



VELLINTON HEALTHCARE

(Earlier Known as Texus Meditech)

Village Rampur Jattan, Trilokpur Road, Kala Amb, Dist. Sirmour-173030. HP

QUALITY CONTROL DEPARTMENT CERTIFICATE OF ANALYSIS

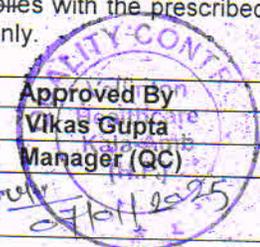
Product Name : Colistican Colistimethate Sodium for injection IP	
Batch No. : GD24L-43D	Mfg. Date : 12/2024
Batch Size : 310 Vials	Exp. Date : 11/2026
Sample Qty. : 50 Vials	Analytical Report No.: GFP20240359
Date of Receiving : 24/12/2024	Date of Completion : 07/01/2025
Mfg. License No. : N-MB/18/201	

S. No.	Tests	Specifications	Observations
1.	Description	A white or almost white powder; hygroscopic filled in transparent glass vial.	A white powder; hygroscopic filled in transparent glass vial.
2.	Identification		
	A (By TLC)	The spot in the chromatogram obtained with the test solution corresponds to those in the chromatogram obtained with reference solution (a) and (b). It also shows a spot with a very low Rf value (2,4-diaminobutyric acid)	Complies
	B (By chemically)	A purple colour is produced	Complies
	C (By chemically)	It gives reaction a of sulphates	Complies
	D (By sodium test)	A dense white precipitate is produced	Complies
3.	Uniformity of weight	± 10.0 % of the average fill weight	Complies
4.	Average fill Weight	159.59 mg ± 2.0 %	159.20 mg
5.	pH	Between (6.5 to 8.50)	7.67
6.	Free colistin	The solution is not more opalescent than opalescent standard OS2.	Complies
7.	Clarity of solution	The solid dissolves completely leaving no visible residue as undissolved matter.	Complies
8.	Particulate matter	Constitute the injection as directed on the label: the solution is essentially free from particles of foreign matter that can be seen on visual inspection.	Complies
9.	Loss on drying	NMT 5.0%	2.45 %
10.	Sterility	Should be sterile	Sterile
11.	Bacterial Endotoxins	NMT 43.75 EU/ml of a solution containing 250000 IU per ml in water for injection.	Less than 43.75 EU/ml
12.	Assay : Each vial contains:		

Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Colistimethate Sodium (Sterile) IP.	2.0 MIU	1.979 MIU	98.95 %	90.0 to 120%

Remarks: In the opinion of the undersigned the sample submitted complies/~~does not complies~~ with the prescribed standard/~~not standard of quality~~, as according to I.P. and IHS with respect to the above test only.

Name	Prepared By	Checked By	Approved By
	Punam Kumari	Anuj Kumar	Vikas Gupta
Designation	Executive	Sr. Executive	Manager (QC)
Sign/ Date			



Format No.: VH/SOP/QC-062/FT01-01