



VELLINTON HEALTHCARE

(Earlier Known as Texus Meditech)

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

QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS

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Product Name	: FLUZICAN 25 Fluphenazine Decanoate Injection IP.		
Batch No.	: A24E-05	Mfg. Date	: 05/2024
Batch Size	: 26070 Ampoules	Exp. Date	: 04/2026
Sample Qty.	: 75 Ampoules	Analytical Report No.: MFP20240031	
Date of Receiving	: 22/05/2024	Date of Completion : 05/06/2024	
Mfg. License No.	: N-MB/18/201		

S. No.	Tests	Specifications	Observations		
1.	Description	A light yellowish colour liquid solution filled in 1 ml clear glass ampoule.	A light yellowish colour liquid solution filled in 1 ml clear 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	1.05 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	24.858 mg	99.43 %	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:-	Signature:- Date:-	Signature:- Date:-
<i>[Signature]</i> 05/06/2024	<i>[Signature]</i> 05/06/2024	<i>[Signature]</i> 05/06/2024

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