

WRS
LI-10

Skant

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

We Serve Since 1982

CERTIFICATE OF ANALYSIS FOR WORKING STANDARD

Name of WS : Lumefantrine Ph. Int.

Batch No. : LUM/BB/041/08/14

Wh Code No : WS/14/046

Mfg. Date : Aug. 2014

Analysis Date : 17.09.2014

Date of Preparation: 20.09.2014

Manufacturer : Prism Industries Ltd.,

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

Exp. Date : Jul. 2017

Sample Qty. : 100.0 gm

Valid up to : 19.09.2016



Sr. No.	Test	Specification	Observation
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 % 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: <u>P. Bhandari</u> Date: <u>20.09.2014</u> Name: Pramod Bhandari Designation: Q.C Executive	Checked by: <u>H. Gheewala</u> Date: <u>20.09.2014</u> Name: Hitesh Gheewala Designation: Q.C Asst. Manager	Head - Quality Control : Date: <u>20.09.2014</u> Name: Mahendra. P Designation: Manager
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