

CERTIFICATE OF ANALYSIS

Product Name	PROMARGAN		
Generic Name	Promethazine Hydrochloride injection IP 50mg/2ml	Product Code	PR
Batch No.	PRA24002	Batch size	250 Liters
Mfg. Date	MAY 2024	Exp. Date	APR.2027
Date of sampling	11/05/2024	Completed Date	27/05/2024
A.R. No.	RLS/FP/240124	Specification No.:	FPS011

Sr. 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 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	159°C
	IDENTIFICATION C	IP	A red colour is produced.	Complies
3	pH	IP	NLT 5.0 and NMT 6.0	5.32
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	IP	NLT 95.0% and NMT 105.0%	99.8 % (24.945 mg/ml)
8	BET	IP	NMT 5.0 EU/mg of Promethazine.	Less than 2.45 EU/mg of Promethazine.
9	STERILITY	IP	Should be sterile	Sterile
10	PHENOL CONTENT	IP	NLT 90.0% and NMT 110.0%	98.7 %

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

	Analysed by	Checked by	Approved by
Signature	<u>PSH</u>	<u>(M)</u>	<u>A</u>
Date	27/05/2024	27/05/2024	27/05/2024