



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.	: A24B-01B	Mfg. Date	: 02/2024
Batch Size	: 5130 Ampoules	Exp. Date	: 09/2026
Sample Qty.	: 70 Ampoules	Analytical Report No.:	MFP20240005
Date of Receiving	: 21/02/2024	Date of Completion	: 26/02/2024
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	Under analysis		
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	25.40 mg	101.6 %	90.0% to 110%

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

Analyzed By QC Officer	Checked By QC Executive	Approved By QC Manager/In-charge
Signature:- Date:- 26/02/2024	Signature:- Date:- 26/02/2024	Signature:- Date:- 26/02/2024

Format No.: VH/SOP/QC-062/FT-01-00