



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 Injection IP | |
| Batch No. : GA24H-60A | Mfg. Date : 08/2024 |
| Batch Size : 5300 Ampoules | Exp. Date : 07/2026 |
| Sample Qty. : 65 Ampoules | Analytical Report No.: AFP20240544 |
| Date of Receiving : 30/08/2024 | Date of Completion : 13/09/2024 |
| 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 | 2.03 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 | 24.863 mg | 99.45 % | 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:- |

Format No.: VH/SOP/QC-062/FT01-00