

Certificate of Analysis Finished Product

Title :		Certificate of Analysis Finished Product	
Product Name	COLISTICAN Injection	A.R. No.	ARN/FP/26/014
Generic Name	Colistimethate Sodium for Injection IP 1MIU	Sampled qty.	45 Vials
Batch No.	ARN2616A	Sampled by	Aakash
Batch Size	10,000 Vials	Sampled on	22/05/2026
Mfg. Date	03/2026	Date of Testing	23/05/2026
Exp. Date	04/2028	Date of Release	07/06/2026

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.	413/vial 7/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				
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		10,00,000 IU	1035500.277 IU	103.55%	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 NAME: NIKHIL SHARMA	Checked by NAME: SUFIYAN ANSARI	Approved NAME: MRS. SWATI DHAWAN
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