



VELLINTON HEALTHCARE

(Earlier Known as Texus Meditech)

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

QUALITY CONTROL DEPARTMENT CERTIFICATE OF ANALYSIS

| | |
|---|---|
| Product Name : FLUZICAN 25 Fluphenazine Decanoate Injection IP. | |
| Batch No. : A25B-07B | Mfg. Date : 02/2025 |
| Batch Size : 25000 Ampoules | Exp. Date : 01/2027 |
| Sample Qty. : 75 Ampoules | Analytical Report No.: MFP20250019 |
| Date of Receiving : 22/02/2025 | Date of Completion : 08/03/2025 |
| Mfg. License No. : N-MB/18/201 | |

| S. No. | Tests | Specifications | Observations | |
|---------------------------|---|--|---|----------------------------|
| 1. | Description | A light yellowish colour liquid solution filled in 1 ml amber colour glass ampoule. | A light yellowish colour liquid solution filled in 1 ml amber colour glass ampoule. | |
| 2. | Identification | | | |
| | Test A 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 | |
| | B (By Chemically) | A red colour is produced in the acid layer. | 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 | 1.05 ml | |
| 5. | Related substances | | | |
| | Fluphenazine impurity | NMT 4.0% | Not detected | |
| | Area of any secondary peak | NMT 1.0% | Not detected | |
| | Sum of area of all secondary peak excluding Fluphenazine impurity | NMT 2.0 % | Not detected | |
| 6. | Particulate matter | | | |
| | ≥ 10µm | NMT 6000 particles/Ampoule | Less than 6000 particles/Ampoule | |
| | ≥ 25µm | NMT 600 particles/Ampoule | Less than 600 particles/Ampoule | |
| 7. | Sterility | Should be Sterile | Sterile | |
| 8. | Bacterial endotoxins | NMT 0.5 EU/mg | Less than 0.5 EU/mg | |
| 9. | Assay : Each ml contains:- | | | |
| Composition: | Labeled Claim | Found | % of labeled amount | Limits % of labeled amount |
| Fluphenazine Decanoate IP | 25.0 mg | 24.42 mg | 97.68 % | 90.0% to 110% |

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

| Name | Prepared By | Checked By | Approved By |
|-------------|--------------|---------------|--------------|
| | Punam Kumari | Anuj Kumar | Vikas Gupta |
| Designation | Executive | Sr. Executive | Manager (QC) |
| Sign/ Date | | | |

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