

**Title : Certificate of Analysis Finished Product**

<b>Product Name</b>	PHENVIL Injection	<b>A.R. No.</b>	ARN/FP/25/052
<b>Generic Name</b>	Pheniramine Maleate Injection IP 2ml	<b>Sampled qty.</b>	45 Ampoules
<b>Batch No.</b>	ARN2547A	<b>Sampled by</b>	Anuj
<b>Batch Size</b>	1,97,700 Ampoule	<b>Sampled on</b>	22/11/2025
<b>Mfg. Date</b>	10/2025	<b>Date of Testing</b>	22/11/2025
<b>Exp. Date</b>	09/2027	<b>Date of Release</b>	12/12/2025

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	5.00
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.	1/Ampoule 0/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	23.522 mg	103.39%	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: FIROJ KHAN	Checked by NAME: SUFIYAN ANSARI	Approved by NAME: MRS. SWATI DEHAWAN
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