WRS 1-14.



ANDS Surviv



beta healthcare international lid an aspen group company

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WORKING STANDARD CERTIFICATE OF ANALYSIS

				· - · · · · · · · · · · · · · · · · · ·	
RAW MATERIAL / WORKING STANDARD:		QC REF NUMBER FOR RAW MATERIAL:			
LUMEFANTRINE Ph. Int.		R1801005			
MANUFACTURER'S NAME: VITAL LABORATORIES PVT LTD		RAW MATERIAL BATCH NUMBER: LUM 117035			
EXPIRY DATE: 07 - 2022					
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 Jun

Date 13/02/2018

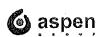
Approved By: Dr. N. Ramaita

Quality Assurance Manager

Sign

1

Date 18/02/2014













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@yitallab.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 Assay	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% Not less than 98,5% and Not
,	(By Potetiometry)	99.8 %	more than 101.0% of C ₃₀ H ₃₂ C ₃ NO, calculated with reference to the dried substance
10.	*Particle size by (sieve test)	93.9 % passes through 60 mesh	90 % passes through 60 mesh
Rem	ark: The sample Complies/ Do Int. specification.	oe s not-Comply with the prese	ribed standard of quality as per Ph.

Generated By	Checked By	Approved By	
Rajesh Maurya 1 28/08/2017	Haresh Singh つえのという	Sanjay Gulavo	
Sr.Officer Q.C.	Sr. Executive Q.C.	Manager Q. A. 28/08/201	}