



CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Code	4010000848	A. R. No.	NL3/FG/03260155
Product Name	Procitil 1ml [Prochlorperazine Mesylate Injection IP]	Batch Size	195454 Ampoules
Batch No.	NL31776001	Sample Quantity	101 Ampoules
Mfg. Date	02/2026	Sampling Done By	Anil Maurya
Exp. Date	01/2029	Date of Receiving	06/03/2026
Analysis start date	06/03/2026	Date of Release	06/03/2026
Mfg. License No.	S-MB/13/136	Specification No.	NL3/AR/IP/FPS402-00
Protocol/Reference	IP/IH	STP No.	NL3/AR/IP/FPT402-00

S.No.	Tests	Specification	Result
1	Description	A clear or almost colourless solution filled in 1ml Amber ampoules snap off with White ring	A clear colourless solution filled in 1 ml Amber ampoules snap off with white ring
2	Identification		
(a)	By IR	Compare the spectrum with that obtained with prochlorperazine mesylate IPRS/WS treated in the same manner or with the reference spectrum of prochlorperazine.	Complies (Refer to Outside Laboratory Report No.: DTRLF-230226032)
(b)	Sulphuric Acid	A red colour is produced	Complies
3	pH	5.50 to 6.50	5.98
4	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 intense than the spot in the chromatogram obtained with reference solution (b)	Complies
5	Extractable Volume	NLT 1.0ml	1.0 ml
6	Assay : Each ml contains	Limits	OBTAINED CLAIM

	Prepared by	Checked by	Approved by
Name	Mohd. Anis	Kapil Kumar	Ramraj Singh Rathore
Department	QC	QC	Quality Control
Designation	Officer	Asst. Manager QC	Head Quality
Date	06/03/2026	06/03/2026	06/03/2026



NITIN LIFESCIENCES LTD. (UNIT-III)
(A COMPANY OF SYNOKEM PHARMACEUTICALS LTD.)
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S.No.	Tests	Specification	Result
	Prochlorperazine Mesylate IP 12.5mg	Release Specification : Not less than 95.0% and not more than 105.0% of labelled claim of Prochlorperazine Mesylate	101.6 %
7	Sterility	Should be Sterile	Sterile
8	Particulate Matter		
(a)	By Visual Inspection	If examined under suitable conditions of visibility with unaided eye, the reconstituted solution should be clear & free from particles.	Complies
(b)	By Light obscuration particle count	≥10 microns NMT 6,000/Container ≥25 microns NMT 600/Container	9.33 0.13
9	Bacterial Endotoxins Test	NMT 17.9EU/mg of Prochlorperazine	Less than 17.9 EU/mg of Prochlorperazine

Remark : The sample complies as per IP/IH specification no. : NL3/AR/IP/FPS402- 00

Remarks : All test Data results refer to B.No.: NL31756001.

Approved Competent Technical Person
Name: Ram Raj Singh Rathore
Qualification : B. Pharma
Registration No.: 38354
Date of Registration: 09/04/2008
Validity : 31/12/2029
State of Registration: Uttar Pradesh

	Prepared by	Checked by	Approved by
Name	Mohd. Anis	Kapil Kumar	Ramraj Singh Rathore
Department	QC	QC	Quality Control
Designation	Officer	Asst. Manager QC	Head Quality
Date	06/03/2026	06/03/2026	06/03/2026

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