

Title :


Certificate of Analysis Finished Product

Product Name	COLISTICAN Injection	A.R. No.	NB/FP/24/350
Generic Name	Colistimethate Sodium for Injection IP 3MIU	Sampled qty.	45 Vials
Batch No.	N24313A	Sampled by	Rakesh
Batch Size	2000 Vials	Sampled on	03/02/2025
Mfg. Date	01/2025	Date of Testing	03/02/2025
Exp. Date	12/2026	Date of Release	18/02/2025

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>	<p>Complies</p> <p>Complies</p> <p>Complies</p> <p>Complies</p>
3.	Uniformity of weight	Average weight $\pm 10\%$	-3.32% & +1.90%
4.	Average weight	Informative.	239.4 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	6.83
7.	Loss on drying	NMT - 5.0% w/w	

Analysis by 

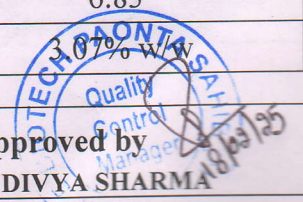
NAME: SUFIYAN ANSARI

Checked by 

NAME: SANDHYA

Approved by 

NAME: DIVYA SHARMA



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8.	Particulate Matter	NMT-6000/vial NMT-600/vial	826/vial 10/vial
	(a.) Sub-Visible particle count (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$		
	(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	30,00,000 IU	2985451.148 IU	99.52%	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/AHS.

Analysis by  NAME: SUFIYAN ANSARI	Checked by  NAME: SANDHYA	Approved by  NAME: DIVYA SHARMA 
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