



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/25/054 |
| Generic Name | Pheniramine Maleate Injection IP 2ml | Sampled qty. | 45 Ampoules |
| Batch No. | ARN2548A | Sampled by | Anuj |
| Batch Size | 1,99,500 Ampoules | Sampled on | 23/11/2025 |
| Mfg. Date | 10/2025 | Date of Testing | 23/11/2025 |
| Exp. Date | 09/2027 | Date of Release | 08/12/2025 |

| 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 | 5.01 |
| 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. | 0/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 | 23.110 mg | 101.58% | 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/HS.

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