

**TYPICAL CERTIFICATE OF ANALYSIS**

Product : Lumefantrine Ph. Int.	Page 1 of 1
Reference : International Pharmacopoeia	
Manufactured By : Prism Industries Pvt Ltd.	Product code : LUM
Self Life (Retest Date) : 3 years	

Sr.No.	TEST	SPECIFICATION	RESULTS
1	Description	A Yellow Crystalline powder	A Yellow Crystalline powder
2	Solubility	Practically insoluble in water; soluble in dichloromethane ; slightly soluble in methanol.	Complies
3	Identification	By IR: The infrared spectrum of the sample should be exhibits maxima at the same wavelength as that of the Lumefantrine working std.	Complies
4	Melting point.	128°C to 132°C	131.4 °C
5	Sulphated ash	Not more than 1.0 mg/gm (0.10%)	0.08 %
6	Heavy metals	Not more than 10 µg/g (10 ppm)	Less than 10 ppm
7	Loss on drying	Not more than 5.0 mg/gm (0.50%)	0.32%
8	Organic Impurities (BY TLC)		
	1) Any other Individual Impurity	Not more than 0.10%	Less than 0.10%
	2) Total impurity	Not more than 0.30%	Less than 0.30%
9	Assay By potentiometer	Not less than 98.5% and not more than 101.0%	99.87%
REMARK: The sample <u>Complies/ does not Comply with</u> the prescribed standard Spec. International Pharmacopoeia.			

	Prepared By (QC Chemist)	Checked By (QC Sr. Chemist)	Approved By (QC In charge)
Name	Nitin Solanki	Sohil Darji	Bhavesh Chauhan
Sign & Date	 10/01/25	 16/01/25	 10/01/25

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