Kwality Pharmaceuticals Limited

Address: Nag Kalan,Majitha Road,Amritsar - 143601 (India)

Finished Product Certificate of Analysis

C/B

Generic Name	Fluphenazine Decanoate Injection IP 25mg/ml	Analytical Report No.	KPL1/QC/AR/FP/2026/2688
Product Name	FLUZICAN 25 INJECTION	Reference Pharmacopoeia	IP
Batch No.	WN517	Batch Size	114000 AMPOULES
Mfg. Date	09/2026	Exp. Date	08/2029
Sample Received on	01/10/2026	Specification No	KPL1/SLS/QC/112/1311
Analysis Initiated on	02/10/2026	Date of Release	15/10/2026

Analytical Data

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

S.No.	Tests	Specifications	Observations
1	Description	Light yellow color oily solution filled in amber glass ampoule having white ring on neck with paper label and sealed.	Light 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 >= 10 µm	Not more than 3000 particles / container	42
	B >= 25 µm	Not more than 300 particles / container	12
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	25.53 mg	102.1%

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

Prepared By	Reviewed By	Approved By	Authorized By
15/10/2026	15/10/2026	15/10/2026	15/10/2026
Data Operator	Asst. Manager QC/Designee	Head QC /Designee	Head QA/Designee