



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 IP	
Batch No. : GA24I-32	Mfg. Date : 09/2024
Batch Size : 25200 Ampoules	Exp. Date : 08/2026
Sample Qty. : 65 Ampoules	Analytical Report No.: AFP20240564
Date of Receiving : 19/09/2024	Date of Completion : 03/10/2024
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.	A clear colourless liquid solution filled in amber glass ampoule.		
2.	Identification				
	A. By IR	Compare the spectrum with that obtained with chlorpromazine hydrochloride IPRS treated in the same manner or with the reference spectrum of Chlorpromazine.	Complies		
	B. BY UV	The resulting solution, when examined in the range 230 nm to 360 nm shows absorption maxima at about 254 nm and 306 nm, 0.45 to 0.480.	Complies		
	C. By Chemically	It responds to the tests B of 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	2.04 ml		
5*	pH	Between (3.40 to 5.40)	3.99		
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.	Bacterial Endotoxins	NMT 6.9 EU/mg of Chlorpromazine hydrochloride.	Less than 6.9 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 IP		25.0 mg	25.79 mg	103.17 %	95.0% to 105%

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:- <i>A</i> 03/10/2024	Signature:- Date:- <i>QW</i> 03/10/2024	Signature:- Date:- <i>S</i> 03/10/2024

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