

Title

:

Certificate of Analysis Finished Product

| | | | |
|----------------------|--|------------------------|--------------|
| 3Product Name | OCTREOCAN 100mcg Injection | A.R. No. | NL/FP/24/419 |
| Generic Name | Octreotide Acetate Injection 100mcg/ml | Sampled qty. | 60 Ampoules |
| Batch No. | A24306C | Sampled by | Boby Kumar |
| Batch Size | 10,080 Ampoules | Sampled on | 28/11/2024 |
| Mfg. Date | 11/2024 | Date of Testing | 28/11/2024 |
| Exp. Date | 10/2026 | Date of Release | 13/12/2024 |

| S. No. | Tests | Specifications | Observations |
|--------|-------------------------------------|--|---|
| 1. | Description | A clear colourless solution filled in clear colour glass ampoule. | A clear colourless solution filled in clear colour glass ampoule. |
| 2. | Identification (By HPLC) | In the Assay, the principal peak in the chromatogram obtained with The test solution corresponds to the peak in the chromatogram obtained with the reference solution. | Complies |
| 3. | Nominal fill volume | NLT-1 ml | 1.0 ml |
| 4. | Extractable Volume | NLT Nominal volume or NMT 110% of Nominal volume. | 1.1 ml |
| 5. | pH | 3.0 to 5.0 | 4.15 |
| 6. | Particulate Matter | | |
| | (a.) Sub-Visible particle count | | |
| | (1.) Particles $\geq 10\mu\text{m}$ | NMT-6000/Ampoule | 30/Ampoule |
| | (2.) Particles $\geq 25\mu\text{m}$ | NMT-600/Ampoule | 1/Ampoule |
| | (b.) Visual | The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally. | Complies |
| 7. | Sterility | No microbial growth should be observed. | Complies |
| 8. | Bacterial Endotoxins | NMT- 0.004 EU/mcg of Octreotide Acetate. | Less than- 0.004 EU/mcg of Octreotide Acetate. |
| 9. | Assay: Each ml contains | | |

| Ingredients | Labeled Claim | Found | % of labeled amount | Limits % of labeled amount |
|--------------------|---------------|------------|---------------------|----------------------------|
| Octreotide Acetate | 100 mcg | 102.44 mcg | 102.44% | 90.0% to 110.0% |

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/IHS.

| | | |
|------------------------------|------------------------------------|-------------------------------------|
| Analysis By NAME: SANDHYA | Checked by NAME: SUFIYAN ANSARI | Approved by NAME: P. N. TRIPATHI |
|------------------------------|------------------------------------|-------------------------------------|

