Pace
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Pace Biotech

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

Title	:	Certificate of Analysis Finished Product

Product Name	**COLISTICAN** Injection	**A.R. No.**	NB/FP/26/258
Generic Name	Colistimethate Sodium for Injection IP	**Sampled qty.**	45 Vials
Batch No.	N26254A	**Sampled by**	Vineet
Batch Size	2,000 Vials	**Sampled on**	16/10/2026
Mfg. Date	10/2026	**Date of Testing**	17/10/2026
Exp. Date	09/2028	**Date of Release**	31/10/2026

S. No.	Tests	Specifications	Observations
1.	Description	A white dry powder filled in clear glass vial.	A white dry powder filled in clear glass vial.
2.	Identification (By TLC)	**A.** The spots in the chromatogram obtained with the test solution correspond to those in the chromatogram obtained with the reference solutions (a) and (b), but shows no spots corresponding to those in the chromatograms obtained with reference solutions (c) and (d). It also shows a spot with a very low RF value (2, 4-diaminobutyric acid). **B.** A purple colour is produced (distinction from colistin Sulphate). **C.** The solution is decolorized and gives the reaction (a) of sulphates **D.** It gives the reaction (b) of sodium salts.	Complies Complies Complies Complies
3.	Uniformity of weight	Average weight ±10%	-7.40% & +5.31%
4.	Average weight	Informative ±2%.	354.8 mg
5.	Free colistin	Dissolve a quantity containing 1,000,000 IU in 3 ml of water, add 0.1 ml of a 10.0 % solution of silicotungstic acid and allow to stand for 10 to 20 seconds the solution is not more opalescence than opalescence standard OS2.	Complies
6.	pH	6.5 to 8.5	7.28
7.	Loss on drying	NMT 5.0% w/w	4.03%w/w
8.	Particulate Matter (A.) Light Obscuration Particle Count Test (1.) Particles ≥10µm (2.) Particles ≥25µm (B.) Visual Particle	 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.	 1,271/vial 9/vial Complies

Name : Mrs. Swati Dhawan
Designation : QC HOD
Qualification : M.Sc. Clinical Microbiology
Registration

Analysis by	Checked by	Approved by
NAME: NIKHIL SHARMA 31/10/26	NAME: SURJEET KAUR 31/10/26	NAME: MRS. SWATI DHAWAN 31/10/26

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9.	Sterility	No microbial growth should be observed.	Complies
10.	Bacterial Endotoxins	NMT 43.75 EU/ml of a solution containing 250,000 IU/ml of water for Injection.	Less than 43.75 EU/ml of a solution containing 250,000 IU/ml of water for Injection.
11.	Assay: (By Microbiology) Each glass vial contains:		

Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Sterile Colistimethate Sodium IP	45,00,000 IU	4602230.7 IU	102.27%	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
31/10/26	31/10/26	31/10/26
NAME: NIKHIL SHARMA	NAME: SURJEET KAUR	NAME: MRS. SWATI DHAWAN

Name : Mrs. Swati Dhawan
Designation : QC HOD
Qualification : M.Sc. Clinical Microbiology
Registration No. : 58040E039593