



AMERICAN REMEDIES HEALTHCARE PVT. LTD.

Vill. Surajpur, Nahan Road, Paonta Sahib, Dist. Sirmour (H.P) 173025

Title

:

Certificate of Analysis Finished Product

Product Name	COLISTICAN Injection	A.R. No.	ARN/FP/25/078
Generic Name	Colistimethate Sodium for Injection IP	Sampled qty.	45 Vials
Batch No.	ARN2587A	Sampled by	Rakesh
Batch Size	7000 Vials	Sampled on	26/12/2025
Mfg. Date	12/2025	Date of Testing	27/12/2025
Exp. Date	11/2027	Date of Release	10/01/2026

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)	<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. A purple colour is produced (distinction from colistin Sulphate).</p> <p>C. The solution is decolorized and gives the reaction (a) of sulphates.</p> <p>D. It gives the reaction (b) of sodium salts.</p>	Complies Complies Complies
3.	Uniformity of weight	Average weight $\pm 10\%$	-1.91% & +2.02%
4.	Average weight	Informative $\pm 2\%$.	165.2 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 OS ₂ .	Complies
6.	pH	6.5 to 8.5	6.65
7.	Loss on drying	NMT 5.0%w/w	2.56%w/w
8.	Particulate Matter	NMT 6000/vial NMT 600/vial Reconstituted the injection vial; the solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be observed on visual inspection.	288/vial 3/vial Complies
	(A.) Light Obscuration Particle Count Test (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (B.) Visual Particle		

Analysis by

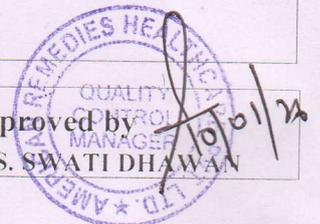
NAME: NIKHIL SHARMA

Checked by

NAME: SUFIYAN ANSARI

Approved by

NAME: MRS. SWATI DHAWAN

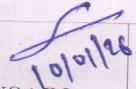


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9.	Sterility	No microbial growth should be observed.	Complies		
10.	Bacterial Endotoxins	NMT 43.75 EU/ml of a solution containing 250,000 IU/ml of water for Injection.	Less than 43.75 EU/ml of a solution containing 250,000 IU/ml of water for Injection.		
11.	Assay: (By Microbiology) Each glass vial contains:				
Ingredients		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Sterile Colistimethate Sodium IP		2,000,000 IU	2050763.21 IU	102.54%	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/HHS.

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