



**Kwality Pharmaceuticals Limited**  
**Address: Nag Kalan, Majitha Road, Amritsar - 143601 (India)**  
**Finished Product Certificate of Analysis**

|                       |                                             |                         |                         |
|-----------------------|---------------------------------------------|-------------------------|-------------------------|
| Generic Name          | Fluphenazine Decanoate Injection IP 25mg/ml | Analytical Report No.   | KPL1/QC/AR/FP/2026/1259 |
| Product Name          | FLUZICAN 25 INJECTION                       | Reference Pharmacopoeia | IP                      |
| Batch No.             | GN7887                                      | Batch Size              | 15000 AMPOULES          |
| Mfg. Date             | 02/2026                                     | Exp. Date               | 01/2028                 |
| Sample Received on    | 15/03/2026                                  | Specification No        | KPL1/SLS/QC/112/1311    |
| Analysis Initiated on | 17/03/2026                                  | Date of Release         | 28/04/2026              |

**Analytical Data**

**Packing Presentation:** AMBER GLASS AMPOULE HAVING WHITE RING ON NECK WITH PAPER LABEL AND SEALED.

| S.No. | Tests                                           |                           | Specifications                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Observations                                                                                                      |          |        |
|-------|-------------------------------------------------|---------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------|----------|--------|
| 1     | Description                                     |                           | Yellow color oily solution filled in amber glass ampoule having white ring on neck with paper label and sealed.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Yellow colored oily solution filled in amber glass ampoule having white ring on neck with paper label and sealed. |          |        |
| 2     | Identification.                                 |                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                   |          |        |
|       | A                                               | Thin layer chromatography | The principal spot in the chromatogram obtained with the injection corresponds to that in the chromatogram obtained with the reference substance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Identified                                                                                                        |          |        |
|       | B                                               | Color test                | A red colour is produced in the acid layer.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Identified                                                                                                        |          |        |
| 3     | Average fill volume                             |                           | Not less than 1 ml                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 1.0 ml                                                                                                            |          |        |
| 4     | Related substance                               |                           | The area of peak corresponding to fluphenazine impurity in the chromatogram obtained with reference solution (b) is not more than 4 times the area of the peak in the chromatogram obtained with reference solution (a) (4.0 percent)<br>The area of any other secondary peak is not more than the area of the principal peak in the chromatogram obtained with reference solution (a) (1.0 percent)<br>The sum of the areas of all the any secondary peaks excluding the peak of fluphenazine impurity is not more than twice the area of the principal peak in the chromatogram obtained with reference solution (a) (2.0 percent) | Not detected<br><br>Not detected<br><br>Not detected                                                              |          |        |
| 5     | Particulate matter test                         |                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                   |          |        |
|       | A                                               | >= 10 µm                  | Not more than 3000 particles / container                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 39                                                                                                                |          |        |
|       | B                                               | >= 25 µm                  | Not more than 300 particles / container                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 0                                                                                                                 |          |        |
| 6     | Bacterial Endotoxins Test                       |                           | Not more than 3.52 Endotoxin unit per mg.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Less than 3.52 Endotoxin unit per mg.                                                                             |          |        |
| 7     | Visible particle test for injection             |                           | Shall be free from visible particle                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | No visible particle observed.                                                                                     |          |        |
| 8     | Sterility Test                                  |                           | Should be sterile.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | It is sterile.                                                                                                    |          |        |
| 9     | Assay                                           |                           | Limit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Claim                                                                                                             | Result   | %age   |
|       | Each ml contains:<br>Fluphenazine Decanoate I.P |                           | 90.0% - 110.0%                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 25 mg                                                                                                             | 26.58 mg | 106.3% |

**Conclusion :** The above product complies with above specifications and meets the standard quality as per IP

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