



ALVENTA PHARMA LIMITED

VILL. KISHANPURA, TEHSIL BADDI- NALAGARH ROAD, DISTT.- SOLAN (H.P) 174101

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Promargan	A.R. No.	FG/G/26A0913
Generic Name	Promethazine Hydrochloride Injection IP	Sample Quantity	65 Ampoules
Batch No.:	AA60501	Sample Received on	17/05/2026
Batch Size:	1.0 Lac	Analysis Date	17/05/2026
Mfg. Date.	05/2026	Release Date	01/06/2026
Exp. Date	04/2028	Page No.:	Page 1 of 2

Sr. No.	Test Parameter	Acceptance Criteria	Result
1.	Description	A clear, colourless liquid filled in 2 ml amber color glass ampoule.	A clear, colourless liquid filled in 2 ml amber color glass ampoule.
2.	Identification:		
	a) By IR	The IR spectrum of the residue matches with the reference spectrum promethazine hydrochloride or with the spectrum obtained with reference standard or working standard of promethazine hydrochloride.	Complies
	b) By Melting point	Melts at about 160°	Complies
	c) By Chemically	A red colour should be produced	Complies
3.	pH	Between 5.0 to 6.0	5.09
4.	Extractable volume	Not less than 2.0 ml	2.05 ml
5.	Particulate Matter	The Solution should be clear, and free from any visible particle.	The Solution is clear, and free from any visible particle.
6.	Bacterial Endotoxins	NMT 5.0 EU/mg of promethazine	Less than 5.0 EU/mg
7.	Sterility	Should be sterile	Sterile
8.	Related Substances	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

Particulars	Prepared By	Checked By	Approved By
Name	Praveen Kumar	Kamal Kant	Subhendra
Designation	Executive	Executive	Head QC
Signature			
Date	01/06/2026	01/06/2026	01/06/2026



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9.	Assay:				
	Each ml contains:	Claim	Limit	mg	%
	Promethazine hydrochloride IP	25 mg	Between 95.0 % to 105.0 % of stated amount. (Between 23.75 mg to 26.25 mg)	24.56 mg	98.24%

Remarks: The above test parameters are complies/ not complies as per IP/BP/USP & In-House Specification.

Particulars	Prepared By	Checked By	Approved By
Name	Praveen Kumar	Kamal Kant	Subhash Chandra
Designation	Executive	Executive	Head QC
Signature			
Date	01/06/2026	01/06/2026	01/06/2026