



VELLINTON HEALTHCARE

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

QUALITY CONTROL DEPARTMENT CERTIFICATE OF ANALYSIS

Product Name : FLUZICAN 25 Fluphenazine Decanoate Injection IP.	Mfg. Date : 12/2025
Batch No. : A25L-04A	Exp. Date : 11/2027
Batch Size : 30130 Ampoules	Analytical Report No.: MFP20250095
Sample Qty. : 65 Ampoules	Date of Completion : 05/01/2026
Date of Receiving : 23/12/2025	
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	1.03 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
Fluphenazine Decanoate IP	25.0 mg	25.07 mg	100.28 %
			Limits % of labeled amount 90.0% to 110.0%

Remarks: In the opinion of the undersigned the sample submitted complies/does not 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 Manisha	Checked By Anuj Kumar	Approved By Yashwant Singh
Designation	Sr. Officer (QC)	Asst. Manager (QC)	Head QC
Sign/ Date	<i>[Signature]</i> 05/01/2026	<i>[Signature]</i> 05/01/2026	<i>[Signature]</i> 05/01/2026

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