

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



## CERTIFICATE OF ANALYSIS FOR WORKING STANDARD

Name of WS

: Lumefantrine Ph. Iut.

Batch No.

: LUM/BB/041/08/14

WS Code No

: WS/14/046

Ref. Std & Lot No.: WS/15:071013

Mfg. Date

: Aug. 2014

Exp. Date : Jul. 2017

Analysis Date

: 17.09.2014

Sample Qty. : 100.0 gm

Date of Preparation: 20.09.2014

Valid up to : 19.09.2016

Manufacturer

: Prism Industries Ltd..

Sr.	Test	Specification	Observation
No.			*
1.	Appearance	A yellow crystalline powder.	A yellow crystalline powder.
2.	Identification: By IR	The infra red absorption spectrum is concordant with the spectrum obtained from Lumefantrine WS.	The infra red absorption spectrum is concordant with the spectrum obtained from Lumefantrine WS.
3.	Loss on Drying	Not more than: 5.0 mg/ gm.	3.4 mg/gm.
4.	Related substance : By HPLC	1. Impurity B : NMT 0.30 % 2. Impurity C : NMT 0.30 % 3.Any other impurity : NMT 0.10 % 4.Total impurity : NMT 0.30 %	Not detected Not detected 0.052 %
5.	Assay: (By Potentiometrically)	Between: 98.5 % to 101.0 % (on Dried basis)	99.83 % (On such basis) 100.2 % (on dried basis)

Remarks: The above sample is complies as per ph. Int. and In-house specification w.r.t above test only.

Prepared by: (B) honolyd

Date:

20.09.2014

Checked by: Date:

Head - Quality Control:

Date:

Name: Pramod Bhandari

Name: Hitesh Gheewala

Name: Mahendra, P

Designation: Q.C Executive

Designation: Q.C Asst. Manager 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