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Surajpur, Paonta sahib Dist. Sirmour (H.P)

Title	:	**Certificate of Analysis Finished Product**

Product Name	**BLUCAN** Injection	**A.R. No.**	NL/FP/26/215
Generic Name	Methylene Blue Injection USP 10ml	**Sampled qty.**	45 Ampoules
Batch No.	A26189A	**Sampled by**	Shivanand
Batch Size	10,100 Ampoules	**Sampled on**	08/09/2026
Mfg. Date	08/2026	**Date of Testing**	09/09/2026
Exp. Date	07/2028	**Date of Release**	23/09/2026

S. No.	Tests	Specifications	Observations
1.	Description	A Blue colour solution filled in amber glass ampoules.	A Blue colour solution filled in amber glass ampoules.
2.	Identification (By HPLC)	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 assay. B. the retention time of the major peak of the sample solution corresponds to that o the standard solution, as obtained in the assay.	Complies
3.	Nominal fill volume	NLT 10.0ml	10.0 ml
4.	Container Content for injection	NLT Nominal volume	10.1 ml
5.	pH	3.0 to 4.5	3.54
6.	Organic Impurities (By HPLC)		
	Azure C	NMT 0.20%	Not Detected
	Azure A	NMT 0.20%	Not Detected
	Azure B	NMT 3.0%	1.842%
	Any Unspecified Degradation Product	NMT 0.20%	0.111%
	Total degradation Product	NMT 5.0%	2.970%
7.	Limit of Azure B	NMT 3.0%	2.154%
8.	Particulate Matter		
	(A.) Microscopic Particle Count Test 1. Particles≥10µm 2. Particles≥25µm	NMT 3000/ampoule NMT 300/ampoule	3/Ampoule 0/Ampoule
	(B.) Visible particles	The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles unintentionally that can be observed on visual inspection.	Complies
9.	Sterility	No microbial growth should be observed.	Complies
10.	Bacterial Endotoxins (IHS)	NMT 2.5 EU/mg of Methylene blue.	Less than 2.5 EU/mg of Methylene Blue.
11.	Assay: (By HPLC) Each ml contains:		

Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Methylene Blue USP	10 mg	10.30125 mg	103.01%	95.0% to 110.0%

Remarks: In the opinion of the undersigned the sample referred to above is/is not of the standard quality as The Drug & Cosmetic Act 1940 and the rules made there under. Complies/not complies as per IP/BP/USP/IHS.

Analysis by 23/09/26	**Checked by** 23/09/26	**Approved by**
NAME: FIROJ KHAN	NAME: SURJEET KAUR	NAME:MRS. SWATI DHAWAN

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