

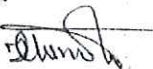
WORKING STANDARD CERTIFICATE OF ANALYSIS

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 13/03/2018



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