



VELLINTON HEALTHCARE

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

QUALITY CONTROL DEPARTMENT CERTIFICATE OF ANALYSIS

Product Name	: CEZOCALM Chlorpromazine Hydrochloride Injection IP		
Batch No.	: GA25I-51A	Mfg. Date	: 09/2025
Batch Size	: 29970 Ampoules	Exp. Date	: 08/2027
Sample Qty.	: 65 Ampoules	Analytical Report No.:	AFP20250599
Date of Receiving	: 27/09/2025	Date of Completion	: 11/10/2025
Mfg. License No.	: N-MB/18/201		

S. No.	Tests	Specifications	Observations		
1.	Description	A colourless or almost colourless solution filled in amber colour glass ampoule.	Clear colourless liquid solution filled in amber colour 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	2.03 ml		
5*	pH	Between (3.40 to 5.40)	3.83		
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	26.17 mg	104.70 %	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.

	Prepared By	Checked By	Approved By
Name	Manisha	Anuj Kumar	Vikas Gupta
Designation	Sr. Officer (QC)	Asst. Manager (QC)	Manager (QC)
Sign/ Date			

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