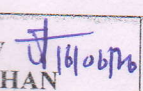
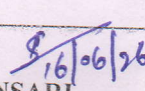
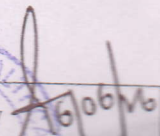


Title
:
Certificate of Analysis Finished Product

Product Name	PROMARGAN Injection	A.R. No.	ARN/FP/26/024
Generic Name	Promethazine Injection IP 2ml	Sampled qty.	45 Ampoules
Batch No.	ARN2623A	Sampled by	Rakesh
Batch Size	1,95,200 Ampoules	Sampled on	01/06/2026
Mfg. Date	05/2026	Date of Testing	02/06/2026
Exp. Date	04/2028	Date of Release	16/06/2026

S. No.	Tests	Specifications	Observations
1.	Description	A clear colourless solution filled in amber glass ampoule.	A clear colourless solution filled in amber glass ampoule.
2.	Identification (By IR)	A. Determine by infrared absorption spectrophotometry. Compare the spectrum with that obtained with promethazine hydrochloride IPRS treated in the same manner or with the reference spectrum of promethazine.	Complies
	(Melting point)	B. To a volume containing 0.2 g of Promethazine Hydrochloride add sufficient potassium carbonate to saturate the solution, extract with two quantities, each of 10 ml, of ether and evaporate the combined extracts to dryness. Dissolve the residue in 2 ml of methanol and pour into a solution of 0.4 g of picric acid in 10 ml of methanol, previously warmed to about 50°. Cool, scratch the sides of the tube to induce crystallisation, allow to stand for 3 to 4 hours and filter. The residue, after washing with methanol and drying, melts at about 160°.	Complies
	(By Chemically)	C. To a volume containing 5 mg of Promethazine Hydrochloride add carefully 2 ml of sulphuric acid and allow to stand 5 minutes; a red colour is produce.	Complies
3.	Nominal fill volume	NLT 2ml	2.0 ml
4.	Extractable volume	NLT Nominal volume or NMT 110% of Nominal volume.	2.1 ml
5.	pH	5.0 to 6.0	5.51

Analysis by 
NAME: FIROJ KHAN
Checked by 
NAME: SUFIYAN ANSARI
Approved by 
NAME: MRS. SWATI DHAWAN

Title

:

Certificate of Analysis Finished Product

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6.	Related substances (By TLC)	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 than the spot in the chromatogram obtained with reference solution (b).	Complies		
7.	Particulate Matter	NMT 6000/Ampoule NMT 600/Ampoule The solution should be essentially free from extraneous, mobile undissolved particles; other than gas bubbles unintentionally that can be seen with naked eye.	14/Ampoule 1/Ampoule Complies		
	(A.) Light Obscuration Particle Count Test 1. Particles $\geq 10 \mu\text{m}$ 2. Particles $\geq 25 \mu\text{m}$ (B.) Visual Particle				
8.	Sterility	No microbial growth should be observed.	Complies		
9.	Bacterial Endotoxins	NMT 5.0 EU/mg of Promethazine hydrochloride	Less than 0.5 EU/mg of Promethazine hydrochloride.		
10.	Assay: (By UV) Each ml contains:				
Ingredients		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Promethazine Hydrochloride IP		25 mg	24.53599 mg	98.14%	95.0% to 105.0%
Remarks: In the opinion of the Analyst, the sample complies with the requirements of the monograph.					

Remarks: In the opinion of the undersigned the sample referred to above is/is not of the standard quality as The Drug & Cosmetic Act 1940 and the rules made there under. Complies/~~not~~ complies as per IP/BP/USP/PHS.

Analysis by [Signature]
NAME: FIROJ KHAN

Checked by [Signature]
NAME: SUFIYAN ANSARI

Approved by [Signature]
NAME: MRS. SWATI DHAWAN

