top of the solvent rise to about 5~10 cm from the origin, dry in air. Spray with vanillin/H_2SO_4 TS and heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Foreign matter: Not more than 5.0%, including endocarp (General rule 6005).
2. Loss on drying: Not more than 12.0% dry at 105℃ for 5 hours (General rule 6015).
3. Total ash: Not more than 7.0% (General rule 6007).
4. Acid-insoluble ash: Not more than 3.0% (General rule 6007).
5. Sulfur dioxide: Not more than 150 ppm (General rule 2525, 6303).
6. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
7. Cadmium (Cd): Not more than 1.0 ppm (General rule 6301).
8. Mercury (Hg): Not more than 0.2 ppm (General rule 6301).
9. Lead (Pb): Not more than 5.0 ppm (General rule 2251, 6301)
10. Aflatoxins
    (1) Aflatoxins (sum of B_1, B_2, G_1 and G_2): Not more than 10.0 ppb (General rule 6307).
    (2) Aflatoxin B_1: Not more than 5.0 ppb (General rule 6307).

Assay:
1. Jujuboside A:
    (1) Mobile phase: Acetonitrile as the mobile phase A, and water as the mobile phase B.
    (2) Reference standard solution: Weigh accurately a quantity of jujuboside A, and dissolve in 70% ethanol to produce a solution containing 0.1 mg per mL.
    (3) Sample solution: Weigh accurately 1.0 g of powdered sample and place it in a 50-mL centrifuge tube, then add accurately 20 mL of 70% ethanol, ultrasonicate for 60 minutes, cool and filter, transfer the filtrate to a 100-mL round bottom flask. Repeat the extraction of the residue one more time. Combine the filtrates and evaporate the filtrates to dryness. Dissolve the residue with 70% ethanol, transfer to a 5-mL volumetric flask and make up to volume 70% ethanol, mix well, filter and use the successive filtrate.
    (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (201 nm) and a column packing L1. The column temperature is maintained at 25℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. The ratio may be adjusted if necessary. The number of theoretical plates of the peak of jujuboside A should not be less than 2,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~15	15→28	85→72
15~28	28	72
28~30	28→70	72→30
30~32	70→95	30→5

    (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.
    Jujuboside A (%)=0.5(r_U/r_S) (C_S) / (W)
    r_U: peak area of jujuboside A of sample solution
    r_S: peak area of jujuboside A of reference standard solution
    C_S: concentration of jujuboside A of reference standard solution (mg /mL)
    W: weight of test sample (g) calculated with dried sample.
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Storage: Refrigerate or store in a cool and dry place, and protect from insects.
Usage: Tranquillizing medicinal (Heart-nourishing tranquillizing medicinal).
Property and flavor: Neutral; sweet and sour.
Meridian tropism: Liver, gallbladder and heart meridians.
Effects: Nourish the heart to tranquilize, relieve sweating and generate fluid.
Administration and dosage: 3~18 g.

Monographs

Concentrated Traditional Chinese Medicine Preparations

延胡索濃縮製劑（顆粒、散）
Corydalis Tuber Concentrated Preparation (Granules, Powder)
Yan Hu-Suo Concentrated Preparation (Granules, Powder)
Yan Hu-Suo Concentrated Preparation (Granules, Powder)

Corydalis Tuber Concentrated Preparation (Granules, Powder) is the dried tuber of *Corydalis yanhusuo* W.T.Wang (Fam. Papaveraceae), which were decocted, or extracted , concentrated, dried, and processed into a concentrated preparation.

It contains not less than 17.0% of dilute ethanol-soluble extractives, not less than 23.0% of water extractives, and not less than 1.0 mg/g of dehydrocorydaline ($C_{22}H_{24}NO_4$).

Thin layer chromatographic identification test:

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of 70% ethanol, ultrasonicate for 10 minutes, filter and use the filtrate.
2. Reference drug solution: Use 1.0 g of the reference drug and prepare with the same method described above.
3. Reference standard solution: Weigh accurately a quantity of tetrahydropalmatine and dissolve in 70% ethanol to produce a solution containing 100 μg/ mL.
4. Procedure: Using *n*-hexane, ethyl acetate, and methanol (7:3:1) as the developing solvent. Apply 10 μL of each of the sample solution, reference drug solution and 2 μL of the reference standard solution to the silica plate with fluorescent agent following the TLC identification test (General rule 1621.3). Once the solvent front rise to about 5~10 cm from the origin, take out the plate, dry in the air. Put it in the iodine tank for about 3 minutes, volatilize the adsorbed iodine on the plate in air. Examine under the ultraviolet light at 365 nm. The test solution should show same color spot with corresponding R_f values as reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 8.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 5.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.1% (General rule 6007).
4. Heavy metals: Total heavy metals not more than 30 ppm. (General rule 6301)
5. Microbial enumeration tests: Not more than 10^5 CFU/g (General rule 3061).
6. No *Escherichia coli* and *Salmonella* should be detected (General rule 3063).
7. Aflatoxins: Aflatoxins (sum of B1, B2, G1 and G2): Not more than 15 ppb (General rule 6307).

Assay:

1. Dehydrocorydaline:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and 0.1% phosphoric acid (v/v) (adjust pH value to 6.0 with triethylamine) as the mobile phase B. The ratio may be adjusted if necessary.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~30	30→60	70→40
30~40	60→80	40→20

   (2) Reference standard solution: Weigh accurately a quantity of dehydrocorydaline nitrate, and dissolve in 75% methanol to produce a solution containing 100 μg/mL. (Equivalent to dehydrocorydaline 85.5 μg)
   (3) Sample solution: Weigh accurately 1.0 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 8 mL of 75% methanol, ultrasonicate for 30 minutes, filter and use the filtrate. Repeat the extraction of the residue one more time. Combine the filtrate, transfer to a 20-mL volumetric flask and make up to volume with 75% methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (266 nm) and a column packing L1 (4.6 mm × 25 cm). The column temperature is maintained at 30℃. The flow rate is 1 mL/min. Inject volume 10 μL.
   (5) System suitability: Inject reference standard solution into the liquid chromatography apparatus for 5 times, and record the peak areas. The relative standard deviation of the peak area of dehydrocorydaline should not be more than 1.5%. The number of theoretical plates of the peak of dehydrocorydaline should not be less than 10,000.
   (6) Procedure: Inject accurately 10 μL of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content according to the following formula.

   Dehydrocorydaline（mg/g）＝0.02(r_U/rs) (Cs) / (W)

   r_U：peak area of dehydrocorydaline of sample solution
   rs：peak area of dehydrocorydaline of reference standard solution
   Cs：concentration of dehydrocorydaline of reference standard solution (μg/mL)
   W：weight of test sample (g) calculated with dried sample.
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).

3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Effects: Activate blood, move qi, and relieve pain.

甘草濃縮製劑（顆粒、散）
Liquorice Root and Rhizome Concentrated Preparation (Granules, Powder)
Gan-Cao Concentrated Preparation (Granules, Powder)
Gan-Cao Concentrated Preparation (Granules, Powder)

Liquorice Root and Rhizome Concentrated Preparation (Granules, Powder) is the dried root and rhizome of *Glycyrrhiza uralensis* Fisch. , *Glycyrrhiza inflata* Batalin or *Glycyrrhiza glabra* L. (Fam. Leguminosae), which were decocted, or extracted , concentrated, dried, and processed into a concentrated preparation.

It contains not less than 30.0% of dilute ethanol-soluble extractives, not less than 30.0% of water extractives, and not less than 21 mg/g of glycyrrhizic acid, ($C_{42}H_{62}O_{16}$).

Thin layer chromatographic identification test:

1. Sample solution: Add 2.0 g of powdered sample to 10 mL of 70% ethanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Use the amount of the medicine contained in the 2.0 g powdered sample and prepare with the same method described above.
3. Reference standard solution: Weigh accurately a quantity of glycyrrhizic acid and dissolve in 70% ethanol to produce a solution containing 1.0 mg/mL.
4. Procedure: Using *n*-butanol, glacial acetic acid, and water (7:1:2) as the developing solvent. Apply 2 μL of each of the above solutions to the silica plate with fluorescent agent following the TLC identification test (General rule 1621.3). Once the solvent front rise to about 5~10 cm from the origin, take out the plate, dry in the air. Examine under the ultraviolet light at 254 nm. The test solution should show same color spot with corresponding R_f values as reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 8.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 6.8% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
4. Heavy metals: Total heavy metals not more than 30 ppm. (General rule 6301)
5. Microbial enumeration tests: Not more than 10^5 CFU/g (General rule 3061).
6. No *Escherichia coli* and *Salmonella* should be detected (General rule 3063).
7. Pesticide residues:
   (1) The total DDT content: Not more than 1.0 ppm (General rule 6305).
   (2) The total BHC content: Not more than 0.9 ppm (General rule 6305).
   (3) The total PCNB content: Not more than 1.0 ppm (General rule 6305)

Assay:

1. Glycyrrhizic acid:
   (1) Mobile phase: A mixture solution of acetonitrile and dilute acetic acid (1 in 15) (2:3). The ratio may be adjusted if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of glycyrrhizic acid and dissolve in 70% ethanol to produce a solution containing 0.25 mg/mL of glycyrrhizic acid.
   (3) Sample solution: Weigh accurately 0.5 g of the powdered sample, then add accurately 70 mL of 70% ethanol, ultrasonicate for 15 minutes, filter and use the filtrate. The residue add accurately 25 mL of 70% ethanol repeat the extraction for once. Combine the filtrate and transfer to a 100-mL volumetric flask and make up to volume with 70% ethanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (254 nm) and a column packing L1 (4.6 mm × 25 cm). The column temperature is maintained at 30℃. The flow rate is 1 mL/min..
   (5) System suitability: Inject reference standard solution into the liquid chromatography apparatus for 5 times, and record the peak areas.The relative standard deviation of the peak area of glycyrrhizic acid should not be more than 1.5%. The number of theoretical plates of the peak of glycyrrhizic acid should not be less than 5,000.
   (6) Procedure: Inject accurately 20 μL of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content according to the following formula.

   Glycyrrhizic acid（mg/g）＝100(r_U/r_S) (C_S) / (W)

   r_U：peak area of glycyrrhizic acid of sample solution

   r_S：peak area of glycyrrhizic acid of reference standard solution

   C_S：concentration of glycyrrhizic acid of reference standard solution (mg/mL)

   W：weight of test sample (g) calculated with dried sample.
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Effects: Tonify the spleen and stomach, suppress cough and resolve phlegm, relax tension to relieve pain, clear heat and detoxicate, moderate drug actions.
Precaution and warning: Incompatible with Sargassum, Euphorbiae Pekinensis Radix, Knoxiae Radix, Kansui Radix, Daphnis Genkwa Flos.

葛根濃縮製劑（顆粒、散）
Puerariae Radix Concentrated Preparation (Granules, Powder)
Ge-Gen Concentrated Preparation (Granules, Powder)
Ge-Gen Concentrated Preparation (Granules, Powder)

Puerariae Radix Concentrated Preparation (Granules, Powder) is the dried root of *Pueraria montana* (Lour.) Merr. var. *lobata* (Willd.) Maesen & S.M. Almeida ex Sanjappa & Predeep (*P. lobata* (Willd.)Ohwi) (Fam. Leguminosae), which were decocted, or extracted , concentrated, dried, and processed into a concentrated preparation.
It contains not less than 25.0% of dilute ethanol-soluble extractives, not less than 27.0% of water extractives, and not less than 28 mg/g of puerarin ($C_{21}H_{20}O_9$).

Thin layer chromatographic identification test:
1. Sample solution: Add 2.0 g of powdered sample to 10 mL of 50% methanol, ultrasonicate for 15 minutes, filter and use the filtrate.
2. Reference drug solution: Use 2.0 g of the reference drug and prepare with the same method described above.
3. Reference standard solution: Weigh accurately a quantity of puerarin and dissolve in 50% methanol to produce a solution containing 1.0 mg/mL.
4. Procedure: Using ethyl acetate, methanol, and water (12:2:1) as the developing solvent. Apply 2 μL of each of the above solutions to the silica plate with fluorescent agent following the TLC identification test (General rule 1621.3). Once the solvent front rise to about 5~10 cm from the origin, take out the plate, dry in the air. Examine under the ultraviolet light at 365 nm. The test solution should show same color spot with corresponding R_f values as reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 8.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 5.5% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.1% (General rule 6007).
4. Heavy metals: Total heavy metals not more than 30 ppm. (General rule 6301)
5. Microbial enumeration tests: Not more than 10^5 CFU/g (General rule 3061).
6. No *Escherichia coli* and *Salmonella* should be detected (General rule 3063).

Assay:
1. Puerarin:
   (1) Mobile phase: Acetonitrile as the mobile phase A, and 0.1% formic acid as the mobile phase B. The ratio may be adjusted if necessary.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~25	10→26	90→74
25~27	26→70	74→30
27~30	70	30

   (2) Reference standard solution: Weigh accurately a quantity of puerarin, and dissolve in 50% methanol to produce a solution containing 100 μg/mL of each.
   (3) Sample solution: Weigh accurately 0.5 g of the powdered sample, then add accurately 30 mL of 50% methanol, ultrasonicate for 30 minutes, filter and use the filtrate. Repeat the extraction of the residue one more time. Combine the filtrate, transfer to a 100-mL volumetric flask and make up to volume with 50% methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (250 nm) and a column packing L1 (4.6 mm × 25 cm). The column temperature is maintained at 30℃. The flow rate is 1 mL/min.
   (5) System suitability: Inject reference standard solution into the liquid chromatography apparatus for 5 times, and record the peak areas.The relative standard deviation of the peak area of puerarin should not be more than 1.5%. The number of theoretical plates of the peak of puerarin should not be less than 3,000.
   (6) Procedure: Inject accurately 10 μL of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content according to the following formula.

   $$\text{Puerarin (mg/g)} = 0.1(r_U/r_S)(C_S)/(W)$$

   r_U: peak area of puerarin of sample solution
   r_S: peak area of puerarin of reference standard solution
   C_S: concentration of puerarin of reference standard solution (μg/mL)
   W: weight of test sample (g) calculated with dried sample.
2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Effects: Resolving the flesh and generate fluid.

大黃濃縮製劑（顆粒、散）
Rhubarb Concentrated Preparation (Granules, Powder)
Da-Huang Concentrated Preparation (Granules, Powder)
Da-Huang Concentrated Preparation (Granules, Powder)

Rhubarb Concentrated Preparation (Granules, Powder) is the dried and peeled root and rhizome of *Rheum palmatum* L., *Rheum tanguticum* Maxim. ex Balf. or *Rheum officinale* Baill. (Fam. Polygonaceae), which were decocted, or extracted, concentrated, dried, and processed into a concentrated preparation.

It contains not less than 35.0% of dilute ethanol-soluble extractives, not less than 30.0% of water extractives, and not less than 13 mg/g of the total amount of aloe-emodin ($C_{15}H_{10}O_5$), rhein ($C_{15}H_8O_6$), emodin, ($C_{15}H_{10}O_5$), chrysophanol ($C_{15}H_{10}O_4$) and physcion ($C_{16}H_{12}O_5$).

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter, and use the filtrate.
2. Reference drug solution: Use 1.0 g of the reference drug and prepare with the same method described above.
3. Reference standard solution: Weigh accurately a quantity of rhein and dissolve in methanol to produce a solution containing 1.0 mg/mL.
4. Procedure: Using petroleum ether (30~60℃), ethyl acetate, and formic acid (15:5:1) as the developing solvent. Apply 2 μL of each of the sample solution, reference drug solution and 1 μL of the reference standard solution to the silica plate with fluorescent agent following the TLC identification test (General rule 1621.3). Once the solvent front rise to about 5~10 cm from the origin, take out the plate, dry in the air. Examine under the ultraviolet light at 365 nm. The test solution should show same color spot with corresponding R_f values as reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 8.0% dry at 105℃ for 5 hours (General rule 6015).
2. Acid-insoluble ash: Not more than 1.0% (General rule 6007).
3. Heavy metals: Total heavy metals not more than 30 ppm. (General rule 6301)
4. Microbial enumeration tests: Not more than 10^5 CFU/g (General rule 3061).
5. No *Escherichia coli* and *Salmonella* should be detected (General rule 3063).

Assay:

1. Aloe-emodin, rhein, emodin, chrysophanol, and physcion:
   (1) Mobile phase: Methanol as the mobile phase A, and 0.1% phosphoric acid as the mobile phase B. The ratio may be adjusted if necessary.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0-20	65→70	35→30
20-35	70→85	30→15
35-40	85	15

   (2) Reference standard solution: Weigh accurately a quantity of aloe-emodin, rhein, emodin, chrysophanol, and physcion and dissolve in methanol to produce a solution containing 80 μg per mL of each of aloe-emodin, rhein, emodin, chrysophanol and 40 μg per mL of physcion. Measure accurately 2 mL of each above, and mix well (a mixture containing 16 μg of each of aloe-emodin, rhein, emodin, chrysophanol and 8 μg of physcion per mL).
   (3) Sample solution: Weigh accurately 0.15 g of powdered sample and place it in a round bottom flask, add accurately 25 mL of methanol and weigh, heat under reflux for 1 hour, cool, and weigh again, replenish the loss of solvent with methanol, shake well and filter. Measure accurately 5 mL of successive filtrate, transfer to a round bottom flask, evaporate the filtrate to dryness, add 10 mL of 8% (v/v) hydrochloric acid, ultrasonicate for 2 minutes, heat under reflux at 60℃ for 1 hour, cool, evaporate the filtrate to dryness. The residue dissolve in methanol and transfer to a 10-mL volumetric flask, make up to volume with methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (254 nm) and a column packing L1 (4.6 mm × 25 cm). The column temperature is maintained at 30℃. The flow rate is about 1 mL/min. Inject volume 10 μL.
   (5) System suitability: Inject reference standard solution into the liquid chromatography apparatus for 5 times, and record the peak areas.The relative standard deviation of the peak area of Aloe-emodin, rhein, emodin, chrysophanol and physcion should not be more than 1.5%. The number of theoretical plates of the peak of Aloe-emodin, rhein, emodin, chrysophanol and physcion should not be less than 3,000.
   (6) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the

content of each component separately according to the following formula, and add up the content of each reference to get the total.

Aloe-emodin, rhein, emodin, chrysophanol, and physcion（mg/g）＝ 0.05(r_U/r_S) (C_S) / (W)

r_U：peak area of aloe-emodin, rhein, emodin, chrysophanol and physcion of sample solution

r_S：peak area of aloe-emodin, rhein, emodin, chrysophanol and physcion of reference standard solution

C_S：concentration of aloe-emodin, rhein, emodin, chrysophanol and physcion of reference standard solution (μg/mL)

W：weight of test sample (g) calculated with dried sample

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

黃芩濃縮製劑（顆粒、散）
Scutellaria Root Concentrated Preparation (Granules, Powder)
Huang-Cin Concentrated Preparation (Granules, Powder)
Huang-Qin Concentrated Preparation (Granules, Powder)

Scutellaria Root Concentrated Preparation (Granules, Powder) is the dried root of *Scutellaria baicalensis* Georgi (Fam. Labiatae), which were decocted, or extracted, concentrated, dried, and processed into a concentrated preparation.

It contains not less than 34.0% of dilute ethanol-soluble extractives, not less than 32.0% of water extractives, and not less than 80 mg/g of Baicalin ($C_{21}H_{18}O_{11}$).

Thin layer chromatographic identification test (General rule 1621.3):

1. Sample solution: Add 1.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
2. Reference drug solution: Take about 1.0 g of reference drug and prepare with the same method described above.
3. Reference standard solution: Weigh accurately a quantity of baicalin and dissolve in methanol to produce a solution containing 1.0 mg per mL.
4. Procedure: Using toluene, ethyl acetate, methanol, and formic acid (10:3:3:2) as the developing solvent. Apply 5 μL of each of the above solutions to the silica plate with fluorescent agent following the TLC identification test (General rule 1621.3). Once the solvent front rises to about 5~10 cm from the origin, take out the plate, dry in the air. Examine under the ultraviolet light at 254 nm, or spray with 1% $FeCl_3$/EtOH TS, examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 8.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 6.5% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.7% (General rule 6007).
4. Total heavy metals: Carry out the method for determination of total heavy metals (General rule 6301). Not more than 30 ppm.
5. Microbial enumeration tests: Not more than 10^5 CFU/g (General rule 3061).
6. It should not contain *Escherichia coli* and *Salmonella* (General rule 3063).

Assay:

1. Baicalin:
   (1) Mobile phase: Acetonitrile containing 0.1% phosphoric acid is used as mobile phase A, and 0.1% phosphoric acid as mobile phase B. The ratio may be adjusted if necessary.
   (2) Reference standard solution: Weigh accurately a quantity of baicalin and dissolve in 70% methanol to produce a solution containing 30 μg/mL.
   (3) Sample solution: Weigh accurately 0.5 g of the powdered sample, then add accurately 80mL of 70% methanol, ultrasonicate for 60 minutes, filter and transfer the filtrate to a 100-mL volumetric flask and make up to volume with 70% methanol, mix well, transfer 1 mL of the solution to 25-mL volumetric flask, make up to volume with 70% methanol, mix well, filter and use the successive filtrate
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (280 nm) and a column packing L1 (4.6 mm × 25 cm). The column temperature is maintained at 30℃. The flow rate is about 1 mL/min. Program the chromatographic gradient system as follows. Inject reference standard solution into the liquid chromatography apparatus for 5 times, and record the peak areas. The relative standard deviation of the peak area of baicalin should not be more than 1.5%. The number of theoretical plates of the peak of baicalin should not be less than 5,000.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~1	25	75
1~16	25→31	75→69
16~30	31→50	69→50
30~35	50	50

(5) Procedure: Inject accurately 20 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Baicalin（mg/g）＝2.5 (r_U/r_S) (C_S) / (W)

r_U：peak area of baicalin of sample solution

r_S：peak area of baicalin of reference standard solution

C_S：concentration of baicalin of reference standard solution (μg/mL)

W：weight of test sample (g) calculated with dried sample

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Effects: Clear heat and dry dampness and purge fire to cool the blood.

半夏瀉心湯濃縮製劑（顆粒、散）
Bansia Siexin Tang Concentrated Preparation (Granules, Powder)
Banxia Xiesin Tang Concentrated Preparation (Granules, Powder)

Reference: 《傷寒論》Shang-Han-Lun
Composition:
Pinelliae Rhizoma 7.5 g, Scutellariae Radix 4.5 g, Zingiberis Rhizoma 4.5 g, Ginseng Radix et Rhizoma 4.5 g, Coptidis Rhizoma 1.5 g, Jujubae Fructus 3.0 g, Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 4.5 g. (Daily dosage 30.0 g)

It contains not less than 24.0% of dilute ethanol-soluble extractives, not less than 29.0% of water extractives, the daily dose of Scutellariae Radix with Baicalin ($C_{12}H_{18}O_{11}$) not less than 154 mg, and Coptidis Rhizoma with Berberine chloride ($C_{20}H_{18}ClNO_4$) not less than 19 mg.

Thin layer chromatographic identification test:

1. **Coptidis Rhizoma (黃連)**
   (1) Sample solution: Add 5.0 g of powdered sample to 15 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
   (2) Reference drug solution: Use 0.1 g of the reference drug and prepare with the same method described above.
   (3) Reference standard solution: Weigh accurately a quantity of berberine chloride and dissolve in methanol to produce a solution containing 1.0 mg/mL.
   (4) Procedure: Using ethyl acetate, glacial acetic acid, isopropanol, and water (6:0.1:4:2) as the developing solvent. Apply 5 μL of each of the sample solution, reference drug solution and 2 μL of the reference standard solution to the silica plate with fluorescent agent following the TLC identification test (General rule 1621.3). Once the solvent front rise to about 5~10 cm from the origin, take out the plate, dry in the air. Examine under the ultraviolet light at 365 nm. The test solution should show same color spot with corresponding R_f values as reference drug solution and the reference standard solution.
2. **Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle (炙甘草)**
   (1) Sample solution: Add 5.0 g of powdered sample to 15 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
   (2) Reference drug solution: Use 1.0 g of the reference drug and prepare with the same method described above.
   (3) Reference standard solution: Weigh accurately a quantity of glycyrrhizic acid and dissolve in methanol to produce a solution containing 1.0 mg/mL.
   (4) Procedure: Using *n*-butanol, glacial acetic acid, and water (7:1:2) as the developing solvent. Apply 5 μL of each of the above solutions to the silica plate with fluorescent agent following the TLC identification test (General rule 1621.3). Once the solvent front rise to about 5~10 cm from the origin, take out the plate, dry in the air. Examine under the ultraviolet light at 254 nm. The test solution should show same color spot with corresponding R_f values as reference drug solution and the reference standard solution.
3. **Scutellariae Radix (黃芩)**
   (1) Sample solution: Add 5.0 g of powdered sample to 15 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
   (2) Reference drug solution: Use 1.0 g of the reference drug and prepare with the same method described above.
   (3) Reference standard solution: Weigh accurately a quantity of baicalin and dissolve in methanol to produce a solution containing 1.0 mg per 3 mL
   (4) Procedure: Using toluene, ethyl acetate, methanol, and formic acid (10:3:3:2) as the developing solvent. Apply 5 μL of each of the above solutions to the silica plate following the TLC identification test (General rule 1621.3). Once the solvent front rise to about 5~10 cm from the origin, take out the plate, dry in the air. Spray with 1% $FeCl_3$/EtOH TS. Examine under visible light. The test solution should show same color spot with corresponding R_f values as reference drug solution and the reference standard solution.
4. **Zingiberis Rhizoma (乾薑)**
   (1) Sample solution: Add 5.0 g of powdered sample to 15 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
   (2) Reference drug solution: Use 1.0 g of the reference drug and prepare with the same method described above.
   (3) Reference standard solution: Weigh accurately a quantity of 6-gingerol and dissolve in methanol to produce a solution containing 1.0 mg/mL
   (4) Procedure: Using *n*-hexane and ethyl acetate (1:1) as the developing solvent. Apply 5 μL of each of the above solutions to the silica plate following the TLC identification test (General rule 1621.3). Once the solvent front rise to about 5~10 cm from the origin, take out the plate, dry in the air. Spray with 2% phosphomolybdic acid/H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under visible light. The test solution should show same color spot with corresponding R_f values as reference drug solution and the reference standard solution.
5. **Ginseng Radix et Rhizoma (人參)**
   (1) Sample solution: Add 2.0 g of powdered sample to 10 mL of 5 % sodium hydroxide and 5 mL of *n*-butanol, shake well, centrifuge and use the the supernatant.

(2) Reference drug solution: Use 1.0 g of the reference drug and prepare with the same method described above.
(3) Reference standard solution: Weigh accurately a quantity of ginsenoside Rg_1 and dissolve in methanol to produce a solution containing 1.0 mg/mL.
(4) Procedure: Using dichloromethane, ethyl acetate, methanol, and water (15:40:22:10) as the developing solvent. Apply 5 μL of each of the sample solution, reference drug solution and 2 μL of the reference standard solution to the silica plate following the TLC identification test (General rule 1621.3). Once the solvent front rise to about 5~10 cm from the origin, take out the plate, dry in the air. Spray with 2% phosphomolybdic acid/H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under visible light. The test solution should show same color spot with corresponding R_f values as reference drug solution and the reference standard solution.

Impurities and other requirements:
1. Loss on drying: Not more than 8.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 5.5% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.5% (General rule 6007).
4. Heavy metals: Total heavy metals not more than 30 ppm. (General rule 6301)
5. Arsenic (As): Not more than 3 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 0.5 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.5 ppm (General rule 6301).
8. Lead (Pb): Not more than 10 ppm (General rule 2251, 6301).
9. Microbial enumeration tests: Not more than 10^5 CFU/g (General rule 3061).
10. No *Escherichia coli* and *Salmonella* should be detected (General rule 3063).

Assay:
1. Baicalin and berberine chloride:
(1) Mobile phase: Acetonitrile as the mobile phase A, and 10 mM potassium dihydrogen phosphate (Adjust pH value to 2.5 with phosphoric acid) as the mobile phase B. The ratio may be adjusted if necessary.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~20	20→45	80→55
20~21	45→80	55→20
21~25	80	20

(2) Reference standard solution: Weigh accurately a quantity of baicalin and berberine chloride and dissolve in 70% methanol to produce a solution containing 12 μg and 2.4 μg per mL of each of baicalin and berberine chloride.
(3) Weigh accurately 0.1 g of the powdered sample, then add accurately 50 mL of 70% methanol, ultrasonicate for 30 minutes, filter and transfer the filtrate to a 50-mL volumetric flask and make up to volume with 70% methanol, mix well, filter and use the successive filtrate.
(4) Chromatographic system: The liquid chromatography is equipped with an UV detector (277 nm for baicalin and 345 nm for berberine chloride) and a column packing L1. The column temperature is maintained at 30℃. The flow rate is 0.8 mL/min.
(5) System suitability: Inject reference standard solution into the liquid chromatography apparatus for 5 times, and record the peak areas.The relative standard deviation of the peak area of baicalin and berberine chloride should not be more than 1.5%. The number of theoretical plates of the peak of baicalin and berberine chloride should not be less than 8,000.
(6) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content according to the following formula.

Baicalin (mg/day)＝[0.05$(r_U/r_S)(C_S)/(W)$] ×daily dose

r_U：peak area of baicalin of sample solution
r_S：peak area of baicalin of reference standard solution
C_S：concentration of baicalin of reference standard solution (μg/mL)
W：weight of test sample (g) calculated with dried sample.

Berberine chloride (mg/day)＝

[0.05$(r_U/r_S)(C_S)/(W)$] ×daily dose

r_U：peak area of berberine chloride of sample solution
r_S：peak area of berberine chloride of reference standard solution
C_S：concentration of berberine chloride of reference standard solution (μg/mL)
W：weight of test sample (g) calculated with dried sample.

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Effects: Harmonize the stomach to downbear counterflow.

Indications: Cold damage induced by early purgation, stuffiness and fullness below the heart, vomiting and borborigmus.

葛根湯濃縮製劑（顆粒、散）
Ge Gen Tang Concentrated Preparation (Granules, Powder)

Ge Gen Tang Concentrated Preparation (Granules, Powder)

Reference: 《傷寒論》Shang-Han-Lun
Composition:
Puerariae Radix 6.0 g, Ephedrae Herba 4.5 g, Cinnamomi Ramulus 3.0 g, Paeoniae Radix Alba 3.0 g, Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 3.0 g, Zingiberis Rhizoma Recens 4.5 g, Jujubae Fructus 4.0 g. (Daily dosage 28.0 g)

It contains not less than 33.0% of dilute ethanol-soluble extractives, not less than 33.0% of water extractives. The daily dose of Puerariae Radix calculated with puerarin ($C_{21}H_{20}O_9$), not less than 91 mg, and the daily dose of Ephedrae Herba calculated with total amount of Ephedrine ($C_{10}H_{15}NO$) and Pseudoephedrine ($C_{10}H_{15}NO$), not less than 28 mg.

Thin layer chromatographic identification test:

1. Puerariae Radix (葛根)

(1) Sample solution: Add 2.0 g of powdered sample to 10 mL each of water and acqua saturated *n*-butanol, ultrasonicate for 30 minutes, stand for layer separation, take the upper layer and use it.
(2) Reference drug solution: Use 1.0 g of the reference drug and prepare with the same method described above.
(3) Reference standard solution: Weigh accurately a quantity of puerarin and dissolve in 50% methanol to produce a solution containing 1.0 mg/mL.
(4) Procedure: Using ethyl acetate, methanol, and water (20:3:2) as the developing solvent. Apply 5 μL of each of the sample solution, reference drug solution and 2 μL of the reference standard solution to the silica plate with fluorescent agent following the TLC identification test (General rule 1621.3). Once the solvent front rise to about 5~10 cm from the origin, take out the plate, dry in the air. Examine under the ultraviolet light at 365 nm. The test solution should show same color spot with corresponding R_f values as reference drug solution and the reference standard solution.

2. Paeoniae Radix Alba (白芍)

(1) Sample solution: Add 2.0 g of powdered sample to 10 mL each of water and acqua saturated *n*-butanol, ultrasonicate for 30 minutes, stand for layer separation, take the upper layer and use it.
(2) Reference drug solution: Use 1.0 g of the reference drug and prepare as the same method described above.
(3) Reference standard solution: Weigh accurately a quantity of paeoniflorin and dissolve in methanol to produce a solution containing 1.0 mg/mL.
(4) Procedure: Using ethyl acetate, methanol, and water (20:3:2) as the developing solvent. Apply 5 μL of each of the sample solution, reference drug solution and 5 μL of the reference standard solution to the silica plate following the TLC identification test (General rule 1621.3). Once the solvent front rise to about 5~10 cm from the origin, take out the plate, dry in the air. Spray with *p*-anisaldehyde/H_2SO_4 TS, heat at 105℃ until the spots become visible. Examine under visible light. The test solution should show same color spot with corresponding R_f values as reference drug solution and the reference standard solution.

3. Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle (炙甘草)

(1) Sample solution: Add 2.0 g of powdered sample to 10 mL each of water and acqua saturated *n*-butanol, ultrasonicate for 30 minutes, stand for layer separation, take the upper layer and use it.
(2) Reference drug solution: Use 1.0 g of the reference drug and prepare with the same method described above.
(3) Reference standard solution: Weigh accurately a quantity of glycyrrhizic acid and dissolve in methanol to produce a solution containing 1.0 mg/mL.
(4) Procedure: Using *n*-butanol, glacial acetic acid, and water (7:1:2) as the developing solvent. Apply 5 μL of each of the sample solution, reference drug solution and 2 μL of the reference standard solution to the silica plate with fluorescent agent following the TLC identification test (General rule 1621.3). Once the solvent front rise to about 5~10 cm from the origin, take out the plate, dry in the air. Examine under the ultraviolet light at 254 nm. The test solution should show same color spot with corresponding R_f values as reference drug solution and the reference standard solution.

4. Ephedrae Herba (麻黃)

(1) Sample solution: Add 2.0 g of powdered sample to 10 mL each of water and acqua saturated *n*-butanol, ultrasonicate for 30 minutes, stand for layer separation, take the upper layer and use it.
(2) Reference drug solution: Use 1.0 g of the reference drug and prepare with the same method described above.
(3) Reference standard solution: Weigh accurately a quantity of ephedrine and dissolve in methanol to produce a solution containing 1.0 mg/mL.
(4) Procedure: Using ethyl acetate, *n*-propanol, glacial acetic acid, and water (4:4:1:2) as the

developing solvent. Apply 5 μL of each of the sample solution, reference drug solution and 2 μL of the reference standard solution to the silica plate following the TLC identification test (General rule 1621.3). Once the solvent front rise to about 5~10 cm from the origin, take out the plate, dry in the air. Spray with ninhydrin/EtOH TS and heat at 105℃ until the spots become visible. Examine under visible light. The test solution should show same color spot with corresponding R_f values as reference drug solution and the reference standard solution.

5. Cinnamomi Ramulus (桂枝)

(1) Sample solution: Add 2.0 g of powdered sample to 10 mL each of water and acqua saturated *n*-butanol, ultrasonicate for 30 minutes, stand for layer separation, take the upper layer and use it.

(2) Reference drug solution: Use 1.0 g of the reference drug and prepare with the same method described above.

(3) Reference standard solution: Weigh accurately a quantity of cinnamic acid and dissolve in methanol to produce a solution containing 1.0 mg/mL.

(4) Procedure: Using ethyl acetate and methanol (20:3) as the developing solvent. Apply 10 μL of each of the sample solution, reference drug solution and 2 μL of the reference standard solution to the silica plate with fluorescent agent following the TLC identification test (General rule 1621.3). Once the solvent front rise to about 5~10 cm from the origin, take out the plate, dry in the air. Examine under the ultraviolet light at 254 nm. The test solution should show same color spot with corresponding R_f values as reference drug solution and the reference standard solution.

6. Zingiberis Rhizoma Recens (生薑)

(1) Sample solution: Add 2.0 g of powdered sample to 10 mL of water, shake well, and then add 25 mL of ether, shake well, evaporate the layer of ether to dryness, dissolve the residue in 2 mL of methanol and use it.

(2) Reference drug solution: Use 1.0 g of the reference drug and prepare with the same method described above.

(3) Reference standard solution: Weigh accurately a quantity of 6-gingerol and dissolve in methanol to produce a solution containing 1.0 mg/mL.

(4) Procedure: Using *n*-hexane and ethyl acetate (1:1) as the developing solvent. Apply 5 μL of each of the sample solution, reference drug solution and 2 μL of the reference standard solution to the silica plate following the TLC identification test (General rule 1621.3). Once the solvent front rise to about 5~10 cm from the origin, take out the plate, dry in the air. Spray with *p*-anisaldehyde/H_2SO_4 TS and heat at 105 ℃ until the spots become visible. Examine under visible light. The test solution should show same color spot with corresponding R_f values as reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 8.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 6.8% (General rule 6007).
3. Acid-insoluble ash: Not more than 1.3% (General rule 6007).
4. Heavy metals: Total heavy metals not more than 30 ppm. (General rule 6301)
5. Arsenic (As): Not more than 3 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 0.5 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.5 ppm (General rule 6301).
8. Lead (Pb): Not more than 10 ppm (General rule 2251, 6301).
9. Microbial enumeration tests: Not more than 10^5 CFU/g (General rule 3061).
10. No *Escherichia coli* and *Salmonella* should be detected (General rule 3063).

Assay:

1. Puerarin, ephedrine, and pseudoephedrine:

(1) Mobile phase: Acetonitrile as the mobile phase A, and 15 mM phosphoric acid as the mobile phase B (Preparation: Take about 800 mL of water, add 0.87 mL of 85% phosphoric acid, mix well, add water to make exactly 1000 mL. The ratio may be adjusted if necessary.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~5	5	95
5~17	5→11	95→89
17~35	11→20	89→80

(2) Weigh accurately a quantity of puerarin, ephedrine and pseudoephedrine, and dissolve in 50% methanol to produce a solution containing 100 μg, 25 μg and 25 μg per mL of each.

(3) Sample solution: Weigh accurately 0.5 g of the powdered sample and place it in a 50-mL centrifuge tube, then add accurately 40 mL of 50% methanol, ultrasonicate for 30 minutes, filter and use the filtrate. Repeat the extraction of the residue one more time. Combine the filtrate, transfer to a 100-mL volumetric flask and make up to volume with 50% methanol, mix well, filter and use the successive filtrate.

(4) Chromatographic system: The liquid chromatography is equipped with an UV detector (250 nm for puerarin, 210 nm for ephedrine and pseudoephedrine) and a column packing L1 (4.6 mm × 25 cm). The column

temperature is maintained at 30℃. The flow rate is 1 mL/min.

(5) System suitability: Inject reference standard solution into the liquid chromatography apparatus for 5 times, and record the peak areas.The relative standard deviation of the peak area of puerarin, ephedrine and pseudoephedrine should not be more than 1.5%. The number of theoretical plates of the peak of puerarin, ephedrine and pseudoephedrine should not be less than 5,000, 3,000 and 3,000 of each..

(6) Procedure: Inject accurately 10 μL of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content according to the following formula.

Puerarin（mg/day）＝[0.1(r_U/r_S)(C_S)/(W)]× daily dose

r_U：peak area of puerarin of sample solution

r_S：peak area of puerarin of reference standard solution

C_S：concentration of puerarin of reference standard solution (μg/mL)

W：weight of test sample (g) calculated with dried sample.

Ephedrine or pseudoephedrine (mg/day) ＝ [0.1(r_U/r_S)(C_S)/(W)] × daily dose

r_U：peak area of ephedrine or pseudoephedrine of sample solution

r_S：peak area of ephedrine or pseudoephedrine of reference standard solution

C_S：concentration of ephedrine or pseudoephedrine of reference standard solution (μg/mL)

W：weight of test sample (g) calculated with dried sample.

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Effects: Promote sweating to release the flesh.
Indications: Wind-cold induced by exopathogen, headache and fever, aversion to cold without sweating, contracture of the nape and neck.

加味逍遙散濃縮製劑（細粒、顆粒、散）
Jaiwei Xiaoyao San Concentrated Preparation (Granules, Powder)
Jiawei Siaoyao San Concentrated Preparation (Granules, Powder)

Reference: 《證治準繩》Jheng-Jhih-Jhun-Sheng
Composition:
Angelicae Sinensis Radix 4.0 g, Atractylodis Macrocephalae Rhizoma 4.0 g, Paeoniae Radix Alba 4.0 g, Bupleuri Radix 4.0 g, Poria 4.0 g, Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 2.0 g, Moutan Radicis Cortex 2.5 g, Gardeniae Fructus 2.5 g, Zingiberis Rhizoma Tostum (or Zingiberis Rhizoma Recens) 4.0 g, Menthae Herba 2.0 g (Daily dosage 33.0 g)
It contains not less than 30.0% of dilute ethanol-soluble extractives, not less than 30.0% of water extractives. The daily dose of Paeoniae Radix Alba and Moutan Radicis Cortex calculated with total Paeoniflorin ($C_{23}H_{28}O_{11}$), not less than 49 mg, and the daily dose of Gardeniae Fructus calculated with geniposide ($C_{17}H_{24}O_{10}$), not less than 53 mg.

Thin layer chromatographic identification test (General rule 1621.3):

1. **Angelicae Sinensis Radix (當歸)**
   (1) Sample solution: Add 5.0 g of powdered sample to 15 mL of methanol, ultrasonicate for 30 minutes, centrifuge, use the supernatant.
   (2) Reference drug solution: Use 1.0 g of the reference drug and prepare with the same method described above.
   (3) Procedure: Using *n*-hexane and ethyl acetate (4:1) as the developing solvent. Apply 5 μL of each of the above solutions to the silica plate with fluorescent agent following the TLC identification test (General rule 1621.3). Once the solvent front rise to about 5~10 cm from the origin, take out the plate, dry in the air. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.
2. **Atractylodis Macrocephalae Rhizoma (白朮)**
   (1) Sample solution: Add 5.0 g of powdered sample to 15 mL of methanol, ultrasonicate for 30 minutes, centrifuge and use the supernatant.
   (2) Reference drug solution: Use 2.0 g of the reference drug and prepare with the same method described above.
   (3) Reference standard solution: Weigh accurately a quantity of atractylenolide II and dissolve in methanol to produce a solution containing 1.0 mg/mL.
   (4) Procedure: Using *n*-hexane and ethyl acetate (4:1) as the developing solvent. Apply 10 μL

of each of the above solutions to the silica plate with fluorescent agent following the TLC identification test (General rule 1621.3). Once the solvent front rises to about 5~10 cm from the origin, take out the plate, dry in the air. Spray with a 20% solution of H_2SO_4/EtOH TS and heat at 105℃ until the spots become visible. Examine under the ultraviolet light at 365 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

3. **Paeoniae Radix Alba and Moutan Radicis Cortex (白芍、牡丹皮)**
   (1) Sample solution: Add 5.0 g of powdered sample to 15 mL of methanol, ultrasonicate for 30 minutes, centrifuge and use the the supernatant.
   (2) Reference drug solution: Use 2.0 g and 1.3 g of the reference drug of Paeoniae Radix Alba and Moutan Radicis Cortex and prepare with the same method described above.
   (3) Reference standard solution: Weigh accurately a quantity of paeoniflorin and dissolve in methanol to produce a solution containing 1.0 mg/mL.
   (4) Procedure: Using ethyl acetate, ethanol, and 4N ammonia solution (2:2:1) as the developing solvent. Apply 5 μL of each of the above solutions to the silica plate with fluorescent agent following the TLC identification test (General rule 1621.3). Once the solvent front rise to about 5~10 cm from the origin, take out the plate, dry in the air. Spray with vanillin/H_2SO_4 TS, heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.
4. **Gardeniae Fructus (梔子、山梔子)**
   (1) Sample solution: Add 5.0 g of powdered sample to 15 mL of methanol, ultrasonicate for 30 minutes, centrifuge and use the the supernatant.
   (2) Reference drug solution: Use 1.3 g of the reference drug and prepare with the same method described above.
   (3) Reference standard solution: Weigh accurately a quantity of geniposide and dissolve in methanol to produce a solution containing 1.0 mg/mL.
   (4) Procedure: Using ethyl acetate, ethanol, and 4N ammonia solution (2:2:1) as the developing solvent. Apply 5 μL of each of the above solutions to the silica plate with fluorescent agent following the TLC identification test (General rule 1621.3). Once the solvent front rises to about 5~10 cm from the origin, take out the plate, dry in the air. Spray with vanillin/H2SO4 TS, heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.
5. **Bupleuri Radix (柴胡)**
   (1) Sample solution: Add 5.0 g of powdered sample to 15 mL of methanol, ultrasonicate for 30 minutes, centrifuge and use the the supernatant.
   (2) Reference drug solution: Use 2.0 g of the reference drug and prepare with the same method described above.
   (3) Procedure: Using ethyl acetate, methyl ethyl ketone, formic acid, and water (5:3:1:1) as the developing solvent. Apply10 μL of each of the above solutions to the silica plate with fluorescent agent following the TLC identification test (General rule 1621.3). Once the solvent front rise to about 5~10 cm from the origin, take out the plate, dry in the air. Spray with 1% *p*-dimethylamino-benzaldehyde/40% H_2SO_4 TS, heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.
6. **Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle (炙甘草)**
   (1) Sample solution: Add 5.0 g of powdered sample to 15 mL of methanol, ultrasonicate for 30 minutes, centrifuge and use the the supernatant.
   (2) Reference drug solution: Use 1.0 g of the reference drug and prepare with the same method described above.
   (3) Reference standard solution: Weigh accurately a quantity of glycyrrhizic acid and dissolve in methanol to produce a solution containing 1.0 mg/mL.
   (4) Procedure: Using ethyl acetate, methyl ethyl ketone, formic acid, and water (8:3:1:1) as the developing solvent. Apply10 μL of each of the above solutions to the silica plate with fluorescent agent following the TLC identification test (General rule 1621.3). Once the solvent front rises to about 5~10 cm from the origin, take out the plate, dry in the air. Spray with *p*-anisaldehyde/H_2SO_4 TS, heat at 105℃ until the spots become visible.

Examine under the ultraviolet light at 254 nm. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

7. **Zingiberis Rhizoma Tostum (or Zingiberis Rhizoma Recens) 煨薑（或生薑）**
   (1) Sample solution: Add 5.0 g of powdered sample to 15 mL of methanol, ultrasonicate for 30 minutes, centrifuge and use the the supernatant.
   (2) Reference drug solution: Use 2.0 g of the reference drug and prepare with the same method described above.
   (3) Procedure: Using dichloromethane and acetone (19:1) as the developing solvent. Apply10 μL of each of the above solutions to the silica plate with fluorescent agent following the TLC identification test (General rule 1621.3). Once the solvent front rises to about 5~10 cm from the origin, take out the plate, dry in the air. Spray with *p*-anisaldehyde/H_2SO_4 TS, heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.
8. **Menthae Herba (薄荷)**
   (1) Sample solution: Add 5.0 g of powdered sample to 15 mL of methanol, ultrasonicate for 30 minutes, centrifuge and use the the supernatant.
   (2) Reference drug solution: Use 1.0 g of the reference drug and prepar with the same method described above.
   (3) Procedure: Using *n*-hexane and ethyl acetate (5:2) as the developing solvent. Apply 5 μL of each of the above solutions to the silica plate with fluorescent agent following the TLC identification test (General rule 1621.3). Once the solvent front rises to about 5~10 cm from the origin, take out the plate, dry in the air. Spray with *p*-anisaldehyde/H_2SO_4 TS, heat at 105℃ until the spots become visible. Examine under visible light. The spots in the chromatogram obtained from the sample solution corresponding in R_f values and color to the spots in the chromatogram obtained from the reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 8.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 10.0% (General rule 6007).
3. Acid-insoluble ash: Not more than 6.0% (General rule 6007).
4. Total heavy metals: Carry out the method for determination of total heavy metals (General rule 6301). Not more than 30 ppm.
5. Arsenic (As): Not more than 3.0 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 0.5 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.5 ppm (General rule 6301).
8. Lead (Pb): Not more than 10 ppm (General rule 2251, 6301).
9. Microbial enumeration tests: Not more than 10^5 CFU/g (General rule 7007).
10. It should not contain *Escherichia coli* and *Salmonella* (General rule 7007).

Assay:

1. Paeoniflorin and geniposide:
   (1) Mobile phase: Acetonitrile containing 0.03% phosphoric acid as the mobile phase A, and phosphoric acid as the mobile phase B. The ratio of the solution varies as required.
   (2) Reference standard solution: Weigh accurately a quantity of paeoniflorin and geniposide and dissolve in 70% methanol to produce a solution containing 30 μg/mL and 40 μg/mL of each.
   (3) Sample solution: Weigh accurately 0.5 g of the powdered sample, then add accurately 35 mL of 70% methanol, ultrasonicate for 30 minutes, filter and transfer the filtrate to a 50-mL volumetric flask and make up to volume with 70% methanol, mix well, filter and use the successive filtrate.
   (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (245 nm) and a column packing L1. The column temperature is maintained at 40℃. The flow rate is 1 mL/min. Program the chromatographic gradient system as follows. Inject reference standard solution into the liquid chromatography apparatus for 5 times, and record the peak areas. The relative standard deviation of the peak area of paeoniflorin and geniposide should not be more than 1.5%. The number of theoretical plates of the peak of paeoniflorin and geniposide should not be less than 5,000 of each.

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0~15	10→12	90→88
15~20	12	88
20~50	12→42	88→58
50~55	42→47	58→53
55~65	47→60	53→40
65~70	60→100	40→0
70~75	100	0

(5) Procedure: Inject accurately 20 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content.

Paeoniflorin (mg/day) = [0.05(r_U/r_S)(C_S)/(W)] × daily dose

r_U: peak area of paeoniflorin of sample solution
r_S: peak area of paeoniflorin of reference standard solution
C_S: concentration of paeoniflorin of reference standard solution (μg/mL)
W: weight of test sample (g) calculated with dried sample.

Geniposide (mg/day) = [0.05(r_U/r_S)(C_S)/(W)] × daily dose

r_U: peak area of geniposide of sample solution
r_S: peak area of geniposide of reference standard solution
C_S: concentration of geniposide of reference standard solution (μg/mL)
W: weight of test sample (g) calculated with dried sample.

2. Water extractives: Carry out the method for determination of water extractives (General rule 6011).
3. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Effects: Soothe the liver and release depression, clear heat to cool the blood.
Indications: Liver depression, blood deficiency and fever, menstrual irregularities, disquieted fearful throbbing.

小青龍湯濃縮製劑（顆粒、散）
Siaocinglong Tang Concentrated Preparation (Granules, Powder)
Xiaoqinglon Tang Concentrated Preparation (Granules, Powder)

Reference: 《傷寒論》Shang-Han-Lun
Composition:
Ephedrae Herba 4.0 g, Paeoniae Radix Alba 4.0 g, Schisandrae Fructus 1.5g, Zingiberis Rhizoma 4.0 g, Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle 4.0 g, Cinnamomi Ramulus 4.0 g, Pinelliae Rhizoma 4.0 g, Asari Radix 1.5 g. (Daily dosage 27.0 g)
It contains not less than 25.2% of dilute ethanol-soluble extractives, not less than 29.8% of water extractives. The daily dose of Paeoniae Radix Alba calculated with paeoniflorin ($C_{23}H_{28}O_{11}$), not less than 46 mg and the daily dose of Ephedrae Herba calculated with total ephedrine ($C_{10}H_{15}NO$) and pseudoephedrine ($C_{10}H_{15}NO$), not less than 19 mg. It should not contain aristolochic acid.

Thin layer chromatographic identification test:

1. **Ephedrae Herba (麻黃)**
   (1) Sample solution: Add 1.0 g of powdered sample to 10 mL each of water-saturated *n*-butanol, shake well, stand several minutes for layer separation, take the upper layer and use it.
   (2) Reference drug solution: Use 1.0 g of the reference drug and prepare with the same method described above.
   (3) Reference standard solution: Weigh accurately a quantity of ephedrine and dissolve in methanol to produce a solution containing 1.0 mg/mL.
   (4) Procedure: Using *n*-butanol, glacial acetic acid, and water (7:1:2) as the developing solvent. Apply 5 μL of each of the above solutions to the silica plate following the TLC identification test (General rule 1621.3). Once the solvent front rise to about 5~10 cm from the origin, take out the plate, dry in the air. Spray with ninhydrin/EtOH TS and heat at 105℃ until the spots become visible. Examine under visible light. The test solution should show same color spot with corresponding R_f values as reference drug solution and the reference standard solution.
2. **Cinnamomi Ramulus (桂枝)**
   (1) Sample solution: Add 2.0 g of powdered sample to 10 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
   (2) Reference drug solution: Use 1.0 g of the reference drug and prepare with the same method described above.
   (3) Reference standard solution: Weigh accurately a quantity of cinnamic acid and dissolve in methanol to produce a solution containing 1.0 mg/mL.
   (4) Procedure: Using ethyl acetate and methanol (20:3) as the developing solvent. Apply 10 μL of each of the sample solution, reference drug solution and 2 μL of the reference standard solution to the silica plate with fluorescent agent following the TLC identification test (General rule 1621.3). Once the solvent front rise to about 5~10 cm from the origin, take out the plate, dry in the air. Examine under the ultraviolet light at 254 nm. The test solution should show same color spot with corresponding R_f values as reference drug solution and the reference standard solution.
3. **Zingiberis Rhizoma (乾薑)**
   (1) Sample solution: Add 5.0 g of powdered sample to 15 mL of methanol, ultrasonicate for 30 minutes, filter and use the filtrate.
   (2) Reference drug solution: Use 3.0 g of the reference drug and prepare with the same method described above.
   (3) Reference standard solution: Weigh accurately a quantity of 6-gingerol and dissolve in methanol to produce a solution containing 1.0 mg/mL.

(4) Procedure: Using *n*-hexane and ethyl acetate (1:1) as the developing solvent. Apply 5 μL of each of the above solutions to the silica plate following the TLC identification test (General rule 1621.3). Once the solvent front rise to about 5~10 cm from the origin, take out the plate, dry in the air. Spray with *p*-anisaldehyde/H_2SO_4 TS, heat at 105℃ until the spots become visible. Examine under visible light. The test solution should show same color spot with corresponding R_f values as reference drug solution and the reference standard solution.

4. Asari Radix (細辛)

(1) Sample solution: Add 1.0 g of powdered sample to 10 mL of water, shake well, and then add 25 mL of ether, shake well, evaporate the layer of ether to dryness, and dissolve the residue in 2 mL of methanol and use it.

(2) Reference drug solution: Use 1.0 g of the reference drug and prepare with the same method described above.

(3) Reference standard solution: Weigh accurately a quantity of asarinin and dissolve in methanol to produce a solution containing 1.0 mg/mL.

(4) Procedure: Using *n*-hexane, toluene, and acetone (3:2:1) as the developing solvent. Apply 20 μL of each of the sample solution, reference drug solution and 5 μL of the reference standard solution to the silica plate following the TLC identification test (General rule 1621.3). Once the solvent front rise to about 5~10 cm from the origin, take out the plate, dry in the air. Spray with a 10% solution of H_2SO_4/EtOH TS, heat at 105℃ until the spots become visible, examine under visible light. The test solution should show same color spot with corresponding R_f values as reference drug solution and the reference standard solution.

5. Schisandrae Fructus (五味子)

(1) Sample solution: Add 3.0 g of powdered sample to 10 mL of 10% sodium hydroxide, shake well, and then add 25 mL of ether, shake well, evaporate the layer of ether to dryness, and dissolve the residue in 2 mL of methanol, use the filtrate.

(2) Reference drug solution: Use 1.0 g of the reference drug and prepare as the same method described above.

(3) Reference standard solution: Weigh accurately a quantity of schizandrin and dissolve in methanol to produce a solution containing 1.0 mg/mL.

(4) Procedure: Using *n*-hexane, ethyl acetate, and glacial acetic acid (10:10:1) as the developing solvent. Apply 10 μL of each of the sample solution, reference drug solution and 5 μL of the reference standard solution to the silica plate with fluorescent agent following the TLC identification test (General rule 1621.3). Once the solvent front rise to about 5~10 cm from the origin, take out the plate, dry in the air. Examine under the ultraviolet light at 254 nm. The test solution should show same color spot with corresponding R_f values as reference drug solution and the reference standard solution.

6. Paeoniae Radix Alba (白芍)

(1) Sample solution: Add 1.0 g of powdered sample to 10 mL each of water and water-saturated *n*-butanol, shake well, stand several minutes for layer separation, take the upper layer and use it.

(2) Reference drug solution: Use 0.5 g of the reference drug and prepare with the same method described above.

(3) Reference standard solution: Weigh accurately a quantity of paeoniflorin and dissolve in methanol to produce a solution containing 1.0 mg/mL.

(4) Procedure: Using ethyl acetate, methanol, and water (20:3:2) as the developing solvent. Apply 5 μL of each of the above solutions to the silica plate following the TLC identification test (General rule 1621.3). Once the solvent front rise to about 5~10 cm from the origin, take out the plate, dry in the air. Spray with *p*-anisaldehyde/H_2SO_4 TS, heat at 105℃ until the spots become visible. Examine under visible light. The test solution should show same color spot with corresponding R_f values as reference drug solution and the reference standard solution.

7. Glycyrrhizae Radix et Rhizoma Praeparatum cum Melle (炙甘草)

(1) Sample solution: Add 2.0 g of powdered sample to 15 mL of 70% ethanol, ultrasonicate for 5 minutes, filter and use the filtrate.

(2) Reference drug solution: Use 1.0 g of the reference drug and prepare with the same method described above.

(3) Reference standard solution: Weigh accurately a quantity of glycyrrhizic acid and dissolve in 70% ethanol to produce a solution containing 5.0 mg/mL.

(4) Procedure: Using *n*-butanol, glacial acetic acid, and water (7:1:2) as the developing solvent. Apply 2 μL of each of the above solutions to the silica plate with fluorescent agent following the TLC identification test (General rule 1621.3). Once the solvent front rise to about 5~10 cm from the origin, take out the plate, dry in the air. Examine under the ultraviolet light at 254 nm. The test solution should show same color spot with corresponding R_f values as reference drug solution and the reference standard solution.

Impurities and other requirements:

1. Loss on drying: Not more than 8.0% dry at 105℃ for 5 hours (General rule 6015).
2. Total ash: Not more than 6.6% (General rule 6007).
3. Acid-insoluble ash: Not more than 0.9% (General rule 6007).
4. Heavy metals: Total heavy metals not more than 30 ppm. (General rule 6301)

5. Arsenic (As): Not more than 3 ppm (General rule 2211, 6301).
6. Cadmium (Cd): Not more than 0.5 ppm (General rule 6301).
7. Mercury (Hg): Not more than 0.5 ppm (General rule 6301).
8. Lead (Pb): Not more than 10 ppm (General rule 2251, 6301).
9. Microbial enumeration tests: Not more than 10^5 CFU/g (General rule 3061).
10. No *Escherichia coli* and *Salmonella* should be detected (General rule 3063).
11. Should not contain aristolochic acids:
    (1) Mobile phase: Weigh accurately 7.8 g of sodium dihydrogen phosphate (NaH_2PO_4 $2H_2O$), add 2 mL of phosphoric acid and water make up to 1,000 mL (It is equivalent to 0.05 M sodium dihydrogen phosphate- phosphoric acid buffer) as an aqueous phase solution. A solution of acetonitrile and aqueous phase solution (9:11) as the mobile phase. The ratio may be adjusted if necessary.
    (2) Reference standard solution: Weigh accurately X mg of aristolochic acid (It is equivalent to 10 mg of aristolochic acid I, X=10×100/F, F refers to the content of aristolochic acid I, which is marked on vial) and dissolve in 75% methanol to 250 mL. Measure accurately 2 mL of the solution and dilute it with 250 mL and use it (contain 0.4 μg/mL of aristolochic acid).
    (3) Sample solution: Weigh accurately the preparation powder equivalent to 2.0 g of Asari Radix, transfer to a round bottom flask, add 50 mL of 75% methanol in water, ultrasonicate for 20 minutes, filter and use the filtrate.
    (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (400 nm) and a column (4.6 mm × 25 cm) packing L1. The column temperature is maintained at 25~40℃. The flow rate is about 1.0 mL/min.
    (5) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and record the chromatogram. If the chromatogram obtained with the sample solution didn't corresponding in the retention time of aristolochic acid I to the chromatogram obtained with the reference standard solution, the sample is acceptable. If the chromatogram obtained with the sample solution correspondings in the retention time of aristolochic acid I to the chromatogram obtained with the reference standard solution, the sample should be retested under different conditions; when the chromatogram obtained with the sample solution did not corresponding in the retention time of aristolochic acid I to the chromatogram obtained with the reference standard solution, the sample should be acceptable.

Assay:

1. Epherine and pseudoephedrine:
    (1) Mobile phase: Add 5 g sodium dodecyl sulfate (SDS) and 1 ml phosphoric acid in 600 mL water, mixed well as aqueous phase solution. A solution of acetonitrile and aqueous phase solution (4:6). The ratio may be adjusted if necessary.
    (2) Reference standard solution: Weigh accurately a quantity of ephedrine and pseudoephedrine and dissolve in 50% methanol to produce a solution containing 0.1 mg/mL of each of ephedrine and pseudoephedrine.
    (3) Weigh accurately 0.5 g of the powdered sample, then add accurately 50 mL of 50% methanol, ultrasonicate for 15 minutes, filter and transfer the filtrate to a 50-mL volumetric flask and make up to volume with 50% methanol, mix well, filter and use the successive filtrate.
    (4) Chromatographic system: The liquid chromatography is equipped with an UV detector (210 nm) and a column packing L1 (4.6 mm × 25 cm). The column temperature is maintained at 30℃. The flow rate is adjusted to the peak retention time of pseudoephedrine and ephedrine is about 18 minutes and 20 minutes.
    (5) System suitability: Inject reference standard solution into the liquid chromatography apparatus for 5 times, and record the peak areas.The relative standard deviation of the peak area of ephedrine and pseudoephedrine should not be more than 1.5%. The number of theoretical plates of the peak of ephedrine and pseudoephedrine should not be less than 5,000.
    (6) Procedure: Inject accurately 20 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content of each component separately according to the following formula, and add up the content of each reference to get the total.

    Ephedrine or pseudoephedrine (mg/day) =

    $$[0.05(r_U/r_S)(C_S)/(W)] \times \text{daily dose}$$

    r_U : peak area of ephedrine or pseudoephedrine of sample solution

    r_S : peak area of ephedrine or pseudoephedrine of reference standard solution

    C_S : concentration of ephedrine or pseudoephedrine of reference standard solution (μg/mL)

    W : weight of test sample (g) calculated with dried sample.

2. Paeoniflorin:
    (1) Mobile phase: A solution of acetonitrile, water, and phosphoric acid (150:850:1). The ratio may be adjusted if necessary.

(2) Reference standard solution: Weigh accurately a quantity of paeoniflorin and dissolve in 50% methanol to produce a solution containing 0.1 mg/mL of paeoniflorin.

(3) Weigh accurately 0.5 g of the powdered sample, then add accurately 50 mL of 50% methanol, ultrasonicate for 15 minutes, filter and transfer the filtrate to a 50-mL volumetric flask and make up to volume with 50% methanol, mix well, filter and use the successive filtrate.

(4) Chromatographic system: The liquid chromatography is equipped with an UV detector (232 nm) and a column packing L1 (4.6 mm × 25 cm). The column temperature is maintained at 30℃. The flow rate is adjusted to the peak retention time of paeoniflorin is about 10 minutes.

(5) System suitability: Inject reference standard solution into the liquid chromatography apparatus for 5 times, and record the peak areas. The relative standard deviation of the peak area of paeoniflorin should not be more than 1.5%. The number of theoretical plates of the peak of paeoniflorin should not be less than 5,000.

(6) Procedure: Inject accurately 10 μL of each of the reference standard solution and the sample solution into the liquid chromatography apparatus, and calculate the content according to the following formula.

Paeoniflorin (mg/day) = [0.05(r_U/r_S)(C_S)/(W)] × daily dose

r_U : peak area of paeoniflorin of sample solution

r_S : peak area of paeoniflorin of reference standard solution

C_S : concentration of paeoniflorin of reference standard solution (μg/mL)

W : weight of test sample (g) calculated with dried sample.

3. Water extractives: Carry out the method for determination of water extractives (General rule 6011).

4. Dilute ethanol extractives: Carry out the method for determination of dilute ethanol-soluble extractives (General rule 6011).

Effects: Release the exterior to dissipate cold, warm the lung and resolve fluid retention.

Indications: Wind-cold induced by exopathogen, internal stagnation of fluid-dampness, aversion to cold with fever, absence of sweating, cough and panting, white and watery phlegm.

Indexes

Reagents and Test Solutions

A

Acetic Acid (61)
Acetic Anhydride (62)
Acetone (62)
Acetonitrile (63)
Alcohol (63)
Alcohol, Aldehyde-free (65)
Alcohol, Dehydrated (65)
Alcohol, Neutralized (65)
Aluminium Trichloride (90)
Aluminium Trichloride TS (91)
Aluminium Nitrate (90)
Ammonia TS (91)
Ammonia TS, Stronger (91)
Ammonium Molybdate (65)
Ammonium Molybdate TS (92)
Ammonium Reineckate (90)
Aniline (66)
p-Anisaldehyde Sulfuric Acid TS (92)
Antimony Trichloride (66)
Antimony Trichloride TS (92)

B

Benzene (66)
Boric Acid (67)
Bromocresol Blue TS (92)
n-Butyl Alcohol (67)

C

Carbon Disulfide (67)
Chloral Hydrate TS (92)
Chloroform (68)
Citric Acid (90)
Cupric Chloride (91)
Cupric Tartrate TS, Alkaline (92)
Cyclohexane (68)

D

Dextrose (68)
Diazo TS (92)
Dibasic Sodium Phosphate (87)
p-Dimethylaminobenzaldehyde (69)
p-Dimethylaminobenzaldehyde TS (92)
3, 5-Dinitrobenzoic Acid (91)
2,4-Dinitrophenylhydrazine (69)
Dinitrophenylhydrazine TS (92)
2,4-Dinitrophenylhydrazine TS, Alcoholic (92)
Dragendorff's Reagent (92)
Dragendorff's Reagent, Modified (93)
Dragendorff's Spray Reagent, Modified (93)

E

Ether (69)
Ether Absolute (70)
Ethyl Acetate (70)
Ethyl Formate (91)

F

Ferric Chloride (91)
Ferric Chloride TS (93)
Ferric Perchlorate TS (93)
Ferrous Sulfate (70)
Ferrous Sulfate TS (93)
Formic Acid (71)
Fuchsin Solution (93)
Fuchsin-Sulfurous Acid TS (93)
Fuller's Earth, Chromatographic (71)

G

Gallic Acid (71)
Gelatin (71)
Glacial Acetic Acid (72)
Glycerin Base TS (93)

H

1 N Hydrochloric Acid (96)
Hexanes Solvent (73)

Hydrazine Sulfate (73)
Hydrochloric Acid (73)
Hydrogen Peroxide (30%) (74)
Hydrogen Peroxide Solution (75)
Hydroxylamine Hydrochloride (75)
Hydroxylamine Hydrochloride TS (93)
Hydroxylamine Hydrochloride-Ethanol TS (93)
n-Hexane (73)

I

0.1 N Iodine (96)
Iodine TS (93)
Isopropyl Alcohol (76)

L

Lead Acetate (77)
Lead Acetate TS (93)

M

Mercuric Nitrate TS (93)
Methyl Alcohol (77)
Methyl Ethyl Ketone (91)
Methyl Orange (95)
Methyl Red (95)
Millon's Reagent (93)
Molisch TS (*α*-Naphthol TS) (93)

N

Nitric Acid (78)
α-Naphthol (78)
β-Naphthol (78)

P

Perchloric Acid (91)
Petroleum Benzin (78)
Phenol (91)
Phenolphthalein TS (95)
Phosphomolybdic Acid (79)
Phosphomolybdic Acid/EtOH TS (94)
Phosphoric Acid (79)
Phosphorus Pentaoxide (80)
Potassium and Mercuric Iodide TS (94)
Potassium Biphosphate (80)
Potassium Chloride (81)
Potassium Ferricyanide (81)
Potassium Ferrocyanide (81)
Potassium Ferrocyanide TS (94)
Potassium Hydroxide (82)
Potassium Hydroxide TS (94)
Potassium Hydroxide-Ethanol TS (94)
Potassium Iodide (82)
Potassium Permanganate (83)
0.1 N Potassium Permanganate (96)
Potassium Permanganate TS (94)

S

Silicotungstic Acid TS (94)
Silver Nitrate (83)
Silver Nitrate TS (94)
Simulated Gastric Fluid (94)
Simulated Intestinal Fluid (94)
Sodium Alizarinsulfonate (84)
Sodium Bicarbonate (84)
Sodium Bisulfite (84)
Sodium Borohydride (85)
Sodium Carbonate (85)
Sodium Fluoride TS (94)
Sodium Hydroxide (85)
1 N Sodium Hydroxide (97)
Sodium Hydroxide Solution (10%) (94)
Sodium Hydroxide TS (94)
Sodium Hypochlorite TS (94)
Sodium Lauryl Sulfate (86)
Sodium Nitrite (87)
Sodium Nitrite-Ethanol TS (94)
Sodium Sulfate, Anhydrous (88)
Sodium Thiosulfate (88)
Starch Indicator TS (95)
Starch-Potassium Iodide TS (94)
Sulfuric Acid (88)
1 N Sulfuric Acid (97)

T

Tetrahydrofuran (89)

Thioacetamide TS (94)

Thioacetamide-Glycerin Base TS (94)

Thymolphthalein (Indicator) (91)

Thymolphthalein TS (94)

Toluene (89)

Triketohydrindene Hydrate (Ninhydrin) (90)

Triketohydrindene Hydrate TS (Ninhydrin TS) (95)

Trinitrophenol (91)

Trinitrophenol TS (Picric Acid TS) (95)

V

Vanillin (90)

Vanillin-Sulfuric Acid TS (95)

Official Names

A

ABRI HERBA	雞骨草	1
ABUTILI SEMEN	苘麻子	2
ACANTHOPANACIS CORTEX	五加皮	3
ACHYRANTHIS BIDENTATAE RADIX	牛膝	4
ACONITI KUSNEZOFFII RADIX	草烏	5
ACONITI LATERALIS RADIX PRAEPARATA	附子	7
ACONITI RADIX	川烏	9
ACORI TATARINOWII RHIZOMA	石菖蒲	10
ADENOPHORAE RADIX	南沙參	11
AGASTACHIS HERBA	藿香	13
AGRIMONIAE HERBA	仙鶴草	13
AILANTHI CORTEX	臭椿皮	14
AKEBIAE CAULIS	木通	15
ALBIZIAE CORTEX	合歡皮	16
ALISMATIS RHIZOMA	澤瀉	18
ALLII MACROSTEMONIS BULBUS	薤白	19
ALLII TUBEROSI SEMEN	韭菜子	20
ALOE	蘆薈	20
ALPINIAE KATSUMADAI SEMEN	草豆蔻	21
ALPINIAE OFFICINARUM RHIZOMA	高良薑	23
ALPINIAE OXYPHYLLAE FRUCTUS	益智	24
AMOMI FRUCTUS	砂仁	26
AMOMI FRUCTUS ROTUNDUS	豆蔻	28
AMPELOPSIS RADIX	白蘞	29
AMYNTHAS ET METAPHIRE	地龍	30
ANDROGRAPHIS HERBA	穿心蓮	31
ANEMARRHENAE RHIZOMA	知母	32
ANGELICAE DAHURICAE RADIX	白芷	34
ANGELICAE PUBESCENTIS RADIX	獨活	35
ANGELICAE SINENSIS RADIX	當歸	37
ANISI STELLATI FRUCTUS	八角茴香	39
AQUILARIAE LIGNUM RESINATUM	沉香	40
ARCTII FRUCTUS	牛蒡子	41
ARECAE PERICARPIUM	大腹皮	42
ARECAE SEMEN	檳榔	43
ARISAEMATIS RHIZOMA	天南星	44
ARMENIACAE SEMEN AMARUM	苦杏仁	46
ARNEBIAE RADIX	紫草	47
ARTEMISIAE ANNUAE HERBA	青蒿	48
ARTEMISIAE ARGYI FOLIUM	艾葉	49
ARTEMISIAE HERBA	茵陳	50
ARTEMISIAE LACTIFLORAE HERBA	劉寄奴	51
ASARI RADIX	細辛	53
ASPARAGI RADIX	天門冬	54
ASTERIS RADIX ET RHIZOMA	紫菀	55
ASTRAGALI COMPLANATI SEMEN	沙苑蒺藜	56
ASTRAGALI RADIX	黃耆	57
ATRACTYLODIS MACROCEPHALAE RHIZOMA	白朮	59
ATRACTYLODIS RHIZOMA	蒼朮	61
AUCKLANDIAE RADIX	木香	62
AURANTII FRUCTUS IMMATURUS	枳實	64
AZEDARACH FRUCTUS	川楝子	65

B

BAMBUSAE CAULIS IN TAENIAS	竹茹	66
BAMBUSAE CONCRETIO SILICEA	天竺黃	67
BENINCASAE SEMEN	冬瓜子	67
BLETILLAE RHIZOMA	白及	68
BOMBYCIS FAECES	蠶砂	70
BOMBYX BATRYTICATUS	白殭蠶	71

BORNEOLUM	冰片	72
BOVIS CALCULUS	牛黄	72
BROUSSONETIAE FRUCTUS	楮實子	73
BUDDLEJAE FLOS	密蒙花	74
BUPLEURI RADIX	柴胡	75
C		
CANNABIS FRUCTUS	火麻仁	77
CARPESII FRUCTUS	鶴蝨	78
CARTHAMI FLOS	紅花	79
CARYOPHYLLI FLOS	丁香	80
CASSIAE SEMEN	決明子	81
CATECHU	兒茶	83
CELOSIAE CRISTATAE FLOS	雞冠花	84
CELOSIAE SEMEN	青葙子	85
CENTELLAE HERBA	積雪草	85
CENTIPEDAE HERBA	鵝不食草	87
CHAENOMELIS FRUCTUS	木瓜	88
CHEBULAE FRUCTUS	訶子	89
CHRYSANTHEMI FLOS	菊花	91
CHUANXIONG RHIZOMA	川芎	92
CIBOTII RHIZOMA	狗脊	94
CICADAE PERIOSTRACUM	蟬蛻	95
CIMICIFUGAE RHIZOMA	升麻	96
CINNAMOMI CORTEX	肉桂	97
CINNAMOMI CORTEX CENTRALIS	桂心	98
CINNAMOMI RAMULUS	桂枝	99
CIRSII HERBA	小薊	100
CIRSII JAPONICI HERBA SEU RADIX	大薊	101
CISTANCHIS HERBA	肉蓯蓉	103
CITRI EXOCARPIUM RUBRUM	橘紅	111
CITRI FRUCTUS IMMATURUS	枳殼	104
CITRI MAXIMAE EXOCARPIUM	化橘紅	105
CITRI RETICULATAE PERICARPIUM	橘皮	107
CITRI RETICULATAE PERICARPIUM VETUM	陳皮	108
CITRI RETICULATAE PERICARPIUM VIRIDE	青皮	109
CITRI SARCODACTYLIS FRUCTUS	佛手柑	112
CLEMATIDIS CAULIS	川木通	113
CLEMATIDIS RADIX ET RHIZOMA	威靈仙	114
CNIDII FRUCTUS	蛇床子	115
CODONOPSIS RADIX	黨參	117
COICIS SEMEN	薏苡仁	119
COPTIDIS RHIZOMA	黃連	120
CORDYCEPS	冬蟲夏草	121
CORNI SARCOCARPIUM	山茱萸	122
CORYDALIS RHIZOMA	延胡索	123
CRASSOSTREAE CONCHA	牡蠣	125
CRATAEGI FRUCTUS	山楂	125
CROCI STIGMA	番紅花	127
CROTONIS SEMEN	巴豆	128
CULLENIAE FRUCTUS	補骨脂	129
CURCULIGINIS RHIZOMA	仙茅	131
CURCUMAE LONGAE RHIZOMA	薑黃	132
CURCUMAE RADIX	鬱金	133
CURCUMAE RHIZOMA	莪朮	134
CUSCUTAE SEMEN	菟絲子	136
CYATHULAE RADIX	川牛膝	137
CYNANCHI ATRATI RADIX ET RHIZOMA	白薇	138
CYNANCHI STAUNTONII RHIZOMA ET RADIX	白前	140
CYNOMORII HERBA	鎖陽	141
CYPERI RHIZOMA	香附	142
D		
DENDROBII CAULIS	石斛	143
DESCURAINIAE SEMEN	葶藶子	223
DESMODII STYRACIFOLII HERBA	廣金錢草	145
DIANTHI HERBA	瞿麥	146
DICHROAE RADIX	常山	147
DICTAMNI CORTEX	白鮮皮	148

DIOSCOREAE HYPOGLAUCAE RHIZOMA	粉萆薢	149
DIOSCOREAE RHIZOMA	山藥	150
DIPSACI RADIX	續斷	151
DOLOMIAEAE RADIX	川木香	153
DRACONIS SANGUIS	血竭	154
DRYNARIAE RHIZOMA	骨碎補	155
DRYOPTERIS CRASSIRHIZOMAE RHIZOMA	貫眾	156
E		
ECKLONIAE THALLUS	昆布	220
ECLIPTAE HERBA	墨旱蓮	157
EPHEDRAE HERBA	麻黃	159
EPIMEDII FOLIUM	淫羊藿	160
EQUISETI HYEMALIS HERBA	木賊	162
ERIOBOTRYAE FOLIUM	枇杷葉	163
ERIOCAULI FLOS	穀精草	165
EUCOMMIAE CORTEX	杜仲	166
EUODIAE FRUCTUS	吳茱萸	167
EUPATORII HERBA	佩蘭	168
EURYALES SEMEN	芡實	169
F		
FAGOPYRI SEMEN	蕎麥	170
FARFARAE FLOS	款冬花	171
FOENICULI FRUCTUS	小茴香	172
FORSYTHIAE FRUCTUS	連翹	173
FRAXINI CORTEX	秦皮	175
FRITILLARIAE CIRRHOSAE BULBUS	川貝母	176
FRITILLARIAE THUNBERGII BULBUS	浙貝母	177
G		
GALLI GIGERII CORNEUM ENDOTHELIUM	雞內金	178
GARDENIAE FRUCTUS	梔子	179
GASTRODIAE RHIZOMA	天麻	180
GECKO	蛤蚧	182
GENTIANAE MACROPHYLLAE RADIX	秦艽	183
GENTIANAE RADIX ET RHIZOMA	龍膽	185
GINKGO SEMEN	白果	187
GINSENG RADIX ET RHIZOMA	人參	187
GLEDITSIAE FRUCTUS	皂莢	190
GLEDITSIAE FRUCTUS ABNORMALIS	豬牙皂	191
GLEDITSIAE SPINA	皂角刺	192
GLEHNIAE RADIX	北沙參	193
GLYCYRRHIZAE RADIX ET RHIZOMA	甘草	193
GRANATI PERICARPIUM	石榴皮	195
GYPSUM FIBROSUM	石膏	196
H		
HAEMATITUM	代赭石	197
HALIOTIDIS CONCHA	石決明	197
HEDYSARI RADIX	紅耆	199
HELMINTHOSTACHYDIS RADIX ET RHIZOMA	倒地蜈蚣	200
HIRUDO	水蛭	200
HOMALOMENAE RHIZOMA	千年健	201
HORDEI FRUCTUS GERMINATUS	麥芽	202
HOUTTUYNIAE HERBA	魚腥草	203
HOVENIAE SEMEN	枳椇子	204
I		
ILICIS PUBESCENTIS RADIX ET CAULIS	毛冬青	205
IMPERATAE RHIZOMA	白茅根	206
INDIGO NATURALIS	青黛	207
INULAE FLOS	旋覆花	209
IRIS RHIZOMA	射干	210
ISATIDIS FOLIUM	大青葉	211
ISATIDIS RADIX	北板藍根	212
J		
JUJUBAE FRUCTUS	大棗	213
JUNCI MEDULLA	燈心草	214

K

KAEMPFERIAE RHIZOMA 山柰 215
KAKI CALYX 柿蒂 216
KANSUI RADIX 甘遂 217
KAOLINUM 滑石 393
KOCHIAE FRUCTUS 地膚子 219

L

LABLAB SEMEN ALBUM 白扁豆 219
LAMINARIAE THALLUS 昆布 220
LEONURI HERBA 益母草 222
LEONURI FRUCTUS 茺蔚子 221
LEPIDII SEMEN 葶藶子 223
LIGUSTICI RHIZOMA ET RADIX 藁本 225
LIGUSTRI LUCIDI FRUCTUS 女貞子 226
LILII BULBUS 百合 228
LINDERAE RADIX 烏藥 229
LIQUIDAMBARIS FRUCTUS 路路通 230
LITCHI SEMEN 荔枝核 231
LITSEAE FRUCTUS 華澄茄 232
LONICERAE FLOS 山銀花 234
LONICERAE JAPONICAE CAULIS 忍冬藤 235
LONICERAE JAPONICAE FLOS 金銀花 237
LOPHATHERI HERBA 淡竹葉 238
LYCII FRUCTUS 枸杞子 239
LYCII RADICIS CORTEX 地骨皮 240
LYCOPI HERBA 澤蘭 241
LYCOPODII HERBA 伸筋草 242
LYGODII SPORA 海金沙 243
LYSIMACHIAE HERBA 金錢草 243

M

MAGNOLIAE CORTEX 厚朴 245
MAGNOLIAE FLOS 辛夷 246
MANTIDIS OÖTHECA 桑螵蛸 248
MAYDIS STYLUS 玉米鬚 249
MENTHAE HERBA 薄荷 249
MERETRICIS SEU CYCLINAE CONCHA 蛤殼 251
MOMORDICAE SEMEN 木鼈子 251
MORI CORTEX 桑白皮 252
MORI FOLIUM 桑葉 253
MORI RAMULUS 桑枝 254
MORINDAE OFFICINALIS RADIX 巴戟天 256
MOSLAE HERBA 香薷 257
MOUTAN RADICIS CORTEX 牡丹皮 258
MUME FRUCTUS 烏梅 259
MYRISTICAE SEMEN 肉豆蔻 260
MYRRHA 沒藥 262

N

NATRII SULFAS 芒硝 262
NELUMBINIS FOLIUM 荷葉 263
NELUMBINIS PLUMULA 蓮子心 264
NELUMBINIS RHIZOMATIS NODUS 藕節 266
NELUMBINIS SEMEN 蓮子 266
NELUMBINIS STAMEN 蓮鬚 267
NEOPICRORHIZAE RHIZOMA 胡黃連 269
NEPETAE HERBA 荊芥 270
NEPETAE SPICA 荊芥穗 271
NOTOGINSENG RADIX ET RHIZOMA 三七 272
NOTOPTERYGII RHIZOMA ET RADIX 羌活 274

O

OLDENLANDIAE DIFFUSAE HERBA 白花蛇舌草 275
OLIBANUM 乳香 277
OPHIOPOGONIS RADIX 麥門冬 278
ORIGANI VULGARIS HERBA 牛至 279
OROXYLI SEMEN 木蝴蝶 280
ORTHOSIPHONIS HERBA 貓鬚草 281
ORYZAE FRUCTUS GERMINATUS 穀芽 282

P

PAEONIAE RADIX ALBA 白芍 283
PAEONIAE RADIX RUBRA 赤芍 284
PANACIS QUINQUEFOLII RADIX 西洋參 286
PATRINIAE HERBA 敗醬 288

PELODISCCI CARAPAX	鼈甲	289
PERILLAE CAULIS	紫蘇梗	289
PERILLAE FOLIUM	紫蘇葉	291
PERILLAE FRUCTUS	紫蘇子	292
PERSICAE SEMEN	桃仁	293
PEUCEDANI RADIX	前胡	295
PHARBITIDIS SEMEN	牽牛子	296
PHELLODENDRI CORTEX	黄蘗	297
PHRAGMITIS RHIZOMA	蘆根	299
PHYTOLACCAE RADIX	商陸	300
PINELLIAE RHIZOMA	半夏	301
PIPERIS FRUCTUS	胡椒	302
PLANTAGINIS HERBA	車前草	303
PLANTAGINIS SEMEN	車前子	305
PLATYCLADI CACUMEN	側柏葉	306
PLATYCLADI SEMEN	柏子仁	307
PLATYCODONIS RADIX	桔梗	308
POGONATHERI HERBA	筆仔草	310
POGOSTEMONIS HERBA	廣藿香	311
POLYGALAE RADIX	遠志	312
POLYGONATI ODORATI RHIZOMA	玉竹	313
POLYGONATI RHIZOMA	黄精	314
POLYGONI AVICULARIS HERBA	萹蓄	315
POLYPORUS	豬苓	316
PORIA	茯苓	317
PORIA CUM PINI RADIX	茯神	319
PORIAE CUTIS	茯苓皮	320
PORTULACAE HERBA	馬齒莧	321
PRINSEPIAE NUX	蕤仁	322
PRUNELLAE SPICA	夏枯草	322
PRUNI SEMEN	郁李仁	324
PSEUDOSTELLARIAE RADIX	太子參	325
PTERIS MULTIFIDAE HERBA	鳳尾草	326
PUERARIAE FLOS	葛花	327
PUERARIAE RADIX	葛根	328
PUERARIAE THOMSONII RADIX	粉葛	330
PULSATILLAE RADIX	白頭翁	331
PYROLAE HERBA	鹿衔草	332
PYRROSIAE FOLIUM	石韋	333
Q		
QUISQUALIS FRUCTUS	使君子	334
R		
RAPHANI SEMEN	萊菔子	336
REHMANNIAE RADIX	地黄	337
REYNOUTRIAE MULTIFLORAE CAULIS	首烏藤	338
REYNOUTRIAE MULTIFLORAE RADIX	何首烏	340
REYNOUTRIAE RHIZOMA ET RADIX	虎杖	341
RHAPONTICI RADIX	漏蘆	343
RHEI RADIX ET RHIZOMA	大黄	344
RHODIOLAE CRENULATAE RADIX ET RHIZOMA	紅景天	346
RHOIS GALLA	五倍子	347
ROSAE LAEVIGATAE FRUCTUS	金櫻子	349
RUBI FRUCTUS IMMATURUS	覆盆子	350
RUBIAE RADIX ET RHIZOMA	茜草	350
RUBRA PORIA	赤茯苓	351
S		
SALVIAE MILTIORRHIZAE RADIX ET RHIZOMA	丹參	353
SANGUISORBAE RADIX	地榆	354
SAPOSHNIKOVIAE RADIX ET RHIZOMA	防風	356
SAPPAN LIGNUM	蘇木	357
SCAPHII SEMEN	胖大海	358
SCHISANDRAE FRUCTUS	五味子	359
SCHISANDRAE SPHENANTHERAE FRUCTUS	南五味子	360
SCORPIO	全蠍	362
SCROPHULARIAE RADIX	玄參	362
SCUTELLARIAE BARBATAE HERBA	半枝蓮	364
SCUTELLARIAE RADIX	黄芩	365

SELAGINELLAE HERBA	卷柏	367
SEMIAQUILEGIAE RADIX	天葵子	368
SENNAE FOLIUM	番瀉葉	369
SEPIAE ENDOCONCHA	海螵蛸	370
SESAMI SEMEN NIGRUM	胡麻仁	371
SIGESBECKIAE HERBA	豨莶草	372
SINAPIS ALBAE SEMEN	白芥子	373
SIPHONOSTEGIAE HERBA	北劉寄奴	374
SIRAITIAE FRUCTUS	羅漢果	375
SMILACIS GLABRAE RHIZOMA	土茯苓	377
SOJAE SEMEN PREPARATUM	淡豆豉	378
SOPHORAE FLAVESCENTIS RADIX	苦參	379
SOPHORAE FLOS ET FLOS IMMATURUS	槐花	380
SOPHORAE FLOS IMMATURUS	槐米	381
SOPHORAE FRUCTUS	槐角	382
SOPHORAE TONKINENSIS RADIX ET RHIZOMA	山豆根	383
SPARGANII RHIZOMA	三稜	385
SPATHOLOBI CAULIS	雞血藤	386
SPIRODELAE HERBA	浮萍	387
STEMONAE RADIX	百部	388
STEPHANIAE TETRANDRAE RADIX	防己	389
STROBILANTHII CUSIAE RHIZOMA ET RADIX	南板藍根	391
STRYCHNI SEMEN	馬錢子	391
T		
TALCUM	滑石	393
TARAXACI HERBA	蒲公英	394
TAXILLI HERBA	桑寄生	395
TETRAPANACIS MEDULLA	通草	397
THLASPI HERBA	葶藶	397
TRACHELOSPERMI CAULIS CUM FOLIUM	絡石藤	399
TRIBULI FRUCTUS	蒺藜	400
TRICHOSANTHIS RADIX	栝樓根	400
TRICHOSANTHIS SEMEN	栝樓仁	401
TRIGONELLAE SEMEN	胡蘆巴	402
TRITICI FRUCTUS LEVIS	浮小麥	404
TSAOKO FRUCTUS	草果	404
TYPHAE POLLEN	蒲黃	405
U		
UNCARIAE RAMULUS CUM UNCIS	鉤藤	406
V		
VACCARIAE SEMEN	王不留行	407
VERBENAE HERBA	馬鞭草	408
VIGNAE SEMEN	赤小豆	410
VIOLAE HERBA	紫花地丁	411
VISCI HERBA	槲寄生	412
VITICIS FRUCTUS	蔓荊子	413
X		
XANTHII FRUCTUS	蒼耳子	415
Z		
ZANTHOXYLI PERICARPIUM	花椒	416
ZINGIBERIS RHIZOMA	乾薑	417
ZINGIBERIS RHIZOMA RECENS	生薑	418
ZIZIPHI SPINOSAE SEMEN	酸棗仁	419

Chinese Names

二劃

【丁、人、八】

丁香 80
人參 187
八角茴香 39

三劃

【三、千、土、大、女、小、山、川】

三七 272
三稜 385
千年健 201
土茯苓 377
大青葉 211
大棗 213
大黃 344
大黃濃縮製劑（顆粒、散） 428
大腹皮 42
大薊 101
女貞子 226
小茴香 172
小青龍湯濃縮製劑（顆粒、散） 438
小薊 100
山豆根 383
山柰 215
山茱萸 122
山楂 125
山銀花 234
山藥 150
川木香 153
川木通 113
川牛膝 137
川芎 92
川貝母 176
川烏 9
川楝子 65

四劃

【丹、五、化、升、天、太、巴、木、毛、水、火、牛、王】

丹參 353
五加皮 3
五味子 359
五倍子 347
化橘紅 105
升麻 96
天竺黃 67
天門冬 54
天南星 44
天麻 180
天葵子 368
太子參 325
巴豆 128
巴戟天 256
木瓜 88
木香 62
木通 15
木賊 162
木蝴蝶 280
木鼈子 251
毛冬青 205
水蛭 200
火麻仁 77
牛至 279
牛黃 72
牛蒡子 41
牛膝 4
王不留行 407

五劃

【仙、代、冬、加、北、半、玄、玉、甘、生、白、石】

仙茅 131
仙鶴草 13
代赭石 197
冬瓜子 67
冬蟲夏草 121
加味逍遙散濃縮製劑（顆粒、散） 435
北沙參 193
北板藍根 212
北劉寄奴 374
半枝蓮 364
半夏 301
半夏瀉心湯濃縮製劑（顆粒、散） 431
玄參 362
玉竹 313
玉米鬚 249
甘草 193
甘草濃縮製劑（顆粒、散） 426
甘遂 217
生薑 418
白及 68
白朮 59
白芍 283
白果 187
白芥子 373
白花蛇舌草 276
白芷 34
白前 140
白扁豆 219
白茅根 206
白頭翁 331

白殭蠶 71
白薇 138
白鮮皮 148
白蘞 29
石決明 197
石韋 333
石斛 143
石菖蒲 10
石榴皮 195
石膏 196

六劃

【全、冰、合、地、百、竹、肉、艾、血、西】

全蠍 362
冰片 72
合歡皮 16
地骨皮 240
地黃 337
地榆 354
地膚子 219
地龍 30
百合 228
百部 388
竹茹 66
肉豆蔻 260
肉桂 97
肉蓯蓉 103
艾葉 49
血竭 154
西洋參 286

七劃

【伸、何、佛、吳、忍、杜、決、沉、沒、沙、牡、皂、芒、豆、赤、車、辛、防】

伸筋草 242
何首烏 340
佛手柑 112
吳茱萸 167
忍冬藤 235
杜仲 166
決明子 81
沉香 40
沒藥 262
沙苑蒺藜 56
牡丹皮 258
牡蠣 125
皂角刺 192
皂莢 190
芒硝 262
豆蔻 28
赤小豆 410
赤芍 284
赤茯苓 351
車前子 305
車前草 303
辛夷 246
防己 389
防風 356

八劃

【乳、佩、使、兒、卷、延、昆、枇、狗、知、羌、艾、花、虎、金、附、青】

乳香 277
佩蘭 168
使君子 334
兒茶 82
卷柏 367
延胡索 123
延胡索濃縮製劑（顆粒、散） 425
昆布 220
枇杷葉 163
狗脊 94
知母 32
羌活 274
艾實 169
花椒 416
虎杖 341
金銀花 237
金錢草 243
金櫻子 349
附子 7
青皮 109
青葙子 85
青蒿 48
青黛 207

九劃

【前、南、厚、威、枳、枸、柏、柿、砂、穿、紅、胖、胡、茼、苦、芫、郁、韭、首、香】

前胡 295
南五味子 360
南沙參 11
南板藍根 391
厚朴 245
威靈仙 114
枳椇子 204
枳殼 104
枳實 64
枸杞子 239
柏子仁 307
柿蒂 216
砂仁 26
穿心蓮 31
紅花 79
紅耆 199
紅景天 346
胖大海 358
胡麻仁 371
胡椒 302
胡黃連 269

胡蘆巴 402
苘麻子 2
苦杏仁 46
苦參 379
芫蔚子 221
郁李仁 324
韭菜子 20
首烏藤 338
香附 142
香薷 257

十劃

【倒、夏、射、柴、栝、桂、桃、桑、桔、浙、浮、海、烏、益、秦、粉、臭、茜、茯、茵、草、荊、荔、馬、骨、高】

倒地蜈蚣 200
夏枯草 322
射干 210
柴胡 75
栝樓仁 401
栝樓根 400
桂心 98
桂枝 99
桃仁 293
桑白皮 252
桑枝 254
桑寄生 395
桑葉 253
桑螵蛸 248
桔梗 308
浙貝母 177
浮小麥 404
浮萍 387
海金沙 243
海螵蛸 370
烏梅 259
烏藥 229
益母草 222
益智 24
秦皮 175
秦艽 183
粉草薢 149
粉葛 330
臭椿皮 14
茜草 350
茯苓 317
茯苓皮 320
茯神 319
茵陳 50
草豆蔻 21
草果 404
草烏 5
荊芥 270
荊芥穗 271
荔枝核 231
馬齒莧 321
馬錢子 391
馬鞭草 408
骨碎補 155
高良薑 23

十一劃

【乾、側、商、密、常、敗、旋、梔、淡、淫、牽、細、荷、莪、蛇、貫、通、連、陳、魚、鹿、麥、麻】

乾薑 417
側柏葉 306
商陸 300
密蒙花 74
常山 147
敗醬 288
旋覆花 209
梔子 179
淡竹葉 238
淡豆豉 378
淫羊藿 160
牽牛子 296
細辛 53
荷葉 263
莪朮 134
蛇床子 115
貫眾 156
通草 397
連翹 173
陳皮 108
魚腥草 203
鹿銜草 332
麥芽 202
麥門冬 278
麻黃 159

十二劃

【楮、款、番、筆、紫、絡、菊、菟、葒、萊、蛤、訶、黃】

楮實子 73
款冬花 171
番紅花 127
番瀉葉 369
筆仔草 310
紫花地丁 411
紫草 47
紫菀 55
紫蘇子 292
紫蘇梗 289
紫蘇葉 291
絡石藤 399
菊花 91
菟絲子 136
葒蓂 397
萊菔子 336
蛤蚧 182

蛤殼 251
訶子 89
黃芩 365
黃芩濃縮製劑（顆粒、散） 429
黃耆 57
黃連 120
黃精 314
黃蘗 297

十三劃
【滑、當、萹、葛、葶、補、路、鉤】
滑石 393
當歸 37
萹蓄 315
葛花 327
葛根 328
葛根湯濃縮製劑（顆粒、散） 433
葛根濃縮製劑（顆粒、散） 427
葶藶子 223
補骨脂 129
路路通 230
鉤藤 406

十四劃
【槐、漏、蒲、蒺、蒼、豨、遠、酸、鳳】
槐角 382
槐花 380
槐米 381
漏蘆 343
蒲公英 394
蒲黃 405
蒺藜 400
蒼朮 61
蒼耳子 415
豨薟草 372
遠志 312
酸棗仁 419
鳳尾草 326

十五劃
【劉、墨、廣、槲、穀、蓮、蓽、蔓、豬】
劉寄奴 51
墨旱蓮 157
廣金錢草 145
廣藿香 311
槲寄生 412
穀芽 282
穀精草 165
蓮子 266
蓮子心 264
蓮鬚 267
蓽澄茄 232
蔓荊子 413
豬牙皂 191
豬苓 316

十六劃
【橘、澤、燈、獨、積、蕎、薤、貓、龍】
橘皮 107
橘紅 111
澤瀉 18
澤蘭 241
燈心草 214
獨活 35
積雪草 85
蕎麥 170
薤仁 322
貓鬚草 281
龍膽 185

十七劃
【薄、薏、薑、薤】
薄荷 249
薏苡仁 119
薑黃 132
薤白 19

十八劃
【檳、瞿、藁、蟬、覆、鎖、雞、鵝】
檳榔 43
瞿麥 146
藁本 225
蟬蛻 95
覆盆子 350
鎖陽 141
雞內金 178
雞血藤 386
雞冠花 84
雞骨草 1
鵝不食草 87

十九劃
【羅、藕】
羅漢果 375
藕節 266

二十劃
【藿、蘆、蘇、黨】
藿香 13
蘆根 299
蘆薈 20
蘇木 357
黨參 117

二十一劃
【續、鶴】
續斷 151
鶴蝨 78

二十四劃
【蠶、鼈】
蠶砂 70
鼈甲 289

二十九劃
【鬱】
鬱金 133

Names in Tongyong Pinyin Form

	A	
Ai Ye	艾葉	49
	B	
Ba Dou	巴豆	128
Ba Ji Tian	巴戟天	256
Ba Jiao Huei Siang	八角茴香	39
Bai Bian Dou	白扁豆	219
Bai Bu	百部	388
Bai Cian	白前	140
Bai Guo	白果	187
Bai He	百合	228
Bai Hua She She Cao	白花蛇舌草	276
Bai Jhih	白芷	34
Bai Jhu	白朮	59
Bai Ji	白及	68
Bai Jiang	敗醬	288
Bai Jiang Can	白殭蠶	71
Bai Jie Zih	白芥子	373
Bai Lian	白薟	29
Bai Mao Gen	白茅根	206
Bai Shao	白芍	283
Bai Sian Pi	白鮮皮	148
Bai Tou Wong	白頭翁	331
Bai Wei	白薇	138
Ban Jhih Lian	半枝蓮	364
Ban Sia	半夏	301
Bansia Xiesin Tang Concentrated Preparation (Granules, Powder)	半夏瀉心湯濃縮製劑（顆粒、散）	431
Bei Ban Lan Gen	北板藍根	212
Bei Liou Ji Nu	北劉寄奴	374
Bei Sha Shen	北沙參	193
Bi Cheng Jia	蓽澄茄	232
Bi Zai Tsao	筆仔草	310
Bie Jia	鱉甲	289
Bin Lang	檳榔	43
Bing Pian	冰片	72
Bo He	薄荷	249
Bo Zih Ren	柏子仁	307
Bu Gu Jhih	補骨脂	129
	C	
Can Sha	蠶砂	70
Cang Er Zih	蒼耳子	415
Cang Jhu	蒼朮	61
Cao Dou Kou	草豆蔻	21
Cao Guo	草果	404
Cao Wu	草烏	5
Ce Bo Ye	側柏葉	306
Chai Hu	柴胡	75
Chan Tuei	蟬蛻	95
Chang Shan	常山	147
Che Cian Cao	車前草	303
Che Cian Zih	車前子	305
Chen Pi	陳皮	108
Chen Siang	沉香	40
Chiao Mai	蕎麥	170
Chih Fu Ling	赤茯苓	351
Chih Shao	赤芍	284
Chih Siao Dou	赤小豆	410
Chong Wei Zih	茺蔚子	221
Chou Chun Pi	臭椿皮	14
Chu Shih Zih	楮實子	73
Chuan Bei Mu	川貝母	176
Chuan Cyong	川芎	92
Chuan Lian Zih	川楝子	65
Chuan Mu Siang	川木香	153
Chuan Mu Tong	川木通	113
Chuan Niou Si	川牛膝	137
Chuan Sin Lian	穿心蓮	31
Chuan Wu	川烏	9
Cian Cao	茜草	350
Cian Hu	前胡	295
Cian Nian Jian	千年健	201
Cian Niou Zih	牽牛子	296
Cian Shih	芡實	169
Ciang Huo	羌活	274
Cin Jiao	秦艽	183

Cin Pi	秦皮	175
Cing Dai	青黛	207
Cing Hao	青蒿	48
Cing Ma Zih	苘麻子	2
Cing Pi	青皮	109
Cing Siang Zih	青葙子	85
Cyuan Sie	全蠍	362
D		
Da Cing Ye	大青葉	211
Da Fu Pi	大腹皮	42
Da Huang	大黃	344
Da-Huang Concentrated Preparation (Granules, Powder)	大黃濃縮製劑（顆粒、散）	428
Da Ji	大薊	101
Da Zao	大棗	213
Dai Jhe Shih	代赭石	197
Dan Dou Chih	淡豆豉	378
Dan Jhu Ye	淡竹葉	238
Dan Shen	丹參	353
Dang Guei	當歸	37
Dang Shen	黨參	117
Dao Di Wu Gong	倒地蜈蚣	200
Deng Sin Cao	燈心草	214
Di Fu Zih	地膚子	219
Di Gu Pi	地骨皮	240
Di Huang	地黃	337
Di Long	地龍	30
Di Yu	地榆	354
Ding Sing	丁香	80
Dong Chong Sia Cao	冬蟲夏草	121
Dong Gua Zih	冬瓜子	67
Dou Kou	豆蔻	28
Du Huo	獨活	35
Du Jhong	杜仲	166
E		
E Bu Shih Tsao	鵝不食草	87
E Jhu	莪朮	134
Er Cha	兒茶	83
F		
Fan Hong Hua	番紅花	127
Fan Sie Ye	番瀉葉	369
Fang Fong	防風	356
Fang Ji	防己	389
Fen Bei Jie	粉萆薢	149
Fen Ge	粉葛	330
Fo Shou Gan	佛手柑	112
Fong Wei Tsao	鳳尾草	326
Fu Ling	茯苓	317
Fu Ling Pi	茯苓皮	320
Fu Pen Zih	覆盆子	350
Fu Ping	浮萍	387
Fu Shen	茯神	319
Fu Siao Mai	浮小麥	404
Fu Zih	附子	7
G		
Gan Cao	甘草	193
Gan-Cao Concentrated Preparation (Granules, Powder)	甘草濃縮製劑（顆粒、散）	426
Gan Jiang	乾薑	417
Gan Suei	甘遂	217
Gao Ben	藁本	225
Gao Liang Jiang	高良薑	23
Ge Gen	葛根	328
Ge-Gen Concentrated Preparation (Granules, Powder)	葛根濃縮製劑（顆粒、散）	427
Ge Gen Tang Concentrated Preparation (Granules, Powder)	葛根湯濃縮製劑（顆粒、散）	433
Ge Hua	葛花	327
Ge Jie	蛤蚧	182
Ge Ke	蛤殼	251
Gou Ci Zih	枸杞子	239
Gou Ji	狗脊	94
Gou Teng	鉤藤	406
Gu Jing Cao	穀精草	165
Gu Suei Bu	骨碎補	155

Gu Ya	穀芽	282
Gua Lou Gen	栝樓根	400
Gua Lou Ren	栝樓仁	401
Guan Jhong	貫眾	156
Guang Huo Siang	廣藿香	311
Guang Jin Cian Cao	廣金錢草	145
Guei Jhih	桂枝	99
Guei Sin	桂心	98
H		
Hai Jin Sha	海金沙	243
Hai Piao Siao	海螵蛸	370
He Huan Pi	合歡皮	16
He Shih	鶴蝨	78
He Shou Wu	何首烏	340
He Ye	荷葉	263
He Zih	訶子	89
Hong Ci	紅耆	199
Hong Hua	紅花	79
Hong Jing Tian	紅景天	346
Hou Pu	厚朴	245
Hu Huang Lian	胡黃連	269
Hu Jhang	虎杖	341
Hu Ji Sheng	槲寄生	412
Hu Jiao	胡椒	302
Hu Lu Ba	胡蘆巴	402
Hu Ma Ren	胡麻仁	371
Hua Jiao	花椒	416
Hua Jyu Hong	化橘紅	105
Hua Shih	滑石	393
Huai Hua	槐花	380
Huai Jiao	槐角	382
Huai Mi	槐米	381
Huang Bo	黃蘗	297
Huang Ci	黃耆	57
Huang Cin	黃芩	365
Huang-Cin Concentrated Preparation (Granules, Powder)	黃芩濃縮製劑（顆粒、散）	429
Huang Jing	黃精	314
Huang Lian	黃連	120
Huo Ma Ren	火麻仁	77
Huo Siang	藿香	13
J		
Jaiwei Xiaoyao San Concentrated Preparation (Granules, Powder)	加味逍遙散濃縮製劑（顆粒、散）	435
Jhe Bei Mu	浙貝母	177
Jhih Jyu Zih	枳椇子	204
Jhih Ke	枳殼	104
Jhih Mu	知母	32
Jhih Shih	枳實	64
Jhih Zih	梔子	179
Jhu Ling	豬苓	316
Jhu Ru	竹茹	66
Jhu Ya Zao	豬牙皂	191
Ji Gu Tsao	雞骨草	1
Ji Guan Hua	雞冠花	84
Ji Li	蒺藜	400
Ji Nei Jin	雞內金	178
Ji Sie Teng	雞血藤	386
Ji Syue Cao	積雪草	85
Jiang Huang	薑黃	132
Jie Geng	桔梗	308
Jin Cian Cao	金錢草	243
Jin Yin Hua	金銀花	237
Jin Ying Zih	金櫻子	349
Jing Jie	荊芥	270
Jing Jieh Suei	荊芥穗	271
Jiou Cai Zih	韭菜子	20
Jyu Hong	橘紅	111
Jyu Hua	菊花	91
Jyu Mai	瞿麥	146
Jyu Pi	橘皮	107
Jyuan Bo	卷柏	367
Jyue Ming Zih	決明子	81
K		
Ku Shen	苦參	379
Ku Sing Ren	苦杏仁	46
Kuan Dong Hua	款冬花	171
Kun Bu	昆布	220

	L	
Lai Fu Zih	萊菔子	336
Li Jhih He	荔枝核	231
Lian Ciao	連翹	173
Lian Syu	蓮鬚	267
Lian Zih	蓮子	266
Lian Zih Sin	蓮子心	264
Liou Ji Nu	劉寄奴	51
Long Dan	龍膽	185
Lou Lu	漏蘆	343
Lu Gen	蘆根	299
Lu Huei	蘆薈	20
Lu Lu Tong	路路通	230
Lu Sian Tsao	鹿銜草	332
Luo Han Guo	羅漢果	375
Luo Shih Teng	絡石藤	399
	M	
Ma Bian Tsao	馬鞭草	408
Ma Chih Sian	馬齒莧	321
Ma Cian Zih	馬錢子	391
Ma Huang	麻黃	159
Mai Men Dong	麥門冬	278
Mai Ya	麥芽	202
Man Jing Zih	蔓荊子	413
Mang Siao	芒硝	262
Mao Dong Ching	毛冬青	205
Mao Syu Tsao	貓鬚草	281
Mei Yao	沒藥	262
Mi Meng Hua	密蒙花	74
Mo Han Lian	墨旱蓮	157
Mu Bieh Zih	木鼈子	251
Mu Dan Pi	牡丹皮	258
Mu Gua	木瓜	88
Mu Hu Dieh	木蝴蝶	280
Mu Li	牡蠣	125
Mu Siang	木香	62
Mu Tong	木通	15
Mu Zei	木賊	162
	N	
Nan Ban Lan Gen	南板藍根	391
Nan Sha Shen	南沙參	11
Nan Wu Wei Zih	南五味子	360
Niou Bang Zih	牛蒡子	41
Niou Huang	牛黃	72
Niou Jhih	牛至	279
Niou Si	牛膝	4
Nyn Jhen Zih	女貞子	226
	O	
Ou Jie	藕節	266
	P	
Pang Da Hai	胖大海	358
Pei Lan	佩蘭	168
Pi Pa Ye	枇杷葉	163
Pian Syu	萹蓄	315
Pu Gong Ying	蒲公英	394
Pu Huang	蒲黃	405
	R	
Ren Dong Teng	忍冬藤	235
Ren Shen	人參	187
Rou Cong Rong	肉蓯蓉	103
Rou Dou Kou	肉豆蔻	260
Rou Guei	肉桂	97
Ru Siang	乳香	277
Ruei Ren	蕤仁	322
	S	
San Ci	三七	272
San Ling	三稜	385
Sang Bai Pi	桑白皮	252
Sang Jhih	桑枝	254
Sang Ji Sheng	桑寄生	395
Sang Piao Siao	桑螵蛸	248
Sang Ye	桑葉	253
Sha Ren	砂仁	26
Sha Yuan Ji Li	沙苑蒺藜	56
Shan Dou Gen	山豆根	383
Shan Jha	山楂	125
Shan Jhu Yu	山茱萸	122
Shan Nai	山柰	215
Shan Yao	山藥	150
Shan Yin Hua	山銀花	234
Shang Lu	商陸	300
She Chuang Zih	蛇床子	115

Shen Jin Cao	伸筋草	242
Sheng Jiang	生薑	418
Sheng Ma	升麻	96
Shih Chang Pu	石菖蒲	10
Shih Di	柿蒂	216
Shih Gao	石膏	196
Shih Hu	石斛	143
Shih Jyue Ming	石決明	197
Shih Jyun Zih	使君子	334
Shih Liou Pi	石榴皮	195
Shih Wei	石韋	333
Shou Wu Teng	首烏藤	338
Shuei Jhih	水蛭	200
Si Lian Cao	豨薟草	372
Si Ming	莙蓂	397
Si Sin	細辛	53
Si Yang Shen	西洋參	286
Sia Ku Cao	夏枯草	322
Sian He Cao	仙鶴草	13
Sian Mao	仙茅	131
Siang Fu	香附	142
Siang Ru	香薷	257
Siao Huei Siang	小茴香	172
Siao Ji	小薊	100
Siaocinglong Tang Concentrated Preparation (Granules, Powder)	小青龍湯濃縮製劑（顆粒、散）	438
Sie Bai	薤白	19
Sie Jie	血竭	154
Sin Yi	辛夷	246
Su Mu	蘇木	357
Suan Zao Ren	酸棗仁	419
Suo Yang	鎖陽	141
Syu Duan	續斷	151
Syuan Fu Hua	旋覆花	209
Syuan Shen	玄參	362
T		
Tai Zih Shen	太子參	325
Tao Ren	桃仁	293
Tian Jhu Huang	天竺黃	67
Tian Kuei Zih	天葵子	368
Tian Ma	天麻	180
Tian Men Dong	天門冬	54
Tian Nan Sing	天南星	44
Ting Li Zih	葶藶子	223
Tong Cao	通草	397
Tu Fu Ling	土茯苓	377
Tu Sih Zih	菟絲子	136
W		
Wang Bu Liou Sing	王不留行	407
Wei Ling Sian	威靈仙	114
Wu Bei Zih	五倍子	347
Wu Jhu Yu	吳茱萸	167
Wu Jia Pi	五加皮	3
Wu Mei	烏梅	259
Wu Wei Zih	五味子	359
Wu Yao	烏藥	229
Y		
Yan Hu Suo	延胡索	123
Yan Hu-Suo Concentrated Preparation (Granules, Powder)	延胡索濃縮製劑（顆粒、散）	425
Ye Gan	射干	210
Yi Jhih	益智	24
Yi Mu Cao	益母草	222
Yi Yi Ren	薏苡仁	119
Yin Chen	茵陳	50
Yin Yang Huo	淫羊藿	160
Yu Jhu	玉竹	313
Yu Jin	鬱金	133
Yu Li Ren	郁李仁	324
Yu Mi Syu	玉米鬚	249
Yu Sing Cao	魚腥草	203
Yuan Jhih	遠志	312
Z		
Zao Jia	皂莢	190
Zao Jiao Cih	皂角刺	192
Ze Lan	澤蘭	241
Ze Sie	澤瀉	18
Zih Cao	紫草	47

Zih Hua Di Ding	紫花地丁	411
Zih Su Geng	紫蘇梗	289
Zih Su Ye	紫蘇葉	291
Zih Su Zih	紫蘇子	292
Zih Wan	紫菀	55

Names in Hanyu Pinyin Form

A		
Ai Ye	艾葉	49
B		
Ba Dou	巴豆	128
Ba Ji Tian	巴戟天	256
Ba Jiao Hui Xiang	八角茴香	39
Bai Bian Dou	白扁豆	219
Bai Bu	百部	388
Bai Guo	白果	187
Bai He	百合	228
Bai Hua She She Cao	白花蛇舌草	276
Bai Ji	白及	68
Bai Jiang	敗醬	288
Bai Jiang Can	白殭蠶	71
Bai Jie Zi	白芥子	373
Bai Lian	白薟	29
Bai Mao Gen	白茅根	206
Bai Qian	白前	140
Bai Shao	白芍	283
Bai Tou Weng	白頭翁	331
Bai Wei	白薇	138
Bai Xian Pi	白鮮皮	148
Bai Zhi	白芷	34
Bai Zhu	白朮	59
Ban Xia	半夏	301
Banxia Siexin Tang Concentrated Preparation (Granules, Powder)	半夏瀉心湯濃縮製劑（顆粒、散）	431
Ban Zhi Lian	半枝蓮	364
Bei Ban Lan Gen	北板藍根	212
Bei Liou Ji Nu	北劉寄奴	374
Bei Sha Shen	北沙參	193
Bi Cheng Jia	蓽澄茄	232
Bi Zai Cao	筆仔草	310
Bie Jia	鼈甲	289
Bin Lang	檳榔	43
Bing Pian	冰片	72
Bo He	薄荷	249
Bo Zi Ren	柏子仁	307
Bu Gu Zhi	補骨脂	129
C		
Can Sha	蠶砂	70
Cang Er Zi	蒼耳子	415
Cang Zhu	蒼朮	61
Cao Dou Kou	草豆蔻	21
Cao Guo	草果	404
Cao Wu	草烏	5
Ce Bo Ye	側柏葉	306
Chai Hu	柴胡	75
Chan Tui	蟬蛻	95
Chang Shan	常山	147
Che Cian Zi	車前子	305
Che Qian Cao	車前草	303
Chen Pi	陳皮	108
Chen Xiang	沉香	40
Chi Shao	赤芍	284
Chi Xiao Dou	赤小豆	410
Chih Fu Ling	赤茯苓	351
Ching Wei Zi	莞蔚子	221
Chou Chun Pi	臭椿皮	14
Chu Shi Zi	楮實子	73
Chuan Bei Mu	川貝母	176
Chuan Lian Zi	川楝子	65
Chuan Mu Tong	川木通	113
Chuan Mu Xiang	川木香	153
Chuan Niu Xi	川牛膝	137
Chuan Qiong	川芎	92
Chuan Sin Lian	穿心蓮	31
Chuan Wu	川烏	9
D		
Da Fu Pi	大腹皮	42
Da Huang	大黃	344
Da-Huang Concentrated Preparation (Granules, Powder)	大黃濃縮製劑（顆粒、散）	428
Da Ji	大薊	101
Da Qing Ye	大青葉	211

Da Zao	大棗	213
Dai Zhe Shi	代赭石	197
Dan Dou Chih	淡豆豉	378
Dan Shen	丹參	353
Dan Zhu Ye	淡竹葉	238
Dang Gui	當歸	37
Dang Shen	黨參	117
Dao Di Wu Gong	倒地蜈蚣	200
Deng Xin Cao	燈心草	214
Di Fu Zi	地膚子	219
Di Gu Pi	地骨皮	240
Di Huang	地黃	337
Di Long	地龍	30
Di Yu	地榆	354
Ding Xiang	丁香	80
Dong Chong Xia Cao	冬蟲夏草	121
Dong Gua Zi	冬瓜子	67
Dou Kou	豆蔻	28
Du Huo	獨活	35
Du Zhong	杜仲	166
E		
E Bu Shi Cao	鵝不食草	87
E Zhu	莪朮	134
Er Cha	兒茶	83
F		
Fan Hong Hua	番紅花	127
Fan Xie Ye	番瀉葉	369
Fang Feng	防風	356
Fang Ji	防己	389
Fen Bei Jie	粉萆薢	149
Fen Ge	粉葛	330
Feng Wei Cao	鳳尾草	326
Fo Shou Gan	佛手柑	112
Fu Ling	茯苓	317
Fu Ling Pi	茯苓皮	320
Fu Pen Zi	覆盆子	350
Fu Ping	浮萍	387
Fu Shen	茯神	319
Fu Xiao Ma	浮小麥	404
Fu Zi	附子	7
G		
Gan Cao	甘草	193
Gan-Cao Concentrated Preparation (Granules, Powder)	甘草濃縮製劑（顆粒、散）	426
Gan Jiang	乾薑	417
Gan Sui	甘遂	217
Gao Ben	藁本	225
Gao Liang Jiang	高良薑	23
Ge Gen	葛根	328
Ge-Gen Concentrated Preparation (Granules, Powder)	葛根濃縮製劑（顆粒、散）	427
Ge Gen Tang Concentrated Preparation (Granules, Powder)	葛根湯濃縮製劑（顆粒、散）	433
Ge Hua	葛花	327
Ge Jie	蛤蚧	182
Ge Ke	蛤殼	251
Gou Ji	狗脊	94
Gou Qi Zi	枸杞子	239
Gou Teng	鉤藤	406
Gu Jing Cao	穀精草	165
Gu Sui Bu	骨碎補	155
Gu Ya	穀芽	282
Gua Lou Gen	栝樓根	400
Gua Lou Ren	栝樓仁	401
Guan Zhong	貫眾	156
Guang Huo Xiang	廣藿香	311
Guang Jin Qian Cao	廣金錢草	145
Guei Sin	桂心	98
Gui Zhi	桂枝	99
H		
Hai Jin Sha	海金沙	243
Hai Piao Xiao	海螵蛸	370
He Huan Pi	合歡皮	16
He shi	鶴蝨	78
He Shou Wu	何首烏	340
He Ye	荷葉	263
He Zi	訶子	89
Hong Hua	紅花	79

Hong Jing Tian	紅景天	346
Hong Qi	紅耆	199
Hou Pu	厚朴	245
Hu Huang Lian	胡黃連	269
Hu Ji Sheng	槲寄生	412
Hu Jiao	胡椒	302
Hu Lu Pa	胡蘆巴	402
Hu Ma Ren	胡麻仁	371
Hu Zhang	虎杖	341
Hua Jiao	花椒	416
Hua Ju Hong	化橘紅	105
Hua Shi	滑石	393
Huai Hua	槐花	380
Huai Jiao	槐角	382
Huai Mi	槐米	381
Huang Bo	黃蘗	297
Huang Jing	黃精	314
Huang Lian	黃連	120
Huang Qi	黃耆	57
Huang Qin	黃芩	365
Huang-Qin Concentrated Preparation (Granules, Powder)	黃芩濃縮製劑（顆粒、散）	429
Huo Ma Ren	火麻仁	77
Huo Xiang	藿香	13
J		
Jhih Jyu Zih	枳椇子	204
Ji Gu Cao	雞骨草	1
Ji Guan Hua	雞冠花	84
Ji Li	蒺藜	400
Ji Nei Jin	雞內金	178
Ji Xie Teng	雞血藤	386
Ji Xue Cao	積雪草	85
Jiang Huang	薑黃	132
Jiawei Siaoyao San Concentrated Preparation (Granules, Powder)	加味逍遙散濃縮製劑（顆粒、散）	435
Jie Geng	桔梗	308
Jin Qian Cao	金錢草	243
Jin Yin Hua	金銀花	237
Jin Ying Zi	金櫻子	349
Jing Jie	荊芥	270
Jing Jie Sui	荊芥穗	271
Jiu Cai Zi	韭菜子	20
Ju Hong	橘紅	111
Ju Hua	菊花	91
Ju Mai	瞿麥	146
Ju Pi	橘皮	107
Juan Bo	卷柏	367
Jue Ming Zi	決明子	81
K		
Ku Shen	苦參	379
Ku Xing Ren	苦杏仁	46
Kuan Dong Hua	款冬花	171
Kun Bu	昆布	220
L		
Lai Fu Zi	萊菔子	336
Li Zhi He	荔枝核	231
Lian Qiao	連翹	173
Lian Xu	蓮鬚	267
Lian Zi	蓮子	266
Lian Zih Sin	蓮子心	264
Liu Ji Nu	劉寄奴	51
Long Dan	龍膽	185
Lou Lu	漏蘆	343
Lu Gen	蘆根	299
Lu hui	蘆薈	20
Lu Lu Tong	路路通	230
Lu Xian Cao	鹿銜草	332
Luo Han Guo	羅漢果	375
Luo Shi Teng	絡石藤	399
M		
Ma Bian Cao	馬鞭草	408
Ma Chi Xian	馬齒莧	321
Ma Huang	麻黃	159
Ma Qian Zi	馬錢子	391
Mai Men Dong	麥門冬	278
Mai Ya	麥芽	202
Man Jing Zi	蔓荊子	413
Mang Xiao	芒硝	262

Mao Dong Ching	毛冬青	205
Mao Xu Cao	貓鬚草	281
Mei Yao	沒藥	262
Mi Meng Hua	密蒙花	74
Mo Han Lian	墨旱蓮	157
Mu Bieh Zih	木鼈子	251
Mu Dan Pi	牡丹皮	258
Mu Gua	木瓜	88
Mu Hu Dieh	木蝴蝶	280
Mu Li	牡蠣	125
Mu Tong	木通	15
Mu Xiang	木香	62
Mu Zei	木賊	162
N		
Nan Ban Lan Gen	南板藍根	391
Nan Sha Shen	南沙參	11
Nan Wu Wei Zi	南五味子	360
Niou Jhih	牛至	279
Niu Bang Zi	牛蒡子	41
Niu Huang	牛黃	72
Niu Xi	牛膝	4
Nu Zhen Zi	女貞子	226
O		
Ou Jie	藕節	266
P		
Pang Da Hai	胖大海	358
Pei Lan	佩蘭	168
Pi Pa Ye	枇杷葉	163
Pian Xu	萹蓄	315
Pu Gong Ying	蒲公英	394
Pu Huang	蒲黃	405
Q		
Qian Cao	茜草	350
Qian Hu	前胡	295
Qian Nian Jian	千年健	201
Qian Niu Zi	牽牛子	296
Qian Shi	芡實	169
Qiang Huo	羌活	274
Qiao Mai	蕎麥	170
Qin Jiao	秦艽	183
Qin Pi	秦皮	175
Qing Dai	青黛	207
Qing Hao	青蒿	48
Qing Ma Zi	苘麻子	2
Qing Pi	青皮	109
Qing Xiang Zi	青葙子	85
Quan Xie	全蠍	362
R		
Ren Dong Teng	忍冬藤	235
Ren Shen	人參	187
Rou Cong Rong	肉蓯蓉	103
Rou Dou Kou	肉豆蔻	260
Rou Gui	肉桂	97
Ru Xiang	乳香	277
Rui Ren	蕤仁	322
S		
San Ling	三稜	385
San Qi	三七	272
Sang Bai Pi	桑白皮	252
Sang Ji Sheng	桑寄生	395
Sang Piao Xiao	桑螵蛸	248
Sang Ye	桑葉	253
Sang Zhi	桑枝	254
Sha Ren	砂仁	26
Sha Yuan Ji Li	沙苑蒺藜	56
Shan Dou Gen	山豆根	383
Shan Nai	山柰	215
Shan Yao	山藥	150
Shan Yin Hua	山銀花	234
Shan Zha	山楂	125
Shan Zhu Yu	山茱萸	122
Shang Lu	商陸	300
She Chuang Zi	蛇床子	115
Shen Jin Cao	伸筋草	242
Sheng Jiang	生薑	418
Sheng Ma	升麻	96
Shi Chang Pu	石菖蒲	10
Shi Di	柿蒂	216
Shi Gao	石膏	196
Shi Hu	石斛	143
Shi Jue Ming	石決明	197
Shi Jun Zi	使君子	334

Shi Liu Pi	石榴皮	195
Shi Wei	石韋	333
Shou Wu Teng	首烏藤	338
Shui Zhi	水蛭	200
Su Mu	蘇木	357
Suan Zao Ren	酸棗仁	419
Suo Yang	鎖陽	141
T		
Tai Zi Shen	太子參	325
Tao Ren	桃仁	293
Tian Kuei Zih	天葵子	368
Tian Ma	天麻	180
Tian Men Dong	天門冬	54
Tian Nan Xing	天南星	44
Tian Zhu Huang	天竺黃	67
Ting Li Zi	葶藶子	223
Tong Cao	通草	397
Tu Fu Ling	土茯苓	377
Tu Si Zi	菟絲子	136
W		
Wang Bu Liu Xing	王不留行	407
Wei Ling Xian	威靈仙	114
Wu Bei Zi	五倍子	347
Wu Jia Pi	五加皮	3
Wu Mei	烏梅	259
Wu Wei Zi	五味子	359
Wu Yao	烏藥	229
Wu Zhu Yu	吳茱萸	167
X		
Xi Lian Cao	豨薟草	372
Xi Ming	薪蓂	397
Xi Xin	細辛	53
Xi Yang Shen	西洋參	286
Xia Ku Cao	夏枯草	322
Xian Mao	仙茅	131
Xiang Fu	香附	142
Xiang Ru	香薷	257
Xiao He Cao	仙鶴草	13
Xiao Hui Xiang	小茴香	172
Xiao Ji	小薊	100
Xiaoqinglon Tang Concentrated Preparation (Granules, Powder)	小青龍湯濃縮製劑（顆粒、散）	438
Xie Bai	薤白	19
Xie Jie	血竭	154
Xin Yi	辛夷	246
Xu Duan	續斷	151
Xuan Fu Hua	旋覆花	209
Xuan Shen	玄參	362
Y		
Yan Hu Su	延胡索	123
Yan Hu-Suo Concentrated Preparation (Granules, Powder)	延胡索濃縮製劑（顆粒、散）	425
Ye Gan	射干	210
Yi Mu Cao	益母草	222
Yi Yi Ren	薏苡仁	119
Yi Zhi	益智	24
Yin Chen	茵陳	50
Yin Yang Huo	淫羊藿	160
Yu Jin	鬱金	133
Yu Li Ren	郁李仁	324
Yu Mi Syu	玉米鬚	249
Yu Xing Cao	魚腥草	203
Yu Zhu	玉竹	313
Yuan Zhi	遠志	312
Z		
Zao Jia	皂莢	190
Zao Jiao Ci	皂角刺	192
Ze Lan	澤蘭	241
Ze Xie	澤瀉	18
Zhe Bei Mu	浙貝母	177
Zhi Ke	枳殼	104
Zhi Mu	知母	32
Zhi Shi	枳實	64
Zhi Zi	梔子	179
Zhu Ling	豬苓	316
Zhu Ru	竹茹	66
Zhu Ya Zao	豬牙皂	191
Zi Cao	紫草	47
Zi Hua Di Ding	紫花地丁	411

Zi Su Geng	紫蘇梗	289
Zi Su Ye	紫蘇葉	291
Zi Su Zi	紫蘇子	292
Zi Wan	紫菀	55

English Names

A

Abrus Herb	雞骨草	1
Acorus Rhizome	石菖蒲	10
Agaric	豬苓	316
Agastache Herb	藿香	13
Aged Tangerine Peel	陳皮	108
Ailanthus Bark	臭椿皮	14
Akebia Stem	木通	15
Alisma Rhizome	澤瀉	18
Aloes	蘆薈	20
American Ginseng	西洋參	286
Anemarrhena Rhizome	知母	32
Areca Nut	檳榔	43
Areca Nut	大腹皮	42
Argy Wormwood Leaf	艾葉	49
Arnebia Root	紫草	47
Asarum Root	細辛	53
Ash Bark	秦皮	175
Asiatic Pennywort Herb	積雪草	85
Asparagus Root	天門冬	54
Astragalus Root	黃耆	57
Atractylodes Rhizome	蒼朮	61

B

Bamboo Shavings	竹茹	66
Bansia Siexin Tang Concentrated Preparation (Granules, Powder)	半夏瀉心湯濃縮製劑（顆粒、散）	431
Banxia Xiesin Tang Concentrated Preparation (Granules, Powder)	半夏瀉心湯濃縮製劑（顆粒、散）	431
Beautiful Sweetgum Fruit	路路通	230
Belvedere Fruit	地膚子	219
Bitter Apricot Seed	苦杏仁	46
Bitter Orange	枳殼	104
Black Sesame	胡麻仁	371
Blackberry-lily Rhizome	射干	210
Blackend Swallowwort Root and Rhizome	白薇	138
Blighted Wheat	浮小麥	404
Boat Sterculia Seed	胖大海	358
Borneol	冰片	72
Buckwheat	蕎麥	170
Buerger Pipewort Flower	穀精草	165
Bupleurum Root	柴胡	75

C

Cablin Patchouli Herb	廣藿香	311
Capejasmine Fruit	梔子	179
Cassia Seed	決明子	81
Cassia Twig	桂枝	99
Cat's Mustache Herb	貓鬚草	281
Catechu	兒茶	83
Cattail Pollen	蒲黃	405
Ceylan Helminthostachys Root and Rhizome	倒地蜈蚣	200
Cherokee Rose Fruit	金櫻子	349
Chicken's Gizzard-membrane	雞內金	178
Chinese Angelica Root	當歸	37
Chinese Arborvitae Twig	側柏葉	306
Chinese Brake Herb	鳳尾草	326
Chinese Dodder Seed	菟絲子	136
Chinese Dwarf Cherry Seed	郁李仁	324
Chinese Eaglewood	沉香	40
Chinese Gall	五倍子	347
Chinese Gentian Root and Rhizome	龍膽	185
Chinese Honeylocust Abnormal Fruit	豬牙皂	191
Chinese Honeylocust Fruit	皂莢	190
Chinese Honeylocust Spine	皂角刺	192
Chinese Mosla Herb	香薷	257
Chinese Pulsatilla Root	白頭翁	331
Chinese Pyrola Herb	鹿銜草	332

Chinese Siphonostegia Herb	北劉寄奴	374
Chinese Starjasmine Stem	絡石藤	399
Chinese Taxillus Twig	桑寄生	395
Chinese Yam	山藥	150
Chingma Abutilon Seed	苘麻子	2
Chrysanthemum Flower	菊花	91
Chuanxiong Rhizome	川芎	92
Cicada Exuviae	蟬蛻	95
Cinnamon Bark	肉桂	97
Cinnamon Central Bark	桂心	98
Clam Shell	蛤殼	251
Clematis Root	威靈仙	114
Clematis Stem	川木通	113
Clove	丁香	80
Coastal Glehnia Root	北沙參	193
Cochinchina Momordica Seed	木鼈子	251
Cocklebur Fruit	蒼耳子	415
Cockscomb Flower	雞冠花	84
Coix Seed	薏苡仁	119
Coloed Mistletoe Herb	槲寄生	412
Coltsfoot Flower Bud	款冬花	171
Combined Spicebush Root	烏藥	229
Common Andrographis Herb	穿心蓮	31
Common Bletilla Tuber	白及	68
Common Burreed Rhizome	三稜	385
Common Carpesium Fruit	鶴蝨	78
Common Cephalanoplos Herb	小薊	100
Common Clubmoss Herb	伸筋草	242
Common Cnidium Fruit	蛇床子	115
Common Curculigo Rhizome	仙茅	131
Common Fenugreek Seed	胡蘆巴	402
Common Knotgrass Herb	萹蓄	315
Common Lophatherum Herb	淡竹葉	238
Common Monkshood Mother Root	川烏	9
Common Vladimiria Root	川木香	153
Coptis Rhizome	黃連	120
Cordyceps	冬蟲夏草	121
Corn Stylus	玉米鬚	249
Cornus Sarcocarp	山茱萸	122
Corydalis Tuber	延胡索	123
Corydalis Tuber Concentrated Preparation (Granules, Powder)	延胡索濃縮製劑（顆粒、散）	425
Costus Root	木香	62
Cowherb Seed	王不留行	407
Croton Seed	巴豆	128
Curcuma Root	鬱金	133
Cuttlebone	海螵蛸	370
Cyathula Root	川牛膝	137
Cyperus Rhizome	香附	142
D		
Dahurian Angelica Root	白芷	34
Dark Plum Fruit	烏梅	259
Dendrobium Stem	石斛	143
Densefruit Pittany Root-bark	白鮮皮	148
Desert-living Cistanche	肉蓯蓉	103
Dichroa Root	常山	147
Dipsacus Root	續斷	151
Diverse Wormwood Herb	劉寄奴	51
Dragon's Blood	血竭	154
Dry Ginger Rhizome	乾薑	417
Dwarf Lilyturf Root	麥門冬	278
E		
Earthworm	地龍	30
East Asian Tree Fern Rhizome	狗脊	94
Edible Kudzuvine Root	粉葛	330
Ephedra Herb	麻黃	159
Epimedium Leaf	淫羊藿	160
Eucommia Bark	杜仲	166
Euodia Fruit	吳茱萸	167
European Verbena	馬鞭草	408
Euryale Seed	芡實	169
F		
Feather Cockscomb Seed	青葙子	85
Fennel Fruit	小茴香	172

Fermented Soybean	淡豆豉	378
Figwortflower Neopicrorhiza Rhizome	胡黃連	269
Fineleaf Nepeta Herb	荊芥	270
Fineleaf Nepeta Spike	荊芥穗	271
Finger Citron	佛手柑	112
Flastem Milkvetch Seed	沙苑蒺藜	56
Fleeceflower Root	何首烏	340
Fleeceflower Stem	首烏藤	338
Floweringquince Fruit	木瓜	88
Forsythia Fruit	連翹	173
Fortune Eupatorium Herb	佩蘭	168
Fortune's Drynaria Rhizome	骨碎補	155
Fragrant Solomonseal Rhizome	玉竹	313
Frankincense	乳香	277
Fresh Ginger Rhizome	生薑	418
G		
Galangal Rhizome	高良薑	23
Gastrodia Tuber	天麻	180
Ge Gen Tang Concentrated Preparation (Granules, Powder)	葛根湯濃縮製劑（顆粒、散）	433
Germinated Barley	麥芽	202
Giant Knotweed Rhizome and Root	虎杖	341
Ginkgo Seed	白果	187
Ginseng Root	人參	187
Glandularstalk St. Paulswort Herb	豨薟草	372
Glossy Privet Fruit	女貞子	226
Golden Hair Grass	筆仔草	310
Great Burdock Achene	牛蒡子	41
Great Burnet Root	地榆	354
Green Tangerine Peel	青皮	109
Grosvenor Shiratia Fruit	羅漢果	375
Gypsum	石膏	196
H		
Hairyvein Agrimonia Herb	仙鶴草	13
Hawthorn Fruit	山楂	125
Heartleaf Houttuynia Herb	魚腥草	203
Hedysarum Root	紅耆	199
Hematite	代赭石	197
Hemp Fruit	火麻仁	77
Heterophylly Falsestarwort Root	太子參	325
Hiraute Shiny Bugleweed Herb	澤蘭	241
Hogfennel Root	前胡	295
Honeysuckle Flower Bud	金銀花	237
Hypoglaucous Collett Yam Rhizome	粉萆薢	149
I		
Immature Bitter Orange	枳實	64
India Madder Root and Rhizome	茜草	350
Indian Bread	茯苓	317
Indian Trum et Flower Seed	木蝴蝶	280
Indigowoad Leaf	大青葉	211
Indigowoad Root	北板藍根	212
Inula Flower	旋覆花	209
J		
Jackinthepulpit Tuber	天南星	44
Jaiwei Xiaoyao San Concentrated Preparation (Granules, Powder)	加味逍遙散濃縮製劑（顆粒、散）	435
Japanese Ampelopsis Root	白蘞	29
Japanese Honeysuckle Stem	忍冬藤	235
Japanese Thistle Herb or Root	大薊	101
Jiawei Siaoyao San Concentrated Preparation (Granules, Powder)	加味逍遙散濃縮製劑（顆粒、散）	435
Jujube Fruit	大棗	213
Jujube Seed	酸棗仁	419
K		
Kaempferia Rhizome	山柰	215
Kansui Root	甘遂	217
Katsumada Galangal Seed	草豆蔻	21
Kelp	昆布	220
Kirilow Rhodiola Root and	紅景天	346

Rhizome		
Kusnezoff Monkshood Root	草烏	5
L		
Ladybell Root	南沙參	11
Lalang Grass Rhizome	白茅根	206
Largeleaf Gentian Root	秦艽	183
Largetrifolious Bugbane Rhizome	升麻	96
Leech	水蛭	200
Lightyellow Sophora Root	苦參	379
Ligusticum Rhizome and Root	藁本	225
Lily Bulb	百合	228
Liquorice Root and Rhizome	甘草	193
Liquorice Root and Rhizome Concentrated Preparation (Granules, Powder)	甘草濃縮製劑（顆粒、散）	426
Lobed Kudzuvine Flower	葛花	327
Longhairy Antenoron Herb	金錢草	243
Longstamen Onion Bulb	薤白	19
Loquat Leaf	枇杷葉	163
Lotus Leaf	荷葉	263
Lotus Plumule	蓮子心	264
Lotus Rhizome Node	藕節	266
Lotus Seed	蓮子	266
Lotus Stamen	蓮鬚	267
Lychee Seed	荔枝核	231
Lygodium Spore	海金沙	243
M		
Magnolia Bark	厚朴	245
Magnolia Flower Bud	辛夷	246
Malaytea Scurfpea Fruit	補骨脂	129
Male Fern Rhizome	貫眾	156
Mantis Egg-case	桑螵蛸	248
Medicine Terminalia Fruit	訶子	89
Mirabilitum	芒硝	262
Mongolian Dandelion Herb	蒲公英	394
Morinda Root	巴戟天	256
Motherwort Fruit	茺蔚子	221
Motherwort Herb	益母草	222
Mountain Spicy Tree Fruit	菴澄茄	232
Mulberry Leaf	桑葉	253
Mulberry Root Bark	桑白皮	252
Mulberry Twig	桑枝	254
Myrrh	沒藥	262
N		
Natural Indigo	青黛	207
Notoginseng Root	三七	272
Notopterygium Rhizome and Root	羌活	274
Nutmeg Seed	肉豆蔻	260
Nux Vomica	馬錢子	391
O		
Obscured Homalomena Rhizome	千年健	201
Orange Magnoliavine Fruit	南五味子	360
Oregano	牛至	279
Oriental Bezoar	牛黃	72
Oriental Wormwood Herb	茵陳	50
Oyster Shell	牡蠣	125
P		
Pagodatree Flower and Flower Bud	槐花	380
Pagodatree Flower Bud	槐米	381
Pale Butterflybush Flower	密蒙花	74
Palmleaf Raspberry Fruit	覆盆子	350
Paper Mulberry Fruit	楮實子	73
Parslane Herb	馬齒莧	321
Patrinia Herb	敗醬	288
Peach Kernel	桃仁	293
Peony Root	白芍	283
Pepper	胡椒	302
Peppermint Herb	薄荷	249
Pepperweed Seed	葶藶子	223
Perilla Fruit	紫蘇子	292
Perilla Leaf	紫蘇葉	291
Perilla Stem	紫蘇梗	289

Persimmon Calyx and Receptacle	柿蒂	216
Pharbitis Seed	牽牛子	296
Phellodendron Bark	黃蘗	297
Philippine Violet Herb	紫花地丁	411
Pilose Asiabell Root	黨參	117
Pinellia Tuber	半夏	301
Pink Herb	瞿麥	146
Plantago Herb	車前草	303
Plantago Seed	車前子	305
Platycladi Seed	柏子仁	307
Platycodon Root	桔梗	308
Pokeberry Root	商陸	300
Polygala Root	遠志	312
Pomegranate Pericarp	石榴皮	195
Prepared Monkshood Daughter Root	附子	7
Pricklyash Peel	花椒	416
Prinsepia Space Insert Nut	蕤仁	322
Prunella Spike	夏枯草	322
Pubescent Angelica Root	獨活	35
Pubescent Holly Root and Stem	毛冬青	205
Pueraria Root	葛根	328
Puerariae Radix Concentrated Preparation (Granules, Powder)	葛根濃縮製劑（顆粒、散）	427
Pummelo Exocarp	化橘紅	105
Pyrrosia Leaf	石韋	333

R

Radish Seed	萊菔子	336
Raisin Tree Seed	枳椇子	204
Rangooncreeper Fruit	使君子	334
Red Peony Root	赤芍	284
Red Poria	赤茯苓	351
Red Sage Root and Rhizome	丹參	353
Red Tangerine Exocarp	橘紅	111
Reed Rhizome	蘆根	299
Rehmannia Root	地黃	337
Rhubarb	大黃	344
Rhubarb Concentrated Preparation (Granules, Powder)	大黃濃縮製劑（顆粒、散）	428
Rice Bean	赤小豆	410
Rice-grain Sprout	穀芽	282
Ricepaperplant Pith	通草	397
Root Poria	茯神	319
Rush Pith	燈心草	214

S

Safflower	紅花	79
Saffron Stigma	番紅花	127
Saposhnikovia Root and Rhizome	防風	356
Sappan Wood	蘇木	357
Schisandra Fruit	五味子	359
Scorpion	全蠍	362
Scouring Rush Herb	木賊	162
Scrophularia Root	玄參	362
Scutellaria Root	黃芩	365
Scutellaria Root Concentrated Preparation (Granules, Powder)	黃芩濃縮製劑（顆粒、散）	429
Sea-ear Shell	石決明	197
Semiaquilegia Root Tuber	天葵子	368
Senna Leaf	番瀉葉	369
Sharpleaf Galangal Fruit	益智	24
Siaocinglong Tang Concentrated Preparation (Granules, Powder)	小青龍湯濃縮製劑（顆粒、散）	438
Sichuan Chinaberry Fruit	川楝子	65
Silktree Albizia Bark	合歡皮	16
Silkworm Dung	蠶砂	70
Shrub Chastetree Fruit	蔓荊子	413
Skullcap Herb	半枝蓮	364
Slenderstyle Acanthopanax Root-bark	五加皮	3
Small Centipeda Herb	鵝不食草	87
Smooth Greenbrier Rhizome	土茯苓	377

Snowbell-leaf Tickclover Herb	廣金錢草	145
Solomonseal Rhizome	黃精	314
Songaria Cynomorium Herb	鎖陽	141
Sophora Fruit	槐角	382
Spirodela Herb	浮萍	387
Spreading Oldenlandia Herb	白花蛇舌草	276
Star Anise Fruit	八角茴香	39
Stemona Root	百部	388
Stephania Tetrandra Root	防己	389
Stiff Silkworm	白殭蠶	71
Strobilanthes Root	南板藍根	391
Suberect Spatholobus Stem	雞血藤	386
Sweet Wormwood Herb	青蒿	48
T		
Tabasheer	天竺黃	67
Talc	滑石	393
Tamarishoid Spikemoss Herb	卷柏	367
Tangerine Peel	橘皮	107
Tansymustard Seed	葶藶子	223
Tatarian Aster Root and Rhizome	紫菀	55
Tendrilleaf Fritillary Bulb	川貝母	176
Thlaspi Herb	葶藶	397
Thunberg Fritillary Bulb	浙貝母	177
Tokay	蛤蚧	182
Tree Peony Bark	牡丹皮	258
Tribulus Fruit	蒺藜	400
Trichosanthes Root	栝樓根	400
Trichosanthes Seed	栝樓仁	401
Tsaoko Amomum Fruit	草果	404
Tuber Onion Seed	韭菜子	20
Tuckahoe Peel	茯苓皮	320
Turmeric Rhizome	薑黃	132
Turtle Shell	鼈甲	289
Twotooth Achyranthes Root	牛膝	4
U		
Uncaria Stem with Hooks	鉤藤	406
Uniflower Swisscentaury Root	漏蘆	343
V		
Vietnamese Sophora Root	山豆根	383
Villous Amomum Fruit	砂仁	26
W		
Waxgourd Seed	冬瓜子	67
White Atractylodes Rhizome	白朮	59
White Hyacinth Bean	白扁豆	219
White Mustard Seed	白芥子	373
Whitefruit Amomim Fruit	豆蔻	28
Wild Honeysuckle Flower Bud	山銀花	234
Willowleaf Swallowwort Rhizome	白前	140
Wolfberry Fruit	枸杞子	239
Wolfberry Rootbark	地骨皮	240
X		
Xiaoqinglon Tang Concentrated Preparation (Granules, Powder)	小青龍湯濃縮製劑（顆粒、散）	438
Y		
Yerbadetajo Herb	墨旱蓮	157
Z		
Zedoaria Rhizome	莪朮	134

Latin names

A

Abrus pulchellus Wall. ex Voigt. subsp. *cantoniensis* (Hance) Verdc. 1
Abutilon theophrasti Medik. 2
Acacia catechu (L.f.) Willd. 83
Acanthopanax gracilistylus W.W.Sm 3
Achyranthes bidentata Blume 4
Aconitum carmichaelii Debeaux 7, 9
Aconitum kusnezoffii Rchb. 5
Acorus tatarinowii Schott 10
Adenophora stricta Miq. 11
Adenophora triphylla (Thunb.) A.DC. 11
Agastache rugosa (Fisch. & C.A.Mey.) Kuntze 13
Agrimonia pilosa Ledeb. 13
Ailanthus altissima (Mill.) Swingle 14
Akebia quinata (Thunb.) Decne. 15
Akebia trifoliata (Thunb.) Koidz. 15
Akebia trifoliata (Thunb.) Koidz. var. *australis* (Diels) Rehder 15
Albizia julibrissin Durazz. 16
Alisma plantago-aquatica L. subsp. *orientale* (Sam.) Sam. 18
Allium chinense G.Don 19
Allium macrostemon Bunge 19
Allium tuberosum Rottler ex Spreng. 20
Aloe ferox Mill. 20
Aloe vera (L.) Burm.f. 20
Alpinia hainanensis K.Schum 21
Alpinia officinarum Hance 23
Alpinia oxyphylla Miq. 24
Amomum compactum Soland ex Maton 28
Amomum longiligulare T.L.Wu 26
Amomum tsao-ko Crevost & Lemarié 404
Amomum villosum Lour. 26
Amomum villosum Lour. var. *xanthioides* (Wall. ex Baker) T.L.Wu & S.J.Chen 26
Ampelopsis japonica (Thunb.) Makino 29
Amynthas aspergillum (E.Perrier) 30
Amynthas pectinifera (Michaelsen) 30
Andrographis paniculata (Burm.f.) Nees 31
Anemarrhena asphodeloides Bunge 32
Angelica dahurica (Hoffm.) Benth. & Hook.f. ex Franch. & Sav. 34
Angelica dahurica (Hoffm.) Benth. & Hook.f. ex Franch. & Sav. cv. 'Hangbaizhi' 34
Angelica dahurica Benth. & Hook.f. var. *formosana* Yen 34
Angelica pubescens Maxim. f. *biserrata* R.H.Shan & C.Q.Yuan 35
Angelica sinensis (Oliv.) Diels 37
Aquilaria sinensis (Lour.) Spreng. 40
Arctium lappa L. 41
Areca catechu L. 42, 43
Arisaema amurense Maxim. 44
Arisaema erubescens (Wall.) Schott 44
Arisaema heterophyllum Blume 44
Arnebia euchroma (Royle) I.M.Johnst. 47
Arnebia guttata Bunge 47
Artemisia annua L. 48
Artemisia argyi H.Lév. & Vaniot 49
Artemisia capillaris Thunb. 50
Artemisia lactiflora Wall. ex DC. 51
Artemisia scoparia Waldst. & Kit. 50
Asarum heterotropoides F.Schmidt f. *mandshuricum* (Maxim.) Kitag. 53
Asarum sieboldii Miq. 53
Asarum sieboldii Miq. var. *seoulense* Nakai 53

Asparagus cochinchinensis (Lour.) Merr. 54
Aster tataricus L.f. 55
Astragalus complanatus R.Br.ex Bunge 56
Astragalus membranaceus (Fisch.) Bunge 57
Astragalus mongholicus Bunge 57
Atractylodes chinensis (DC.) Koidz. 61
Atractylodes lancea (Thunb.) DC. 61
Atractylodes macrocephala Koidz. 59
Aucklandia costus Falc. 62

B

Bambusa beecheyana Munro var. *pubescens* (P.F.Li) W.C.Lin 66
Bambusa textilis McClure 67
Bambusa tuldoides Munro 66
Beauveria bassiana (Bals.-Criv.) Vuill. 71
Benincasa hispida (Thunb.) Cogn. 67
Bletilla formosana (Hayata) Schltr. 68
Bletilla striata (Thunb.) Rchb.f. 68
Bombyx mori Linnaeus 70, 71
Bos taurus domesticus Gmelin 72
Boswellia carterii Birdw. 277
Broussonetia papyrifera (L.) Vent. 73
Buddleja officinalis Maxim. 74
Bupleurum chinense DC. 75
Bupleurum scorzonerifolium Willd. 75
Buthus martensii Karsch 362

C

Caesalpinia sappan L. 357
Cannabis sativa L. 77
Carpesium abrotanoides L. 78
Carthamus tinctorius L. 79
Celosia argentea L. 85
Celosia cristata L. 84
Centella asiatica (L.) Urb. 85
Centipeda minima (L.) A.Braun & Asch. 87
Chaenomeles speciosa (Sweet) Nakai 88
Chrysanthemum morifolium Ramat. 91
Cibotium barometz (L.) J.Sm. 94
Cimicifuga dahurica (Turcz.) Maxim. 96
Cimicifuga foetida L. 96
Cimicifuga heracleifolia Kom. 96
Cinnamomum camphora (L.) J.Presl 72
Cinnamomum cassia (L.) J.Presl 97, 98, 99
Cirsium arvense (L.) Scop. 100
Cirsium japonicum DC. 101
Cistanche deserticola Y.C.Ma 103
Cistanche tubulosa (Schenk) Wight 103
Citrus aurantium L. 64, 104
Citrus maxima (Burm.) Merr. 105
Citrus maxima 'Tomentosa' 105
Citrus medica L. var. *sarcodactylis* Swingle 112
Citrus reticulata Blanco 107, 108, 109, 111
Citrus sinensis (L.) Osbeck 64
Clematis armandii Franch. 113
Clematis chinensis Osbeck 114
Clematis hexapetala Pall. 114
Clematis montana Buch.-Ham. ex DC. 113
Clematis terniflora DC. var. *manshurica* (Rupr.) Ohwi 114
Cnidium monnieri (L.) Cusson 115
Codonopsis pilosula (Franch.) Nannf. 117
Codonopsis pilosula (Franch.) Nannf. var. *modesta* (Nannf.) L.T. Shen 117
Codonopsis tangshen Oliv. 117
Coix lacryma-jobi L. var. *ma-yuen* (Rom.Caill.) Stapf 119
Commiphora molmol (Engl.) Engl. ex Tschirch 262
Commiphora myrrha (T.Nees) Engl. 262
Coptis chinensis Franch. 120
Coptis deltoidea C.Y.Cheng & P.K.Hsiao 120

Coptis teeta Wall. 120
Cornus officinalis Siebold & Zucc. 122
Corydalis yanhusuo W.T.Wang 123, 425
Crassostrea gigas (Thunberg) 125
Crassostrea rivularis (Gould) 125
Crataegus pinnatifida Bunge 125
Crataegus pinnatifida Bunge var. *major* N.E.Br. 125
Crocus sativus L. 127
Croton tiglium L. 128
Cryptotympana atrata (Fabricius) 95
Cullen corylifolium (L.) Medik. 129
Curculigo orchioides Gaertn. 131
Curcuma kwangsiensis S.G.Lee & C.F.Liang 133, 134
Curcuma longa L. 132, 133
Curcuma phaeocaulis Valeton 133, 134
Curcuma wenyujin Y.H.Chen & C.Ling 133, 134
Cuscuta australis R.Br. 136
Cuscuta chinensis Lam. 136
Cyathula officinalis K.C.Kuan 137
Cyclina sinensis (Gmelin) 251
Cynanchum atratum Bunge 138
Cynanchum glaucescens (Decne.) Hand.-Mazz. 140
Cynanchum stauntonii (Decne.) Schltr. ex H.Lév. 140
Cynanchum versicolor Bunge 138
Cynomorium coccineum L. subsp. *songaricum* (Rupr.) J.Léonard 141
Cyperus rotundus L. 142

D

Daemonorops draco (Willd.) Blume 154
Dendrobium chrysanthum Wall. ex Lindl. 143
Dendrobium chrysotoxum Lindl. 143
Dendrobium fimbriatum Hook. 143
Dendrobium loddigesii Rolfe 143
Dendrobium nobile Lindl. 143
Dendrobium officinale Kimura & Migo 143
Dendrobium tosaense Makino 143
Descurainia sophia (L.) Webb ex Prantl 223
Desmodium styracifolium (Osbeck) Merr. 145
Dianthus chinensis L. 146
Dianthus superbus L. 146
Dichroa febrifuga Lour. 147
Dictamnus dasycarpus Turcz. 148
Dioscorea collettii Hook.f. var. *hypoglauca* (Palib.) S.J.Pei & C.T.Ting 149
Dioscorea doryophora Hance 150
Dioscorea japonica Thunb. 150
Dioscorea polystachya Turcz. 150
Diospyros kaki L.f. 216
Dipsacus inermis Wall. 151
Dolomiaea souliei (Franch.) C.Shih 153
Dolomiaea souliei (Franch.) C.Shih var. *cinerea* (Y.Ling) Q.Yuan 153
Drynaria roosii Nakaike 155
Dryobalanops sumatrensis (J.F.Gmel.) Kosterm. 72
Dryopteris crassirhizoma Nakai 156

E

Ecklonia kurome Okam. 220
Eclipta prostrata (L.) L. 157
Ephedra equisetina Bunge 159
Ephedra intermedia Schrenk & C.A.Mey. 159
Ephedra sinica Stapf 159
Epimedium brevicornu Maxim. 160
Epimedium koreanum Nakai 160
Epimedium pubescens Maxim. 160
Epimedium sagittatum (Siebold & Zucc.) Maxim. 160
Equisetum hyemale L. 162
Eriobotrya japonica (Thunb.) Lindl. 163

Eriocaulon buergerianum Körn. 165
Eucommia ulmoides Oliv. 166
Euodia ruticarpa (A.Juss.) Benth. 167
Euodia ruticarpa (A.Juss.) Benth. var. *bodinieri* (Dode) C.C.Huang 167
Euodia ruticarpa (A.Juss.) Benth. var. *officinalis* (Dode) C.C.Huang 167
Eupatorium fortunei Turcz. 168
Euphorbia kansui S.L.Liou ex S.B.Ho 217
Euryale ferox Salisb. 169

F

Fagopyrum esculentum Moench 170
Foeniculum vulgare Mill. 172
Forsythia suspensa (Thunb.) Vahl 173
Fraxinus chinensis Roxb. 175
Fraxinus chinensis Roxb. subsp. *rhynchophylla* A.E. Murray 175
Fraxinus stylosa Lingelsh. 175
Fritillaria cirrhosa D.Don 176
Fritillaria delavayi Franch. 176
Fritillaria przewalskii Maxim. ex Batalin 176
Fritillaria taipaiensis P.Y.Li 176
Fritillaria thunbergii Miq. 177
Fritillaria unibracteata P.K Hsiao & K.C.Hsia 176
Fritillaria unibracteata P.K.Hsiao & K.C.Hsia var. *wabuensis* (S.Y.Tang & S.C.Yueh) Z.D.Liu, Shu Wang & S.C.Chen 176

G

Gallus gallus domesticus Brisson 178
Gardenia jasminoides J.Ellis 179
Gastrodia elata Blume 180
Gekko gecko (Linnaeus) 182
Gentiana crassicaulis Duthie ex Burkill 183
Gentiana dahurica Fisch. 183
Gentiana macrophylla Pall. 183
Gentiana manshurica Kitag. 185
Gentiana rigescens Franch. 185
Gentiana scabra Bunge 185
Gentiana straminea Maxim. 183
Gentiana triflora Pall. 185
Ginkgo biloba L. 187
Gleditsia sinensis Lam. 190, 191, 192
Glehnia littoralis F.Schmidt ex Miq. 193
Glycine max (L.) Merr. 378
Glycyrrhiza glabra L. 193, 426
Glycyrrhiza inflata Batalin 193, 426
Glycyrrhiza uralensis Fisch. 193, 426

H

Haliotis asinina Linnaeus 197
Haliotis discus hannai Ino 197
Haliotis diversicolor Reeve 197
Haliotis laevigata Donovan 197
Haliotis ovina Gmelin 197
Haliotis ruber Leach 197
Hedysarum polybotrys Hand.-Mazz. 199
Helminthostachys zeylanica (L.) Hook. 200
Hierodula patellifera Serville 248
Hirudo nipponia Whitman 200
Homalomena occulta (Lour.) Schott 201
Hordeum vulgare L. 202
Houttuynia cordata Thunb. 203
Hovenia acerba Lindl. 204
Hovenia dulcis Thunb. 204
Hovenia trichocarpa Chun & Tsiang 204

I

Ilex pubescens Hook. & Arn. 205
Illicium verum Hook.f. 39
Imperata cylindrica (L.) Raeusch. 206
Inula britannica L. 209
Inula japonica Thunb. 209
Iris domestica (L.) Goldblatt & Mabb. 210
Isatis tinctoria L. 207, 211, 212

J

Juncus effusus L. 214

K

Kaempferia galanga L. 215

Kochia scoparia (L.) Schrad. 219

L

Lablab purpureus (L.) Sweet 219

Laminaria japonica Aresch. 220

Leonurus japonicus Houtt. 221, 222

Lepidium apetalum Willd. 223

Ligusticum chuanxiong Hort. 92

Ligusticum jeholense (Nakai & Kitag.) Nakai & Kitag. 225

Ligusticum sinense Oliv. 225

Ligusticum sinense Oliv. 225

Ligustrum lucidum W.T.Aiton 226

Lilium brownii F.E.Br. var. *viridulum* Baker 228

Lilium pumilum Redouté 228

Lilium lancifolium Thunb. 228

Lindera aggregata (Sims) Kosterm. 229

Liquidambar formosana Hance 230

Litchi chinensis Sonn. 231

Litsea cubeba (Lour.) Pers. 232

Lonicera hypoglauca Miq. 234

Lonicera japonica Thunb. 235, 237

Lonicera macrantha (D.Don) Spreng. 234

Lophatherum gracile Brongn. 238

Lycium barbarum L. 239, 240

Lycium chinense Mill. 239, 240

Lycopodium japonicum Thunb. 242

Lycopus lucidus Turcz. & Benth. 241

Lycopus lucidus Turcz. var. *hirtus* Regel 241

Lygodium japonicum (Thunb.) Sw. 243

Lysimachia christinae Hance 243

M

Magnolia biondii Pamp. 246

Magnolia denudata Desr. 246

Magnolia officinalis Rehder & E.H.Wilson var. *biloba* Rehder & E.H. Wilson 245

Magnolia officinalis Rehder & E.H.Wilson 245

Magnolia sprengeri Pamp. 246

Melia azedarach L. 65

Mentha canadensis L. 249

Meretrix meretrix (Linnaeus) 251

Metaphire guillelmi (Michaelsen) 30

Metaphire vulgaris (Chen) 30

Momordica cochinchinensis (Lour.) Spreng. 251

Morinda officinalis F.C.How 256

Morus alba L. 252, 253, 254

Mosla chinensis 'Jiangxiangru' 257

Mosla chinensis Maxim. 257

Myristica fragrans Houtt. 260

N

Nelumbo nucifera Gaertn. 263, 264, 266, 267

Neopicrorhiza scrophulariiflora (Pennell) D.Y.Hong 269

Nepeta tenuifolia Benth. 270, 271

Notopterygium franchetii H.Boissieu 274

Notopterygium incisum K.C.Ting ex H.T.Chang 274

O

Oldenlandia diffusa (Willd.) Roxb. 276

Ophiocordyceps sinensis (Berk.) G.H.Sung, J.M.Sung, Hywel-Jones & Spatafora 121

Ophiopogon japonicus (Thunb.) Ker Gawl 278

Origanum vulgare L. 279

Oroxylum indicum (L.) Benth. ex Kurz 280

Orthosiphon aristatus (Blume) Miq. 281

Oryza sativa L. 282

P

Paeonia lactiflora Pall. 283, 284
Paeonia suffruticosa Andrews 258
Paeonia veitchii Lynch 284
Panax ginseng C.A.Mey. 187
Panax notoginseng (Burkill) F.H.Chen 272
Panax quinquefolius L. 286
Patrinia villosa Juss. 288
Pelodiscus sinensis (Wiegmann) 289
Perilla frutescens (L.) Britton 289, 291, 292
Peucedanum praeruptorum Dunn 295
Pharbitis nil (L.) Choisy 296
Pharbitis purpurea (L.) Voigt 296
Phellodendron amurense Rupr. 297
Phellodendron chinense C.K.Schneid. 297
Phragmites australis (Cav.) Trin. ex Steud. 299
Phyllostachys nigra (Lodd.) Munro var. *henonis* (Mitford) Stapf ex Rendle 66
Phytolacca acinosa Roxb. 300
Phytolacca americana L. 300
Pinellia ternata (Thunb.) Makino 301
Piper nigrum L. 302
Plantago asiatica L. 303, 305
Plantago depressa Willd. 303, 305
Platycladus orientalis (L.) Franco 306, 307
Platycodon grandiflorus (Jacq.) A.DC. 308
Pogonatherum crinitum (Thunb.) Kunth 310
Pogostemon cablin (Blanco) Benth. 311
Polygala sibirica L. 312
Polygala tenuifolia Willd. 312
Polygonatum cyrtonema Hua 314
Polygonatum kingianum Collett & Hemsl. 314
Polygonatum odoratum (Mill.) Druce 313
Polygonatum sibiricum Redouté 314
Polygonum aviculare L. 315
Polygonum tinctorium W.T.Aiton 207
Polyporus umbellatus (Pers.) Fr. 316
Portulaca oleracea L. 321
Prinsepia uniflora Batalin 322
Prinsepia uniflora Batalin var. *serrata* Rehder 322
Prunella vulgaris L. 322
Prunus armeniaca L. 46
Prunus armeniaca L. var. *ansu* Maxim. 46
Prunus davidiana (Carrière) Franch. 293
Prunus humilis Bunge 324
Prunus japonica Thunb. 324
Prunus mandshurica (Maxim.) Koehne 46
Prunus mume (Siebold) Siebold & Zucc. 259
Prunus pedunculata (Pall.) Maxim. 324
Prunus persica (L.) Batsch 293
Prunus sibirica L. 46
Pseudostellaria heterophylla (Miq.) Pax 325
Pteris multifida Poir. 326
Pueraria montana (Lour.) Merr. var. *lobata* (Willd.) Maesen & S.M.Almeida ex Sanjappa & Predeep 327, 328, 330, 427
Pueraria montana (Lour.) Merr. var. *thomsonii* (Benth.) M.R.Almeida 327. 330
Pulsatilla chinensis (Bunge) Regel 331
Punica granatum L. 195
Pyrola decorata Andres 332
Pyrola calliantha Andres 332
Pyrrosia lingua (Thunb.) Farw. 333
Pyrrosia petiolosa (Christ) Ching 333
Pyrrosia sheareri (Baker) Ching 333

Q

Quisqualis indica L. 334

R

Raphanus sativus L. 336
Rehmannia glutinosa Libosch. 337

Reynoutria japonica Houtt. 341
Reynoutria multiflora (Thunb.) Moldenke 338, 340
Rhaponticum uniflorum (L.) DC. 343
Rheum officinale Baill. 344, 428
Rheum palmatum L. 344, 428
Rheum tanguticum Maxim. ex Balf. 344, 428
Rhodiola crenulata (Hook.f. & Thomson) H.Ohba 346
Rhus chinensis Mill. 347
Rhus potaninii Maxim. 347
Rhus punjabensis J.L.Stewart var. *sinica* (Diels) Rehder & E.H.Wilson 347
Rosa laevigata Michx. 349
Rubia cordifolia L. 350
Rubus chingii Hu 350

S

Salvia miltiorrhiza Bunge 353
Sanguisorba officinalis L. 354
Sanguisorba officinalis L.var. *longifila* (Kitag.) T.T.Yu & C.L.Li 354
Saposhnikovia divaricata (Turcz.) Schischk. 356
Scaphium affine (Mast.) Pierre 358
Schisandra chinensis (Turcz.) Baill. 359
Schisandra sphenanthera Rehder & E.H.Wilson 360
Schizostachyum chinense Rendle 67
Schlechtendalia chinensis (Bell) 347
Scrophularia ningpoensis Hemsl. 362
Scutellaria baicalensis Georgi 365, 429,
Scutellaria barbata D.Don 364
Selaginella pulvinata (Hook. & Grev.) Maxim. 367
Selaginella tamariscina (P.Beauv.) Spring 367
Semiaquilegia adoxoides (DC.) Makino 368
Senna alexandrina Mill 369
Senna obtusifolia (L.) H.S.Irwin & Barneby 81
Senna tora (L.) Roxb. 81
Sepia esculenta Hoyle 370
Sepiella inermis (Van Hasselt) 370
Sesamum indicum L. 371
Sigesbeckia glabrescens (Makino) Makino 372
Sigesbeckia orientalis L. 372
Sigesbeckia pubescens (Makino) Makino 372
Sinapis alba L. 373
Siphonostegia chinensis Benth. 374
Siraitia grosvenorii (Swingle) C.Jeffrey ex A.M.Lu & Zhi.Y.Zhang 375
Smilax glabra Roxb. 377
Sophora flavescens Aiton 379
Sophora tonkinensis Gagnep. 383
Sparganium stoloniferum (Graebn.) Buch.-Ham. ex Juz. 385
Spatholobus suberectus Dunn 386
Spirodela polyrrhiza (L.) Schleid. 387
Statilia maculata Thunberg 248
Stemona japonica (Blume) Miq. 388
Stemona sessilifolia (Miq.) Miq. 388
Stemona tuberosa Lour. 388
Stephania tetrandra S.Moore 389
Strobilanthes cusia (Nees) Kuntze 207, 391
Strychnos nux-vomica L. 391
Styphnolobium japonicum (L.) Schott 380, 381, 382
Syzygium aromaticum (L.) Merr. & L.M.Perry 80

T

Taraxacum formosanum Kitam. 394
Taraxacum mongolicum Hand.-Mazz. 394
Taxillus chinensis (DC.) Danser 395
Tenodera sinensis Saussure 248
Terminalia chebula Retz. 89

Terminalia chebula Retz. var. *tomentella* (Kurz) C.B.Clarke 89
Tetrapanax papyrifer (Hook.) K.Koch 397
Thlaspi arvense L. 397
Trachelospermum jasminoides (Lindl.) Lem. 399
Tribulus terrestris L. 400
Trichosanthes kirilowii Maxim. 400, 401
Trichosanthes rosthornii Harms 400, 401
Trigonella foenum-graecum L. 402
Triticum aestivum L. 404
Tussilago farfara L. 171
Typha angustifolia L. 405
Typha orientalis C.Presl 405

U

Uncaria gambir (W.Hunter) Roxb. 83
Uncaria hirsuta Havil. 406
Uncaria lanosa Wall. var. *appendiculata* (Benth.) Ridsale 406
Uncaria macrophylla Wall. 406
Uncaria rhynchophylla (Miq.) Miq. 406
Uncaria sinensis (Oliv.) Havil. 406

V

Vaccaria hispanica (Mill.) Rauschert 407
Verbena officinalis L. 408
Vigna umbellata (Thunb.) Ohwi & H.Ohashi 410
Viola philippica Cav. 411
Viscum coloratum (Kom.) Nakai 412
Vitex trifolia L. 413
Vitex trifolia L. subsp. *litoralis* Steenis 413

W

Whitmania acranulata (Whitman) 200
Whitmania pigra (Whitman) 200
Wolfiporia extensa (Peck) Ginns 317, 319, 320, 351

X

Xanthium sibiricum Patrin ex Widder 415

Z

Zanthoxylum bungeanum Maxim. 416
Zanthoxylum schinifolium Siebold & Zucc. 416
Zea mays L. 249
Zingiber officinale Roscoe 417, 418
Ziziphus jujuba Mill. var. *spinosa* (Bunge) Hu ex H.F.Chow 419
Ziziphus jujuba Mill. 213, 419

Title: Taiwan Herbal Pharmacopeia 4th Edition English Version
Publishing Agent: Ministry Health and Welfare, Taiwan, R.O.C.
Publisher: Jui-Yuan Hsueh
English Edition Editorial Committee
Editor in Chief：Jui-Yuan Hsueh (薛瑞元)
Deputy Editors in Chief：Chung-Liang Shih (石崇良)、Yi-Tsau Huang (黃怡超)、Yi-Chang Su (蘇奕彰)
Editors: Ching-Chiung Wang (王靜瓊)、Yu-Ling Ho (何玉鈴)、Chien-Chih Yu (余建志)、Shoei-Sheng Lee (李水盛)、Wei-Chu Li (李威著)、Jaung-Geng Lin (林昭庚)、Lie-Chwen Lin (林麗純)、I-Tsai Ma (馬逸才)、Yuan-Shiun Chang(張永勳)、Kuang-Hsiung Chang (張光雄)、Chieh-Fu Chen (陳介甫)、Chiung-Tong Chen (陳炯東)、Ih-Sheng Chen (陳益昇)、Ming-Jaw Don (董明兆)、Wei-Li Liu (劉韋利)、Shorong-Shii Liou (劉崇喜)、Tsai-Pei Hsieh (謝采蓓)、Hung-Rong Yen (顏宏融)、Chi-Fang Lo (羅吉方)。(In stroke order of Chinese last names)
Editorial Commissioner: Taiwan Herbal Pharmacopeia 4th Edition Committee
Address: No.488, Sec. 6, Zhongxiao E. Rd., Nangang Dist., Taipei City 115, Taiwan (R.O.C.)
Website: http://www.mohw.gov.tw
Tel: +886-2-8590-6666
Fax: +886-2-8590-7076
Date of Publication: December, 2022
Edition: Fourth edition, First print
Printed by: Hung Chyi Printing Co., LTD.
Tel: +886-4-23140788
Exhibition Place:
Government Publications Bookstore Sungjiang Branch
F1, No. 209, Sung Jiang Road, Taipei City 104, Taiwan, R.O.C.
Tel: (02) 2518-0207
http://www.govbooks.com.tw
Wunan Cultural Square
No. 6 Zhongshan Road, Taichung City 400, Taiwan, R.O.C.
Tel: (04) 2226-0330 ext. 821
http://www.wunanbooks.com.tw
Other type edition: Chinese version edition
Price: NTD 800

GPN: 1011101509 **ISBN:** 978-626-7137-69-7

9 786267 137697

GPN 1011101509
ISBN 9786267137697