

Title

Certificate of Analysis Finished Product

Product Name	Polycan B 5L IU Injection	A.R. No.	NB/FP/25/198
Generic Name	Polymyxin B for Injection IP 500000IU/Units	Sampled qty.	45 Vials
Batch No.	N25188B	Sampled by	Anuj Verma
Batch Size	1000 Vials	Sampled on	04/09/2025
Mfg. Date	08/2025	Date of Testing	05/09/2025
Exp. Date	07/2027	Date of Release	19/09/2025

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 $\pm 10\%$	-5.91% & +6.63%
4.	Average weight	Informative $\pm 2\%$.	96.5 mg
5.	pH	5.0 to 7.5	6.03
6.	Sulphated ash	Not more than 5.0%	1.24%
7.	Loss on drying	Not more than 7.0%	1.83%
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.	539.67/vial 47.67/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
Polymyxin B Sulphate IP (Sterile) Eq. to Polymyxin B	500000 IU	503542.85 IU	100.71%	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/HS.

Analysis by NAME: NIKHIL SHARMA	Checked by NAME: SUFIYAN ANSARI	Approved NAME: MRS. SWATI DHAWAN
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