WRS A 5-13



beta healthcare international ltd an aspen group company

A5-13

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 / WOR ARTEMETHER	KING STANDARD:	QC REF NUME R1801004	BER FOR RAW MATERI	AL:
MANUFACTURER'S NA VITAL LABORATORIES		RAW MATERIAL BATCH NUMBER: ATMO 817009		
STANDARDIZATION DA		MANUFACTURING DATE: 08 - 2017		
BIHABIERE		EXPIRY DATE: 07 - 2021		
WS QUANTITY: 50G	*	WS NUMBER: R1801004		= 8 9
	,		14 ¥ **	
TEST	SPECIFICATION	g a	RESULTS	ilia ilia an
Description	White or almost white crystalline powder		Complies	n
Identification	As per the international Pharmacopoeia		Complies	
Loss on Drying/ Water	NMT 5.0mg/g		2.5mg/g	167
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 Dlund

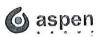
Date 13/03/2018

Approved By: Dr. N. Ramaita

Quality Assurance Manager

Sign |

Date 18/08/2018







## Laboratories Pvt. Ltd

(Formerly known as Vital Health Care Pvt. Ltd)
Plant-I: Plot No.1416-21,1507,1601,1601/3 & 4,G.l.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 201	17
A.R. No	:	ATMO/056/17	Exp. Date	1	JUL 202	ľ
Batch Qty	:	226.67 Kg	Date of released	1,	21/08/20	17
CAS NO	1	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	0.35%	Not more than 0.5 %	
	Any Other Impurity	0.15%	Not more than 0.25 %	
	Total impurities	0.50%	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	
18 8/6	*Particle size by (sieve test)	100 % passes through 60 mesh	90 % passes through 60 mesh	
	nark: The sample Compl rma./Inhouse Specificati	es/ Does-not-Comply with the prescri on.	bed standard of quality as per Int.	

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