

Title

:

Certificate of Analysis Finished Product

| | | | |
|--------------|---|-----------------|--------------|
| Product Name | VANCAN 1000 Injection | A.R. No. | NB/FP/24/355 |
| Generic Name | Vancomycin Hydrochloride for Injection IP 1gm | Sampled qty. | 45 Vials |
| Batch No. | N24327A | Sampled by | Rakesh |
| Batch Size | 5000 Vials | Sampled on | 06/02/2025 |
| Mfg. Date | 02/2025 | Date of Testing | 06/02/2025 |
| Exp. Date | 01/2027 | Date of Release | 21/02/2025 |

| S. No. | Tests | Specifications | Observations |
|--------|----------------------------------|---|--|
| 1. | Description | A white dry powder filled in clear glass vial. | A white dry powder filled in clear glass vial. |
| 2. | Identification | <p>A. In the test for Vancomycin B, the retention time of the principle peak in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with reference solution.</p> <p>B. It gives reaction (A) of chloride.</p> | Complies |
| 3. | Appearance of solution | A 10%w/v solution of Vancomycin hydrochloride is clear and the absorbance of the solution at 450 nm is not more than 0.1. | Complies |
| 4. | Uniformity of weight | Average weight \pm 10 % | -1.91% & +2.22% |
| 5. | Average weight | Informative. | 1089.6 mg |
| 6. | pH | 2.5 to 4.5 (5%w/v solution of Vancomycin HCl). | 2.78 |
| 7. | Vancomycin B | NLT- 88.0% | 98.26% |
| 8. | Related substances (By HPLC) | | |
| | Any secondary peak | NMT- 4.0% | 0.52% |
| | Sum of all secondary peaks | NMT- 12.0% | 1.74% |
| 9. | Water | NMT- 5% w/w | 2.20%w/w |
| 10. | Particulate Matter | | |
| | (a.) Sub-Visible particle count | | |
| | (1.) Particles \geq 10 μ m | NMT-6000/vial | 177/vial |
| | (2.) Particles \geq 25 μ m | NMT-600/vial | 1/vial |
| | (b.) Visual | 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 |

Analysis by

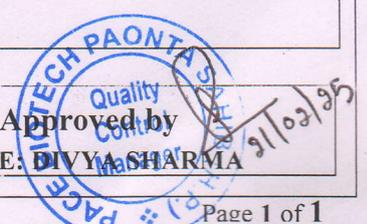
NAME: SUFIYAN ANSARI

Checked by

NAME: SANDHYA

Approved by

NAME: DIVYA SHARMA



Pace

Add Pace To Health

Pace Biotech

Surajpur, Paonta sahib Dist. Sirmour (H.P)

Title

:

Certificate of Analysis Finished Product

| | | | |
|--------------|---|-----------------|--------------|
| Product Name | VANCAN 1000 Injection | A.R. No. | NB/FP/24/355 |
| Generic Name | Vancomycin Hydrochloride for Injection IP 1gm | Sampled qty. | 45 Vials |
| Batch No. | N24327A | Sampled by | Rakesh |
| Batch Size | 5000 Vials | Sampled on | 06/02/2025 |
| Mfg. Date | 02/2025 | Date of Testing | 06/02/2025 |
| Exp. Date | 01/2027 | Date of Release | 21/02/2025 |

| | | | | | |
|--|--|---|-------------------------------------|---------------------|----------------------------|
| 11. | Sterility | No microbial growth should be observed. | Complies | | |
| 12. | Bacterial Endotoxins | NMT- 2.5 EU/ml of Vancomycin. | Less than- 2.5 EU/ml of Vancomycin. | | |
| 13. | Assay: (By Microbiology) Each glass vial Contains : | | | | |
| Ingredients | | Labeled Claim | Found | % of labeled amount | Limits % of labeled amount |
| Vancomycin Hydrochloride (Sterile) IP Eq. to Vancomycin (As sterile freeze dried powder) | | 1000 mg | 1006.507 mg | 100.65% | 90.0% to 115.0% |

Remarks: In the opinion of the undersigned the sample referred to above is/ ~~is not~~ of the standard quality as The Drug & Cosmetic Act 1940 and the rules made there under. Complies/ ~~not complies~~ as per IP/BP/USP/HHS. →

| | | |
|-------------------------------------|-----------------------------|-----------------------------------|
| Analysis by NAME: SUFIYAN ANSARI | Checked by NAME: SANDHYA | Approved by NAME: DIVYA SHARMA |
|-------------------------------------|-----------------------------|-----------------------------------|

