

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 

Date 13/02/2018

Approved By: Dr. N. Ramaita

Quality Assurance Manager

Sign 

Date 13/02/2018



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.
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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 Potentiometry)	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 Rajesh Maurya Sr. Officer Q.C.	Checked By Haresh Singh Sr. Executive Q.C.	Approved By Sanjay Gulave Manager Q. A.
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