

## Tamman Titoe Pharma Pvt Ltd 56-57, Sideo Pharmaceutical Complex, Alathur-603 110, Tamilnadu.

## QUALITY CONTROL DEPARTMENT

Certificate of Analysis of Finished Product

(Under Drug And Cosmetic Act. 1940 & The Rules There Under)

Report No: TT/FG/189/24-25 Report Date: 22-07-2024

Name of the product

:PROCITIL Injection 1ml

Generic Name

: Prochlorperazine Mesylate Injection I.P

Batch No.

: PP403

Batch Size

: 108000

Mfg. Date.

: JULY-2024

Exp. Date.

: JUNE-2027

Quantity of Sample

:100 Nos

Date of Sampling

:07-07-2024

Date of Commencement of analysis

:07-07-2024

Oute of Completion of analysis

: 21-07-2024

| TEST NAME  | SPECIFICATION  | OBSERVATION                  |
|--|--|------------------------------|
| Description:   | A clear, colourless solution.  | A clear, colourless solution |
| Identification: A.(BY IR )                                   | The spectrum with that obtained with prochlorperazine mesylate RS treated in the same manner or with the reference spectrum of prochlorperazine.   | Complies to IP specification |
| B. Colour reaction   | A red colour is produced   | Complies to IP specification |
| pH   | 5.5 to 6.5   | 5.96                         |
| Extractable Volume   | NLT- 1.0 ml/Ampoule  | 1.1 ml                       |
| Particulate matter   | No visible particles   | No visible particles         |
| Related Substances   | Any secondary spot in the chromatogram obtained with the test solution is not more intense than the spot in the chromatogram obtained with reference solution(a)and not more than one such spot is more than the spot in the chromatogram obtained with reference solution.(b) | Complies to IP specification |
| Sterility Test   | To comply as per IP  | Complies                     |
| Assay  | 95.0 % to 105%   | 100.96%                      |
| Each ml contains:<br>Prochlorperazine Mesylate I.P<br>12.5mg | 11.875 mg to 13.125mg  | 12.62mg                      |

OBSERVATION:

In the opinion of the undersigned the sample referred to above is of Standard Quality/Not Standard Quality as

in the act and the rules made there under for the reason given below.

REMARKS

COMPLIES AS PER IP WITH RESPECT TO THE ABOVE TESTS ONLY CARRIEDOUT.

Analysed By By
Date: 2017/24

Person In

Date: