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CERTIFICATE OF ANALYSIS

No. of Certificate: 2019/GF/R 05

No. of sample: 2019/GF/R 03 RFT reference No.: GF02/R34 - 12/2018/08/NIDQC

Sample information

Name of product (INN, brand name(s), etc.):

Lumartem *(Artemether 20mg + Lumefantrine 120mg tablets)*

Country of destination: Tanzania

Dosage form: Tablet (FDC) Strength: 20mg + 120 mg

Marketing authorization number (if applicable):

Description (appearance of container and contents): 24 tablets/ 1blister/ box

Batch number(s): ID83547 Registration number:

Required storage conditions: Store below 30°C, protected from light

Date received: 12/02/2019 Date of manufacture: 11/2018

Expiry date: 10/2021

Name and address of original manufacturer:

Telephone: Fax:

Name and address of re-packer/trader (if applicable):

Telephone: Fax:

Tests required: *Quality Control*

Test results

Test procedure (reference to test procedure)		Result (if applicable)	Acceptance criteria (limits)
1.	**Description**	Yellow, round, uncoated tablets with a break line on one side and plain on the other side	
2.	**Identification** - *Int'.P* By TLC	Conform	The principal spots obtained with test solution correspond in position and appearance with Artemether and Lumefantrine spots obtained with reference solution
	By HPLC	Conform	Retention times of two principal peaks obtained with test solution correspond to Artemether peak and Lumefantrine peak obtained with reference solution
3.	**Uniformity of mass for single dosage preparation** - *Int'.P*	Conform (min = 0.3453 g max = 0.3575 g; average= 0.3514 g)	± 5.0% of average mass.

4.	**Dissolution** - *In-house method* ***Artemether*** By HPLC	Conform (47%; 57%; 58%; 57%; 57%; 63%; 66%; 60%; 60%; 59%; 46%; 56%)	NLT 45% (Q) of the labeled amount of Artemether ($C_{16}H_{26}O_5$) is dissolved in 1 Hr
		Conform (89%; 91%; 87%; 83%; 86%; 91%)	NLT 65% (Q) of the labeled amount of Artemether ($C_{16}H_{26}O_5$) is dissolved in 3 Hrs
	Lumefantrine By HPLC	Conform (85%; 84%; 83%; 84%; 81%; 85%)	NLT 60% (Q) of the labeled amount of Lumefantrine ($C_{30}H_{32}Cl_3NO$) is dissolved in 45 mins
5.	**Related substances** - *Int'.P* By TLC Impurity A	Conform	NMT 1.5%
	Impurity B (artenimol)	Conform	NMT 1.0%
	Impurity C	Conform	NMT 0.5%
	Impurity D (α-artemether)	Conform	NMT 0.3%
	Others	Conform	NMT 0.2%
6.	**Assay** - *Int'.P* By HPLC ***Artemether***	Conform (96.5%)	NLT 90.0% and NMT 110.0% of the labeled amount of Artemether ($C_{16}H_{26}O_5$)
	Lumefantrine	Conform (98.1%)	NLT 90.0% and NMT 110.0% of the labeled amount of Lumefantrine ($C_{30}H_{32}Cl_3NO$)

Conclusions: The sample (2019/GF/R 03) complies with the International Pharmacopoeia Edition 8th and In-house specification

Compliance with acceptance criteria: Yes [X] No [ ]

Date test performed/finalized: 21/2/2019

Name and address of head of laboratory/authorized person: DOAN CAO SON - 48, Hai Ba Trung Street, Hoan Kiem District, Hanoi - Vietnam

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Hanoi, 22 February, 2019

VICE DIRECTOR

VIỆN KIỂM NGHIỆM THUỐC TRUNG ƯƠNG

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