



# VELLINTON HEALTHCARE

(Earlier Known as Texus Meditech)

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

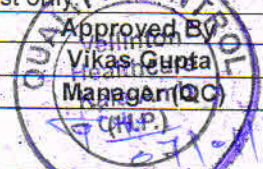
## QUALITY CONTROL DEPARTMENT CERTIFICATE OF ANALYSIS

<b>Product Name : COLISTICAN</b> Colistimethate Sodium for injection IP	
<b>Batch No. : GD24L-41F</b>	<b>Mfg. Date : 12/2024</b>
<b>Batch Size : 5020 Vials</b>	<b>Exp. Date : 11/2026</b>
<b>Sample Qty. : 50 Vials</b>	<b>Analytical Report No.: GFP20240357</b>
<b>Date of Receiving : 24/12/2024</b>	<b>Date of Completion : 07/01/2025</b>
<b>Mfg. License No. : N-MB/18/201</b>	

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	79.80 mg ± 2.0 %	79.40 mg
5.	pH	Between (6.5 to 8.50)	8.23
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%	3.01 %
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.	1.0 MIU	0.95167 MIU	95.17 %	90.0 to 120%

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

<b>Name</b>	<b>Prepared By</b> Punam Kumari	<b>Checked By</b> Anuj Kumar	
<b>Designation</b>	<b>Executive</b>	<b>Sr. Executive</b>	
<b>Sign/ Date</b>	<i>[Signature]</i> 07/01/2025	<i>[Signature]</i> 07/01/2025	

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