

**Nixi Laboratories Pvt. Ltd.**

Village Mouza Ogli, Sadhaura Road, Kala-Amb, District Sirmour -173030,
Himachal Pradesh (INDIA).

CERTIFICATE OF ANALYSIS FINISHED PRODUCTS

Product Name	COLISTICAN 3	AR. No.	NL/DI/FG/26/352
Generic Name	Colistimethate Sodium for Injection IP 3 million IU		
Mother Batch No.	D26AQ002	Reference	IP
Child Batch No.	D26AQ002A	Batch Size	1050 Vials
Mfg. Date	04/2026	Exp. Date	03/2028
Specification No. (STS No)	QC/DPI/FG/STS/007-03	Standard Test Procedure No.	QC/DPI/FG/STP/007
Sample Quantity	70 Vials	Sampling Date	11/04/2026
Release Date	29/04/2026		

Sr.No.	TEST	SPECIFICATION	OBSERVATION
1.	Description	White to off white crystalline powder filled in 10 ml tubular clear glass vial, plugged with grey rubber stopper and sealed with flip off aluminum seal.	White crystalline powder filled in 10 ml tubular clear glass vial, plugged with grey rubber stopper and sealed with flip off aluminum seal.
2.	Identification: (A) By Thin-Layer Chromatography (TLC) (B) By Chemical (C) By Chemical (Reaction (a) of Sulphates) (D) By Chemical (Reaction (b) of sodium salts)	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). A purple colour is produced. A white precipitate is formed. No precipitate is formed.	Complies Complies Complies Complies
3.	Clarity of solution	The solution is not more opalescent than opalescence standard.	Complies
4.	Constitutes of solution	The constituted injection is not significantly less clear than an equal volume of the diluent or of water for injection contained in a	Complies

	ANALYSED BY	CHECKED BY	APPROVED BY
Name	Saurav Kumar	Ganesh Jaiswal	Aditya Singh
Designation	Chemist QC	Sr.Executive QC	Asst. Manager QC
Signature			
Date	29/04/26	29/04/26	29/04/26



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		similar container and examined in the same manner. The reconstitutes time is 180 seconds maximum.	
5.	Average filled weight	Filled weight $\pm 5.0\%$	244.70 mg
6.	Uniformity of filled weight	Average filled weight $\pm 5.0\%$	-2.86 % to +3.64%
7.	pH (At $25^{\circ}\text{C} \pm 2^{\circ}\text{C}$)	6.5 to 8.5	7.35
8.	Free Colistin	The solution is not more opalescent than opalescence standard.	Complies
9.	Particulate matter		
	Visible Particles:	Should be free from visible particles	Complies
	For sub visible particles: Equal to or greater than $10\mu\text{m}$ Equal to or greater than $25\mu\text{m}$	NMT 6000 particles/container NMT 600 particles/container	816.0particles/container 5.0particles/container
10.	Sterility	Should comply the test of sterility	Complies
11.	Bacterial Endotoxin	NMT 43.75 EU/ml of a solution containing 250000 IU/ml in Water for Injection.	Complies
12.	Loss on Drying (At $60^{\circ}\text{C}, 0.7\text{KPa}$ for 3 hours)	NMT 5.0 %	1.50%

13.	Assay:
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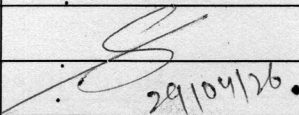
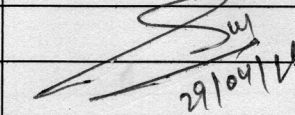
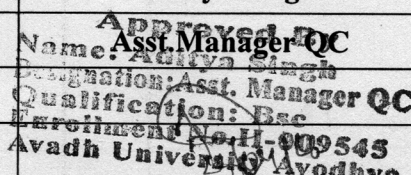
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Sr.No.	TEST	SPECIFICATION	OBSERVATION
	Each Vial contains: ColistimethateSodium IP 3000000 IU (As Sterile.Lyophilized Powder)	2700000 IU to 3600000 IU (90.0% to 120.0%)	2997900.00 IU (99.93%)

RESULT: The above sample ~~COMPLIES/DOES NOT COMPLY~~ as per Specification No- QC/DPI/FG/STS/007-03.

CONCLUSION: In the opinion of the under signed the sample referred above is of **STANDARD QUALITY** / ~~IS NOT STANDARD QUALITY~~ as defined in the Drugs & Cosmetics Act, 1940 and the rules made here under further.

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