



Finished Product Certificate of Analysis

C/B

Generic Name	Fluphenazine Decanoate Injection IP 25mg/ml	Analytical Report No.	KPL1/QC/AR/FP/2026/2702
Product Name	FLUZICAN 25 INJECTION	Reference Pharmacopoeia	IP
Batch No.	GN8690	Batch Size	15000 AMPOULES
Mfg. Date	05/2026	Exp. Date	04/2029
Sample Received on	26/06/2026	Specification No	KPL1/SLS/QC/112/1311
Analysis Initiated on	26/06/2026	Date of Release	14/07/2026

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) 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) 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 Not detected Not detected
5	Particulate matter test					
	A	$\geq 10\ \mu\text{m}$	Not more than 3000 particles / container			56
	B	$\geq 25\ \mu\text{m}$	Not more than 300 particles / container			17
6	Bacterial Endotoxins		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: Fluphenazine Decanoate I.P.		90.0% - 110.0%	25 mg	25.45 mg	101.8%

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

14/07/2026

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