



VELLINTON HEALTHCARE

Village Rampur Jattan, Trilokpur Road, Kala Amb, Dist. Sirmour.

QUALITY CONTROL DEPARTMENT CERTIFICATE OF ANALYSIS

| | |
|--|---|
| Product Name : NALOPID Naloxone Injection IP | |
| Batch No. : GA25L-46A | Mfg. Date : 12/2025 |
| Batch Size : 49950 Ampoules | Exp. Date : 11/2027 |
| Sample Qty. : 75 Ampoules | Analytical Report No.: AFP20250761 |
| Date of Receiving : 21/12/2025 | Date of Completion : 05/01/2026 |
| Mfg. Lic. No. : N-MB/18/201 | |

| S. No. | Tests | Specifications | Observations |
|--------|-----------------------------|---|--|
| 1. | Description | A clear colourless liquid solution filled in 1 ml amber glass ampoule. | Clear colourless liquid solution filled in 1 ml amber glass ampoule. |
| 2. | Identification | | |
| | A. 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 |
| | B. By TLC | The principal spot in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with the reference solution. | Complies |
| 3. | Uniformity of filled volume | Not less than nominal volume | Min: 1.0 ml Max: 1.1 ml |
| 4. | Average fill volume | Not less than 1 ml | 1.03 ml |
| 5. | pH | Between (3.0 to 4.50) | 4.45 |
| 6. | Particulate Matter | | |
| | ≥ 10µm | NMT 6000 particles/Ampoule | Less than 6000 particles/ Ampoule |
| | ≥ 25µm | NMT 600 particles/Ampoule | Less than 6000 particles/ Ampoule |
| 7. | Related substances | Any secondary spot in the chromatogram obtained with the test solution is not more intense than the spot in the chromatogram obtained with the reference solution (0.5%). | Complies |
| 8. | Bacterial Endotoxins | NMT 70 Eu/mg | Less than 70 Eu/mg |
| 9. | Sterility | Should be Sterile | Sterile |
| 10. | Assay : Each ml contains:- | | |

| Composition: | Labeled Claim | Found | % of labeled amount | Limits % of labeled amount |
|--|---------------|-----------|---------------------|----------------------------|
| Naloxone Hydrochloride IP Eq. to anhydrous Naloxone Hydrochloride | 400 mg | 400.96 mg | 100.24 % | 95.0% to 105 % |

Remarks: In the opinion of the undersigned the sample submitted complies/does not comply with the prescribed standard/not standard of quality, as according to IP and IHS with respect to the above test only.

| | Prepared By | Checked By | Approved By |
|-------------|------------------|--------------------|----------------|
| Name | Manisha | Anuj Kumar | Yashwant Singh |
| Designation | Sr. Officer (QC) | Asst. Manager (QC) | Head QC |
| Sign/ Date | | | |

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