

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

: Dec. 2017 Exp. Date

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.			
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.

Checked by: Bhomolon Head - Quality Control: Prepared by: 27.07.2014 Date: Date: Date: Name: Pramod Bhandari Name: Mahendra. P Name: Hemant Patil Designation: Manager Designation: Q.C Executive Designation: Q.C Chemist

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