



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/10-24-2165
Generic name	Methylene Blue Injection USP 1.0%		
Batch no.	L2401034	Date of Analysis	19/10/2024
Mfg date	10/2024	Date of Release	03/11/2024
Exp. date	09/2027	Batch size	16500 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	4.45
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%	9.967mg 99.96%

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

Designation	Analyzed by		Approved by
	QC Officer	Microbiologist	QC Manager
Sign			
Date	3/11/2024	03/11/2024	03/11/2024

