



# 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</b> : Polycan B Polymyxin B Sulphate for injection USP 500000 IU	
<b>Batch No.</b> : GD24E-21D	<b>Mfg. Date</b> : 05/2024
<b>Batch Size</b> : 1101 Vials	<b>Exp. Date</b> : 04/2026
<b>Sample Qty.</b> : 50 Vials	<b>Analytical Report No.:</b> GFP20240131
<b>Date of Receiving</b> : 18/05/2024	<b>Date of Completion</b> : 01/06/2024
<b>Mfg. License No.</b> : 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	81.45 mg	81.50 mg		
5.	pH	5.0 to 7.50 (Determined on 5mg/ml solution)	6.52		
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)	2.13 %		
10	Loss on drying	NMT 7.0% (Determined on 100 mg under vacuum at 60° for 3 hours.	4.49 %		
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	554673.58 IU	110.93 %	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	QC Manager/ In-charge
Signature:- 	Signature:- 	Signature:- 
Date:- 01/06/2024	Date:- 01/06/2024	Date:- 01/06/2024

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

