



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	AR No.	OR/FLI/10-24-2166
Generic name	Methylene Blue Injection USP 1.0%	Date of Analysis	19/10/2024
Batch no.	L2401035	Date of Release	03/11/2024
Mfg date	10/2024	Batch size	16500 Ampoules
Exp. date	09/2027		

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	4.48
4.	Organic Impurities	Should be complies as per USP	Complies
5.	Average extractable fill volume	Not less than 10ml	Complies
6.	Uniformity of fill volume	Not less than 10ml & not more than 10.9ml	10.0ml
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	03/11/2024	03/11/2024	03/11/2024

