



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.	: GA23L-30C	Mfg. Date	: 12/2023
Batch Size	: 5050 Ampoules	Exp. Date	: 11/2025
Sample Qty.	: 65 Ampoules	Analytical Report No.:	AFP20230468
Date of Receiving	: 22/12/2023	Date of Completion	: 05/01/2024
Mfg lic. no.	: N-MB/18/201		

S. No.	Tests	Specifications	Observations	
1.	Description	A colourless or almost colourless solution filled in amber glass ampoule.	A colourless 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	Should be complies	Complies	
	C. By Chemically	It responds to the tests B 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	2.04 ml	
*5.	pH	Between (3.40 to 5.40)	4.81	
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 particle /Container	
8.	Bacterial Endotoxins	NMT 6.9 EU/mg	Less than 6.9 USP EU,mg	
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	24.90 mg	99.60 %	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:-	Signature:- Date:-	Signature:- Date:-
 05/01/2024	 05/01/2024	 05/01/2024

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