

TAMMAN TITOE



Tamman Titoe Pharma Pvt Ltd
56-57, Sidco 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/498/24-25

Report Date: 18-01-2025

Name of the product : PROCITIL Injection 1ml
Generic Name : Prochlorperazine Mesylate Injection I.P
Batch No. : PP501
Batch Size : 104000
Mfg. Date. : JAN-2025
Exp. Date. : DEC-2027
Quantity of Sample : 100 Nos
Date of Sampling : 02-01-2025
Date of Commencement of analysis : 02-01-2025
Date of Completion of analysis : 17-01-2025

TEST NAME	SPECIFICATION	OBSERVATION
Description:	A clear, colourless solution.	A clear, colourless solution
Identification: A.(BY IR) B. Colour reaction	The spectrum with that obtained with prochlorperazine mesylate RS treated in the same manner or with the reference spectrum of prochlorperazine. A red colour is produced	Complies to IP specification Complies to IP specification
pH	5.5 to 6.5	5.67
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 Each ml contains : Prochlorperazine Mesylate I.P 12.5mg	95.0 % to 105% 11.875 mg to 13.125mg	98.88% 12.36mg

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 CARRIED OUT.

Analysed By: *L. H.*
Date: 18/01/2025

Checked By: *[Signature]*
Date: 18/01/2025

Person In Charge of Testing
Date: 18/01/25

