

**CERTIFICATE OF ANALYSIS**

Product Name	PROMARGAN		
Generic Name	Promethazine Hydrochloride injection IP 50mg/ml	Product Code	PR
Batch No	PRA24001	Batch size	250 Liters
Mfg. Date	MAR.2024	Exp. Date	FEB.2026
Date of sampling	04/03/2024	Completed Date	18/03/2024
A.R. No	RLS/FP/240051	Specification No:	FPS011

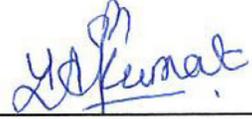
Sl. No.	Tests	Method	Specification	Results
1	DESCRIPTION	IP/IH	A clear, colourless or almost colourless solution filled in dark glass container	A clear, colourless solution filled in 2 ml dark amber ampoule with blue dot.
2	IDENTIFICATION A	IP	Compare the spectrum with that obtained with promethazine hydrochloride RS/WS treated with same maner or with the reference spectrum of promethazine.	Complies
	IDENTIFICATION B	IP	Melting point at about 160°C	158°C
	IDENTIFICATION C	IP	A red colour is produced.	Complies
3	pH	IP	NLT 5.0 and NMT 6.0	5.34
4	EXTRACTABLE VOLUME	IP	NLT 2.0 ml	2.0 ml
5	PARTICULATE MATTER	IP	Clear and practically free from particles when observed by visual inspection by the unaided eyes.	Complies
6	RELATED SUBSTANCE	IP	Any spot corresponding to isopromethazine in the chromatogram obtained with the test solution is not more intense than the spot in the chromatogram obtained with reference solution ( c ). Any other 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

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7	ASSAY (Each ml of solution contains 25 mg of Promethazine)	IP	NLT 95.0% and NMT 105.0%	99.8 % (24.945mg/ml)
8	BET	IP	NMT 5.0 EU/ mg of promethazine	Less than 2.45 EU/mg
9	STERILITY	IP	Should be sterile	Sterile
10	PHENOL CONTENT	IP	NLT 90.0% and NMT 110.0%	98.6 %

Remarks: The material complies as per IP and In-house specification.

	Analysed by	Checked by	Approved by
Signature			
Date	22/05/2024	22/05/2024	22/05/2024