



VELLINTON HEALTHCARE

(Earlier Known as Texus Meditech)

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

QUALITY CONTROL DEPARTMENT

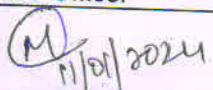
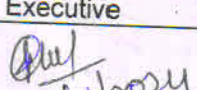
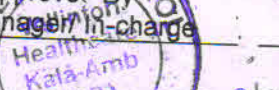
CERTIFICATE OF ANALYSIS

Product Name : POLYCAN B 5L IU Polymyxin B for injection USP	
Batch No. : GD23L-16B	Mfg. Date : 12/2023
Batch Size : 1056 Vials	Exp. Date : 11/2025
Sample Qty. : 50 Vials	Analytical Report No.: GFP20230282
Date of Receiving : 19/12/2023	Date of Completion : 11/01/2024
Mfg. License No. : N-MB/18/201	

S. No.	Tests	Specifications	Observations
1.	Description	A white or almost white crystalline powder filled in transparent glass vial.	A white crystalline powder filled in transparent glass vial.
2.	Identification (By TLC)	Should be complies with USP	Complies
3.	Uniformity of weight	± 10.0 % of the average fill weight	Complies
4.	Average fill Weight	80.43 mg	80.39 mg
5.	pH	5.0 to 7.50 (Determined on 5mg/ml solution)	6.55
6.	Clarity of solution	The solid dissolves completely leaving no visible residue as undissolved matter.	Complies
7.	Particulate Matter	The solution is essentially free from particles of foreign matter that can be seen on visual inspection.	Complies
8.	Sterility	Should be Sterile	Sterile
9.	Residue on ignition	NMT 5.0 % (Determine on 1.0g)	1.56 %
10.	Loss on drying	NMT 7.0% (Determined on 100 mg under vacuum at 60° for 3 hours.	3.52 %
11.	Assay : Each vial contains:-		

Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Polymyxin B Sulphate (Sterile)USP Eq. to Polymyxin B.	500000 IU	549894.47 IU	109.98 %	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 USP & IHS with respect to the above test only.

Analyzed By QC Officer	Checked By QC Executive	Approved By QC Manager in-charge
Signature:- 	Signature:- 	Signature:- 
Date:- 11/01/2024	Date:- 11/01/2024	Date:- 11/01/2024

Format No.: VH/SOP/QC-062/FT01-00

