

Title : Certificate of Analysis Finished Product

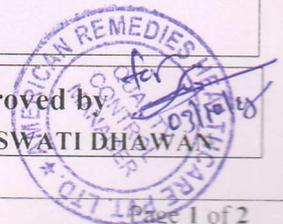
Product Name	COLISTICAN Injection	A.R. No.	ARN/FP/25/021
Generic Name	Colistimethate Sodium for Injection IP 1MIU	Sampled qty.	45 Vials
Batch No.	ARN2530A	Sampled by	Rakesh
Batch Size	5000 Vials	Sampled on	18/09/2025
Mfg. Date	09/2025	Date of Testing	18/09/2025
Exp. Date	08/2027	Date of Release	03/10/2025

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. 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>	<p>Complies</p> <p>Complies</p> <p>Complies</p> <p>Complies</p>
3.	Uniformity of weight	Average weight $\pm 10\%$	-8.81% & +3.34%
4.	Average weight	Informative $\pm 2\%$.	86.4 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 OS ₂ .	Complies
6.	pH	6.5 to 8.5	6.90
7.	Loss on drying	NMT 5.0%w/w	1.54%w/w
8.	Particulate Matter	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.	Complies
	(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	1114.00/vial 114.66/vial

Analysis by Nikhil Sharma / 03/10/2025
 NAME: NIKHIL SHARMA

Checked by Sufiyan Ansari / 03/10/25
 NAME: SUFIYAN ANSARI

Approved by Mrs. Swati Dhawan / 03/10/25
 NAME: MRS. SWATI DHAWAN



Title

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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		1,000,000 IU	1,002,352.12 IU	100.24%	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~~.

Analysis by *18/09/2025*
NAME: NIKHIL SHARMA

Checked by *18/09/2025*
NAME: SUFIYAN ANSARI

Approved by *18/09/2025*
NAME: MRS. SWATI DHAWAN

