WRS A5-13

A5-13

BETA HEALTHCARE

beta healthcare international ltd
an aspen group company

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WORKING STANDARD CERTIFICATE OF ANALYSIS

RAW MATERIAL / WORKING STANDARD: ARTEMETHER	QC REF NUMBER FOR RAW MATERIAL: R1801004
MANUFACTURER'S NAME: VITAL LABORATORIES PVT LTD	RAW MATERIAL BATCH NUMBER: ATMO 817009
STANDARDIZATION DATE: 12 03 2018	MANUFACTURING DATE: 08 - 2017
	EXPIRY DATE: 07 - 2021
WS QUANTITY: 50G	WS NUMBER: R1801004

TEST	SPECIFICATION	RESULTS
Description	White or almost white crystalline powder	Complies
Identification	As per the international Pharmacopoeia	Complies
Loss on Drying/ Water	NMT 5.0mg/g	2.5mg/g
Assay	97.0 – 102.0%	99.3%

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 13/03/2018

Approved By: Dr. N. Ramaita

Quality Assurance Manager

Sign

Date 18/03/2018

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

aspen

R1801004

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	: Artemether Int. Ph.			Page 1 of 1
Batch No	: ATMO 817009	Mfg. Date	: AUG 2017	
A.R. No	: ATMO/056/17	Exp. Date	: JUL 2021	
Batch Qty	: 226.67 Kg	Date of released	: 21/08/2017	
CAS NO	: 71963-77-4			

Sr.	TEST	RESULTS	SPECIFICATION
1.	Description	White crystalline Powder.	White crystals or a white crystalline powder.
2.	Solubility	Practically insoluble in water, Very soluble in dichloromethane and acetone, freely soluble in ethyl acetate and dehydrated ethanol.	Practically insoluble in water, Very soluble in dichloromethane and acetone, freely soluble in ethyl acetate and dehydrated ethanol
3.	Identification	Complies	As per International Pharmacopoeia.
4.	Melting Range	86°C to 89°C	86°C to 90°C
5.	Specific Optical Rotation (1% w/v solution in dehydrated Alcohol)	+171.29°	+166° to +173°
6.	Sulphated Ash	0.7 mg/g	Not more than 1.0mg/g
7.	Loss on drying	2.19 mg/g	Not more than 5.0mg/g
8.	Related substance (By HPLC) Any Single Impurity Any Other Impurity Total impurities	 0.35% 0.15% 0.50%	 Not more than 0.5 % Not more than 0.25 % Not more than 1.0 %
9.	Assay(By HPLC) on dried basis	99.3%	Not less than 97.0% and Not more than 102. 0 % on dried basis
10.	*Particle size by (sieve test)	100 % passes through 60 mesh	90 % passes through 60 mesh

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

*Inhouse

Generated By	Checked By	Approved By
Nilesh Tandel Sr. Officer Q.C. 21/08/2017	Haresh Singh 21/08/2017 Sr. Executive Q.C.	Akshay Koli Officer Q.A. 21/08/2017