WRS L 1-14.

A WRS B/13 [illegible]

BETA HEALTHCARE

beta healthcare international ltd
an aspen group company

mogadishu road off lunga lunga road industrial area nairobi kenya
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WORKING STANDARD CERTIFICATE OF ANALYSIS

RAW MATERIAL / WORKING STANDARD: LUMEFANTRINE Ph. Int.	QC REF NUMBER FOR RAW MATERIAL: R1801005
MANUFACTURER'S NAME: VITAL LABORATORIES PVT LTD	RAW MATERIAL BATCH NUMBER: LUM 117035
STANDARDIZATION DATE: 12 03 2018	MANUFACTURING DATE: 08 – 2017
	EXPIRY DATE: 07 - 2022
WS QUANTITY: 50G	WS NUMBER: R1801005

TEST	SPECIFICATION	RESULTS
Description	White or almost white crystalline powder	Complies
Identification	The infrared absorption spectrum obtained from the sample should be concordant to infrared absorption spectrum obtained from Lumefantrine Chemical reference Standard.	Complies
Loss on Drying/ Water	NMT 5.0mg/g	2.99mg/g
Assay	98.50 – 101.0%	99.8%

Conclusion: This material complies/ ~~does not comply~~ as per the International pharma requirements hence suitable/~~not suitable~~ for use as working standard. Shall be used for a one year period

Prepared By: Clifton Odhiambo

Quality Control Manager

Sign [signature]

Date 13/02/2018

Approved By: Dr. N. Ramaita

Quality Assurance Manager

Sign [signature]

Date 18/02/2018

NATIONAL QUALITY CONTROL LABORATORY
RECEIVED
15 MAY 2018
TEL: 2726963 / 3544525/30
FAX: 2718073
P. O. Box 29726 – 00202, NAIROBI

WRS
L1-14

A 5-13 Addnl

R1801005

A 5-13 Addnl

Vital Laboratories Pvt. Ltd

(Formerly known as Vital Health Care Pvt. Ltd)

Plant-I : Plot No.1416-21,1507,1601,1601/3 & 4,G.I.D.C. Estate, Phase III, VAPI-396 195. Dist. Valsad, Gujarat, (INDIA).Phone: +91-260-2424744-8, Fax: +91-260-2430587.

Email : vitallab@vitallab.com, Web: www.vitallab.com

CERTIFICATE OF ANALYSIS

Product	: Lumefantrine Ph. Int.			Page 1 of 1
Batch No	: LUM 117035	Mfg. Date	: AUG 2017	
A.R. No	: LUM/056/17	Exp. Date	: JUL 2022	
Batch Qty	: 750.07 Kg	Date of released	: 28/08/2017	
CAS No	: 82186-77-4			

Sr.	TEST	RESULTS	SPECIFICATION
1.	Description	A Yellow crystalline Powder.	A Yellow crystalline Powder
2.	Solubility	Complies	Practically insoluble in water-soluble in dichloromethane, slightly soluble in methanol
3.	Identity test: Test C by IR	Complies	Either tests A and B or Test C
4.	Heavy metals	Complies	Not more than 10µg/g
5.	Melting range	129°C to 131°C	128°C to 132°C
6.	Sulphated ash	0.6 mg/g	Not more than 1.0mg/g
7.	Loss on Drying	2.99 mg/g	Not more than 5mg/g
8.	Related substance (By HPLC) Impurity B Impurity C Individual impurity Total Impurities	 Not Detected Not Detected 0.03% 0.07 %	 Not more than 0.3 % Not more than 0.3 % Not more than 0.10% Not more than 0.5%
9.	Assay (By Potetiometry)	99.8 %	Not less than 98.5% and Not more than 101.0% of $C_{30}H_{32}Cl_3NO$, calculated with reference to the dried substance
10.	*Particle size by (sieve test)	93.9 % passes through 60 mesh	90 % passes through 60 mesh

Remark: The sample **Complies/ ~~Does not Comply~~** with the prescribed standard of quality as per **Ph. Int.** specification.

Generated By	Checked By	Approved By
Rajesh Maurya Sr.Officer Q.C. 28/08/2017	Haresh Singh Sr. Executive Q.C. 28/08/2017	Sanjay Gulave Manager Q. A. 28/08/2017