

Pace

Add Pace To Health

Pace Biotech

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

Certificate of Analysis Finished Product

Title	:	
Product Name	COLISTICAN Injection	A.R. No.
Generic Name	Colistimethate Sodium for Injection IP 4.5 MIU	Sampled qty.
Batch No.	N26053A	Sampled by
Batch Size	2,000 Vials	Sampled on
Mfg. Date	05/2026	Date of Testing
Exp. Date	04/2028	Date of Release

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 $\pm 10\%$	-6.92% & +7.73%
4.	Average weight	Informative $\pm 2\%$.	374.2 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	6.95
7.	Loss on drying	NMT 5.0% w/w	2.52%w/w
8.	Particulate Matter (A.) Light Obscuration Particle Count Test (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (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.	101/vial 1/vial Complies

Name : Mrs. Swati Dhawan

Designation : QC HOD

Qualification : Approved by Microbiology

Signature : MRS. SWATI DHAWAN

Punjab Technical University, Jalandhar

Analysis by
NAME: NIKHIL SHARMA

Checked by
NAME: SUFIYAN ANSARI

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Title

:

Certificate of Analysis Finished Product

Product Name	COLISTICAN Injection	A.R. No.	NB/FP/26/053
Generic Name	Colistimethate Sodium for Injection IP 4.5 MIU	Sampled qty.	45 Vials
Batch No.	N26053A	Sampled by	Rakesh
Batch Size	2,000 Vials	Sampled on	22/05/2026
Mfg. Date	05/2026	Date of Testing	23/05/2026
Exp. Date	04/2028	Date of Release	07/06/2026

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 Colistimithate Sodium IP		45,00,000 IU	4547101.289 IU	101.05%	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/HS.

Name : Mrs. Swati Dhawan

Designation : QC HOD

Qualification : B.Sc. in Microbiology

Approved by: 07/06/26

NAME: MRS. SWATI DHAWAN

Punjab Technical University, Jalandhar

Analysis by

NAME: NIKHIL SHARMA

Checked by

NAME: SUFIYAN ANSARI