

Pace

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Pace Biotech

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

Title	:	Certificate of Analysis Finished Product	
Product Name	BLUCAN Injection	A.R. No.	NL/FP/26/076
Generic Name	Methylene Blue Injection USP 10ml	Sampled qty.	45 Ampoules
Batch No.	A26058A	Sampled by	Vineet
Batch Size	9,110 Ampoules	Sampled on	29/05/2026
Mfg. Date	05/2026	Date of Testing	29/05/2026
Exp. Date	04/2028	Date of Release	12/06/2026

S. No.	Tests	Specifications	Observations		
1.	Description	A Blue colour solution filled in clear glass ampoules.	A Blue colour solution filled in clear 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	3.57		
6.	Organic Impurities (By HPLC)				
	Azure C	NMT 0.20%	0.021%		
	Azure A	NMT 0.20%	0.164%		
	Azure B	NMT 3.0%	1.827%		
	Any Unspecified Degradation Product	NMT 0.20%	0.169%		
	Total degradation Product	NMT 5.0%	4.046%		
7.	Limit of Azure B	NMT 3.0%	1.589%		
8.	Particulate Matter (A.) Microscopic Particle Count Test 1. Particles≥10µm 2. Particles≥25µm (B.) Visible particles	NMT 3000/ampoule NMT 300/ampoule The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles unintentionally that can be observed on visual inspection.	7/Ampoule 0/Ampoule 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	10.01754 mg	100.18%	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 NAME: SHAHRUKH KHAN	Checked by NAME: RAMANJEET SINGH	Qualification: M.Sc. Clinical Microbiology NAME: MRS. SWATI DHAWAN
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