



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 Sulphate for injection USP | |
| Batch No. : GD24J-17A | Mfg. Date : 09/2024 |
| Batch Size : 1038 Vials | Exp. Date : 08/2026 |
| Sample Qty. : 50 Vials | Analytical Report No.: GFP20240297 |
| Date of Receiving : 17/10/2024 | Date of Completion : 04/11/2024 |
| 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 | 78.68 mg ± 2% | 77.96 mg | | |
| 5. | pH | 5.0 to 7.50 (Determined on 5mg/ml solution) | 6.04 | | |
| 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) | 4.62 % | | |
| 10. | Loss on drying | NMT 7.0% (Determined on 100 mg under vacuum at 60° for 3 hours. | 5.49 % | | |
| 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 | 534754.65 IU | 106.95 % | 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 USP & IHS with respect to the above test only.

| Analyzed By QC Officer | Checked By QC Executive | Approved By QC Manager/ In-charge |
|---|---|---|
| Signature:- Date:- <i>A. D. 17/10/2024</i> | Signature:- Date:- <i>D. W. 04/11/2024</i> | Signature:- Date:- <i>[Signature] 04/11/2024</i> |

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