

Pace

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Pace Biotech

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

Certificate of Analysis Finished Product

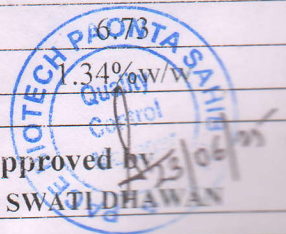
Title	:		
Product Name	COLISTICAN Injection	A.R. No.	NB/FP/25/086
Generic Name	Colistimethate Sodium for Injection IP 1 Million IU	Sampled qty.	45 Vials
Batch No.	N25090D	Sampled by	Har Gyan Singh
Batch Size	5000 Vials	Sampled on	08/06/2025
Mfg. Date	06/2025	Date of Testing	08/06/2025
Exp. Date	05/2027	Date of Release	23/06/2025

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)	<p>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).</p> <p>B. Dissolve a quantity containing 125,000IU in 5 ml of water. Heat 0.5 ml of this solution with 0.5 ml of chromotropic acid-sulphuric acid solution at 100° for 30 minutes; a purple colour is produced (distinction from colistin Sulphate).</p> <p>C. Dissolve a quantity containing 625,000 IU in 1 ml of 1 M hydrochloric acid; add 0.5 ml of 0.01 M iodine. The solution is decolorized and gives the reaction (a) of sulphates</p> <p>D. It gives the reaction of sodium salts.</p>	Complies Complies Complies Complies
3.	Uniformity of weight	Average weight $\pm 10\%$	-8.48% & +7.00%
4.	Average weight	Informative.	82.7 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.	Loss on drying	NMT - 5.0% w/w	

Analysis by 23/06/2025
NAME: NIKHIL SHARMA

Checked by 23/06/25
NAME: SUFIYAN ANSARI

Approved by 23/06/25
NAME: SWATI DHAWAN



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8.	Particulate Matter			
	(a.) Sub-Visible particle count			
	(1.) Particles $\geq 10\mu\text{m}$	NMT-6000/vial	3740/vial	
	(2.) Particles $\geq 25\mu\text{m}$	NMT-600/vial	3/vial	
	(b.) Visual	The solution is free from particles of foreign matter particles that can be observed on visual inspection.	Complies	
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	1,000,000 IU	1,001,137.85 IU	100.11%	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 23/06/2025
NAME: NIKHIL SHARMA

Checked by 29/06/25
NAME: SUFIYAN ANSARI

Approved by 23/06/25
NAME: SWATI DHAWAN

