

**Pace**

Add Pace To Health

**Pace Biotech**

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

Title

**Certificate of Analysis Finished Product**

<b>Product Name</b>	<b>POLYCAN B Injection</b>	<b>A.R. No.</b>	NB/FP/25/364
<b>Generic Name</b>	Polymyxin B for Injection IP 5MIU	<b>Sampled qty.</b>	45 Vials
<b>Batch No.</b>	N25390D	<b>Sampled by</b>	Anuj Verma
<b>Batch Size</b>	1000 Vials	<b>Sampled on</b>	17/02/2026
<b>Mfg. Date</b>	02/2026	<b>Date of Testing</b>	18/02/2026
<b>Exp. Date</b>	01/2028	<b>Date of Release</b>	05/03/2026

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 $\pm 10\%$	-4.46% & +3.96%
4.	Average weight	Informative $\pm 2\%$ .	99.8 mg
5.	pH	5.0 to 7.5	6.38
6.	Sulphated ash	Not more than 5.0%	2.45%
7.	Loss on drying	Not more than 7.0%	4.04%
8.	Particulate Matter (A.) Light Obscuration Particle Count Test 1. Particles $\geq 10 \mu\text{m}$ 2. Particles $\geq 25 \mu\text{m}$ (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.	119/vial 2/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	506737.2906 IU	101.35%	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/PhS.

Analysis by  
NAME: NIKHIL SHARMA

Checked by  
NAME: SURESH ANSARI

Approved by

Registration No. 133593  
Qualification: Ph.D. Clinical Microbiology