



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. : A24G-02A	Mfg. Date : 07/2024
Batch Size : 15470 Ampoules	Exp. Date : 06/2026
Sample Qty. : 75 Ampoules	Analytical Report No.: MFP20240054
Date of Receiving : 05/07/2024	Date of Completion : 19/07/2024
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	1.02 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	24.86 mg	99.44 %	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:-	Signature:- Date:-	Signature:- Date:-

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