TYPICAL CERTIFICATE OF ANALYSIS

Product	: Lumefantrine USP		Page **1** of **1**
Reference	: US 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**	Freely soluble in N,N-dimethylformamide, in chloroform, and in ethyl acetate; soluble in dichloromethane; slightly soluble in ethanol and in methanol; practically insoluble in water.	Complies
3	**Identification** **A) By IR** **B) BY HPLC**	**By IR:** The infrared spectrum of the sample should be exhibits maxima at the same wavelength as that of the Lumefantrine working std. **BY HPLC:** The retention time of the Lumefantrine peak of the sample solution corresponds to that of the standard solution, as obtained in the Assay.	Complies Complies
4	**Residue on Ignition**	NMT 0 .1 %	0.02%
5	**Clarity of Solution**	The sample solution shows the same or more clarity than water, dichloromethane, or the Standard Suspension.	Complies
6	**Organic Impurities (BY HPLC)**		
	1)Desbutyl Lumefantrine	NMT 0.05 %	ND
	2) Any other Individual Impurity	NMT 0.10 %	0.02%
	3)Total impurity	NMT 0.30 %	0.02%
7	**Assay (BY HPLC)**	NLT 98.0% and NMT 102.0%	99.80%
REMARK: The sample Complies/ ~~does not Comply~~ with the prescribed Spec USP.			

	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	10/01/25	10/01/25

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