



# VELLINTON HEALTHCARE

(Earlier Known as Texus Meditech)

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

## QUALITY CONTROL DEPARTMENT CERTIFICATE OF ANALYSIS

Product Name : CEZOCALM Chlorpromazine Hydrochloride Injection USP	
Batch No. : GA25F-72A	Mfg. Date : 06/2025
Batch Size : 60.0 Ltr.	Exp. Date : 05/2027
Sample Qty. : 65 Ampoules	Analytical Report No.: AFP20250437
Date of Receiving : 30/06/2025	Date of Completion : 14/07/2025
Mfg. License No. : N-MB/18/201	

S. No.	Tests	Specifications	Observations	
1.	Description	A colourless or almost colourless solution filled in amber glass ampoule.	Clear colourless liquid solution filled in amber glass ampoule.	
2.	Identification			
	A. By TLC	The <i>R<sub>F</sub></i> value of the Principal spot obtained from the test solution corresponds to that obtained from the Standard solution.	Complies	
	B. By Chemically	It responds to the tests for chloride.	Complies	
3.	Uniformity of filled volume	Not less than nominal volume	Min: 2.0 ml Max: 2.1 ml	
4.	Average fill volume	Not less than 2 ml	2.05 ml	
5.	pH	Between (3.40 to 5.40)	3.81	
6.	Related substances	Should be complies	Complies	
7.	Particulate Matter			
	≥ 10µm	NMT 6000 particles/Container	Less than 6000 particles/Container	
	≥ 25µm	NMT 600 particles/ Container	Less than 600 particles/Container	
8.	Limit of Chlorpromazine sulfoxide	The area and intensity of the only other spot in the test specimen chromatogram, other than the principal spot, are not greater than those of the spot from the Standard preparation (5.0%).	Complies	
8.	Bacterial Endotoxins	NMT 6.9 USP EU/mg of Chlorpromazine hydrochloride.	Less than 6.9 USP EU/mg of Chlorpromazine hydrochloride.	
9.	Sterility	Should be Sterile	Sterile	
10.	Assay : Each ml contains:-			
Composition:	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Chlorpromazine hydrochloride USP	25.0 mg	26.12 mg	104.49 %	95.0% to 105.0 %

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 USP and IHS with respect to the above test only.

Name	Prepared By Punam Kumari	Checked By Anuj Kumar	Approved By Vikas Gupta
Designation	Executive	Asst. Manager (QC)	Manager (QC)
Sign/ Date	<i>Punam Kumari</i>	<i>Anuj Kumar</i>	<i>Vikas Gupta</i>

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