

S Kant HEALTHCARE Ltd. 1802 - 1805, GIDC, Phase III, Vapi – 396 195 (Gujarat), India



CERTIFICATE OF ANALYSIS FOR WORKING STANDARD

Name of WS

: Artemether Ph. Int.

Batch No.

: AT-R-14060

WS Code No

: WS/14/007

Ref. Std & Lot No.: ICRS & 1.1

Mfg. Date

: Jul. 2014

Exp. Date

: Dec. 2017

Analysis Date

: 26.07.2014

Sample Qty.: 150.0 gm

Date of Preparation: 27.07.2014

Valid up to : 26.07.2016

Manufacturer

: S Kant Healthcare Ltd.

Sr.	Test	Specification	Observation
No.	a -		
1.	Appearance	White crystals or a white, crystalline powder.	A white crystalline powder.
2.	Identification: By IR	The infra red absorption spectrum is concordant with the spectrum obtained from Artemether RS.	The infra red absorption spectrum is concordant with the spectrum obtained from Artemether IC RS.
3.	Loss on Drying	Not More than: 5 mg/g.	1.4 mg/g.
4.	Assay: by HPLC	Between: 97.0 % to 102.0 % (on dried basis)	99.65 % (on as is basis) 99.8 % (on dried basis)
5.	Related substance: By HPLC 1. Single Maximum Impurity 2. Any other Impurity 3. Total Impurity	Not more than 0.50 % Not more than 0.25 % Not more than 1.00 %	0.157 % 0.106 % 0.263 %

Remarks: The above sample is complies as per the Ph. Int. and in house specification w.r.t above test only.

Prepared by:

Date:

Checked by: Bhomolon 27.07.2014 Date:

Head - Quality Control:

Date:

Name: Hemant Patil

Name: Pramod Bhandari

Name: Mahendra. P

Designation: Q.C Chemist

Designation: Q.C Executive

Designation: Manager

Reg. Head office: 3-A, Shivsagar Estate, Dr. A.B. Road, Worli, Mumbai - 400 018. India. Tel : (+91-22) 66227575, Fax : (+91-22) 66227500.

FORMAT No.: SK/QC/022-05/00

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No.	9-1	2	
1.	Арреагансе	White crystals or a white, crystalline powder.	A white crystalline powder.
2.	Identification: By IR	The infra red absorption spectrum is concordant with the spectrum obtained from Artemether RS.	The infra red absorption spectrum is concordant with the spectrum obtained from Artemether IC RS.
3.	Loss on Drying	Not More than: 5 mg/g.	1.4 mg/g.
4.	Assay: by HPLC	Between: 97.0 % to 102.0 % (on dried basis)	99.65 % (on as is basis) 99.8 % (on dried basis)
5.	Related substance : By HPLC		e n
	1. Single Maximum Impurity	Not more than 0.50 %	0.157 %
	2. Any other Impurity	Not more than 0.25 %	0.106 %
	3. Total Impurity	Not more than 1.00 %	0.263 %

Remarks: The above sample is complies as per the Ph. Int. and in house specification w.r.t above test only.

Prepared by: 107.2014 Date:

Checked by: (

B homology 27-07-2014

Head - Quality Control:

Designation: Manager

Date:

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Date: Name: Pramod Bhandari

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