HEALTHCARE

beta healthcare international ltd an aspen group company

mogadishu road off lunga lunga road industrial area nairobi kenya p.o. box 42569 00100 nairobi kenya registration number C.947 tel +254 20 6530106 fax +254 20 556 198 info@betashelys.com www.aspenpharma.com www.betacare.co.ke www.shelysafrica.com

WORKING STANDARD CERTIFICATE OF ANALYSIS

RAW MATERIAL / WOI			ER FOR RAW MATERIAL:	+
LUMEFANTRINE Ph. Int.		R1801005		
MANUFACTURER'S NAME:		RAW MATERIAL BATCH NUMBER:		
VITAL LABORATORIES PVT LTD		LUM 117035		
STANDARDIZATION DATE: 12 03 2018		MANUFACTURING DATE: 08 – 2017		
		EXPIRY DATE:	07 - 2022	
WS QUANTITY: 50G		WS NUMBER: R	1801005	*
TEST	SPECIFICATION		RESULTS	3
	<u></u>		4 19	
Description	White or almost white crystalline powder		Complies	74
Identification	The infrared absorption from the sample should		Complies	
	infrared absorption spectrum obtained from Lumefantrine Chemical reference Standard.			
Loss on Drying/ Water	NMT 5.0mg/g		2.99mg/g	et av
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

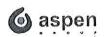
Date 13/02/2018

Approved By: Dr. N. Ramaita

Quality Assurance Manager

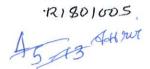
Sign

Date 18/02/2014











Laboratories Pvt. Ltd

(Formerly known as Vital Health Care Pvt. Ltd)

Plant-1: 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	1	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 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.	es-not-Gomply with the presc	ribed standard of quality as per Ph.		

Generated By	Checked By	Approved By
Rajesh Maurya 12/02/2017 Sr.Officer Q.C.	Haresh Singh 28 08 2017 Sr. Executive O.C.	Sanjay Gulave August Manager O. A. 281081201