



# 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/25/102
Generic Name	Pheniramine Maleate Injection IP 2ml	Sampled qty.	45 Ampoules
Batch No.	ARN2596A	Sampled by	Anuj Verma
Batch Size	2,00,000 Ampoules	Sampled on	05/03/2026
Mfg. Date	01/2026	Date of Testing	06/03/2026
Exp. Date	12/2027	Date of Release	20/03/2026

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	4.97
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 $\geq 10 \mu\text{m}$ 2. Particles $\geq 25 \mu\text{m}$ (B) Visible Particles	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.	28/Ampoule 1/Ampoule 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	23.15067 mg	101.76%	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/AHS.

Analysis by NAME: RAMANJEET SINGH	Checked by NAME: NIKHIL SHARMA	Approved by NAME: MRS. SWATI DEWAN
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