



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 Fluphenazine Decanoate Injection IP.	
Batch No. : A24I-06A	Mfg. Date : 09/2024
Batch Size : 9910 Ampoules	Exp. Date : 08/2026
Sample Qty. : 75 Ampoules	Analytical Report No.: MFP20240085
Date of Receiving : 24/09/2024	Date of Completion : 08/10/2024
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	1.04 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	Limits % of labeled amount
Fluphenazine Decanoate IP	25.0 mg	24.724 mg	98.90 %	90.0% to 110%

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.

Analyzed By QC Officer	Checked By QC Executive	Approved By QC Manager/ In-charge
Signature:- Date:- 08/10/2024	Signature:- Date:- 08/10/2024	Signature:- Date:- 08/10/2024

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