

**AMERICAN REMEDIES HEALTHCARE PVT. LTD.**

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

**Title****Certificate of Analysis Finished Product**

<b>Product Name</b>	COLISTICAN Injection	<b>A.R. No.</b>	ARN/FP/25/077
<b>Generic Name</b>	Colistimethate Sodium for Injection IP 1 MIU	<b>Sampled qty.</b>	45 Vials
<b>Batch No.</b>	ARN2586A	<b>Sampled by</b>	Aakash
<b>Batch Size</b>	10,000 Vials	<b>Sampled on</b>	26/12/2025
<b>Mfg. Date</b>	12/2025	<b>Date of Testing</b>	26/12/2025
<b>Exp. Date</b>	11/2027	<b>Date of Release</b>	09/01/2026

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><b>A.</b> 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>B.</b> A purple colour is produced (distinction from colistin Sulphate).</p> <p><b>C.</b> The solution is decolorized and gives the reaction (a) of sulphates.</p> <p><b>D.</b> It gives the reaction (b) of sodium salts.</p>	Complies  Complies  Complies
3.	Uniformity of weight	Average weight $\pm 10\%$	-5.59% & +2.45%
4.	Average weight	Informative $\pm 2\%$ .	84.6 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 <sub>2</sub> .	Complies
6.	pH	6.5 to 8.5	7.01
7.	Loss on drying	NMT 5.0%w/w	2.55%w/w

Analysis by

NAME: NIKHIL SHARMA

Checked by

NAME: SUFIYAN ANSARI

Approved by

NAME: MRS. SWATI DHAWAN



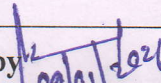
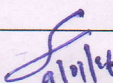
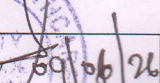
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8.	Particulate Matter			
	(A.) Light Obscuration Particle Count Test (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (B.) Visual Particle	NMT 6000/vial NMT 600/vial Reconstituted the injection vial; the solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be observed on visual inspection.	576/vial 11/vial 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 Colistimethate Sodium IP		1,000,000 IU	1012071.984 IU	101.21% 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  NAME: NIKHIL SHARMA	Checked by  NAME: SUFIYAN ANSARI	Approved by  NAME: MRS. SWATI DHAWAN
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