Pace
Add Pace To Health

Pace Biotech

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

Title	:	Certificate of Analysis Finished Product

Product Name	**POLYCAN-B** Injection	**A.R. No.**	NB/FP/26/155
Generic Name	Polymyxin B for Injection IP 5LIU	**Sampled qty.**	45 Vials
Batch No.	N26142D	**Sampled by**	Rakesh
Batch Size	1,000Vials	**Sampled on**	09/08/2026
Mfg. Date	08/2026	**Date of Testing**	10/08/2026
Exp. Date	07/2028	**Date of Release**	26/08/2026

S. No.	Tests	Specifications	Observations
1.	Description	A white dry powder filled in amber glass vial.	A white dry powder filled in amber glass vial.
2.	Identification (By TLC)	The principal spots in the chromatogram obtained with the test solution correspond to those in the chromatogram obtained with the working standard solution.	Complies
3.	Uniformity of Weight	Average weight ±10%	-2.59% & +5.86%
4.	Average weight	Informative ±2%.	92.3 mg
5.	pH	5.0 to7.5	6.78
6.	Sulphated ash	Not more than 5.0%	2.24%
7.	Loss on drying	Not more than 7.0%	4.01%
8.	Particulate Matter (A.) Light Obscuration Particle Count Test 1.Particles ≥10 µm 2.Particles ≥25 µm (B.) Visible Particles	NMT 6000/vial NMT 600/vial The reconstituted solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be observed on visual inspection.	2,260/vial 16/vial Complies
9.	Pyrogen	Complies with test of Pyrogen.	Complies
10.	Sterility	No microbial growth should be observed.	Complies
11.	Bacterial Endotoxins	NMT 0.023EU/Units of Polymyxin B Sulphate.	Less than 0.023 EU/Units of Polymyxin B Sulphate.
12.	Assay: (By Microbiology) Each glass vial contains:		

Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Sterile Polymyxin B Sulphate IP Eq. to Polymyxin B	500000 IU	515226.42 IU	103.05%	90.0 to 120.0%

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	Checked by	Approved by
NAME: NIKHIL SHARMA 26/08/26	NAME: SURJEET KAUR 26/08/26	NAME: MRS. SWATI DHAWAN 26/08/26

Name : Mrs. Swati Dhawan
Designation : QC HOD
Qualification : M.Sc. Clinical Microbiology
Registration No. : 580408039292
Punjab Technical University, Jalandhar