OSCAR REMEDIES PVT. LTD
Oscar House, Badi Majra, Yamuna Nagar-135001, (HARYANA) INDIA
(AN ISO 9001:2015 & GMP CERTIFIED COMPANY)

CERTIFICATE OF ANALYSIS (FINISH PRODUCT)

Name of product	**Blucan Injection 10mg/ml**	AR No.	OR/FLI/11-24-2194
Generic name	Methylene Blue Injection USP 1.0%		
Batch no.	L2401117	Date of Analysis	03/11/2024
Mfg date	11/2024	Date of Release	18/11/2024
Exp. date	10/2027	Batch size	15000 Ampoules

S. No.	Test	Specification	Result
1.	Description	Blue colour solution filled in 10 ml sterile glass ampoule.	Complies
2.	Identification	A. The UV absorption spectra of the major peak of the Sample solution exhibit maxima and minima at the same wavelengths as those of the corresponding peak of the Standard solution , as obtained in the Assay. B. The retention time of the major peak of the Sample solution correspond to that of the Standard solution ,as obtained in the Assay.	Complies
3.	pH	Limit: 3.0 to 4.5	4.42
4.	Organic Impurities	Should be complies as per USP	Complies
5.	Average extractable fill volume	Not less than 10ml	10.1ml
6.	Uniformity of fill volume	Not less than 10ml & not more than 10.5ml	Complies
7.	Sterility	Should be sterile	Complies
8.	Bacterial Endotoxins	Not more than 2.5 USP Endotoxin Units/ ml	Less than 2.5 USP EU/ml
9.	Particulate Matter	Should be free from foreign visible particles when examine visually.	Complies
10.	Assay	Each ml contains : Methylene Blue USP 10 mg Limit (%) : 95% to 105%	9.958mg 99.58%

Remark: The sample complies / does not complies as per IP/BP/USP/IH with respect to above test.

	Analyzed by		Approved by
Designation	**QC Officer**	**Microbiologist**	**QC Manager**
Sign			
Date	18/11/2024	18/11/2024	18/11/2024

OSCAR REMEDIES PVT. LTD. QUALITY CONTROL

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