AMERICAN REMEDIES HEALTHCARE PVT. LTD.

Vill. Surajpur, Nahan Road, Paonta Sahib, Dist. Sirmour (H.P) 173025

Title	:	Certificate of Analysis Finished Product

Product Name	**PHENVIL** Injection	**A.R. No.**	ARN/FP/26/089
Generic Name	Pheniramine Maleate Injection IP 2ml	**Sampled qty.**	45 Ampoules
Batch No.	ARN2679A	**Sampled by**	Shivanand
Batch Size	99,500 Ampoules	**Sampled on**	07/10/2026
Mfg. Date	09/2026	**Date of Testing**	08/10/2026
Exp. Date	08/2028	**Date of Release**	22/10/2026

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 TLC)	The principal spot in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with the reference solution.	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	4.5 to 5.5	4.64
6.	Related substances (By TLC)	Any secondary spot in the chromatogram obtained with the test solution is not more intense than the spot in the chromatogram obtained with the reference solution.	Complies
7.	Particulate Matter		
	(A) Light Obscuration Particle Count Test 1.Particles ≥10 µm 2.Particles ≥25 µm	NMT 6000/ampoule NMT 600/ampoule	8/Ampoule 0/Ampoule
	(B) Visible Particles	The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles unintentionally that can be seen with naked eye.	Complies
8.	Sterility	No microbial growth should be observed.	Complies
9.	Bacterial Endotoxins (IHS)	NMT 5.14 EU/mg of Pheniramine.	LT 5.14 EU/mg of Pheniramine.
10.	Assay: (By UV) Each ml contains:		

Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Pheniramine Maleate IP	22.75 mg	23.77919 mg	104.52%	90.0% to 110.0%

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/IHS.~~

Analysis by	Checked by	Approved by
22/10/26	22/10/26	22/10/26
NAME: PANKAJ YADAV	NAME: SURJEET KAUR	NAME: MRS. SWATI DHAWAN

Name : Mrs. Swati Dhawan
Designation : QC HOD
Qualification : M.Sc. Clinical Microbiology
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