



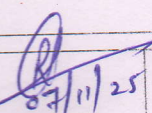
AMERICAN REMEDIES HEALTHCARE PVT. LTD.

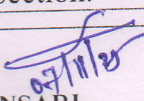
Vill. Surajpur, Nahan Road, Paonta Sahib, Dist. Sirmour (H.P) 173025

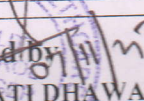
Title : Certificate of Analysis Finished Product

| | | | |
|--------------|----------------------------|-----------------|---------------|
| Product Name | LABECANOL Injection | A.R. No. | ARN/FP/25/039 |
| Generic Name | Labetalol Injection IP 4ml | Sampled qty. | 45 Ampoules |
| Batch No. | ARN2538A | Sampled by | Anuj Verma |
| Batch Size | 40,000 Ampoules | Sampled on | 17/10/2025 |
| Mfg. Date | 09/2025 | Date of Testing | 17/10/2025 |
| Exp. Date | 08/2027 | Date of Release | 07/11/2025 |

| S. No. | Tests | Specifications | Observations |
|--------|---|---|--|
| 1. | Description | A colourless or pale yellow solution filled in clear glass ampoule. | A colorless or pale yellow solution filled in clear glass ampoule. |
| 2. | Identification (By IR) | A. On the residue, determine by infrared absorption spectrophotometry. Compare the spectrum with that obtained with labetalol hydrochloride IPRS, treated in the same manner or with the reference spectrum of labetalol. | Complies |
| | (By HPLC) | B. In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with reference solution (a). | Complies |
| 3. | Nominal fill volume | NLT 4ml | 4.0 ml |
| 4. | Extractable Volume | NLT Nominal volume or NMT 110% of Nominal volume. | 4.1 ml |
| 5. | pH | 3.5 to 4.5 | 4.17 |
| 6. | Free carboxylic acid and other related substances (by TLC) | | |
| | 5-[1-hydroxy-2-(1-methyl-3-Phenylpropylamino) ethyl] Salicylic acid | NMT 2.0% | Not Detected |
| | Any other secondary peak | NMT 0.5% | Not Detected |
| 7. | Particulate Matter | | |
| | (A.) Light Obscuration Particle Count Test 1. Particles $\geq 10 \mu\text{m}$ 2. Particles $\geq 25 \mu\text{m}$ (B.) Visual | NMT 6000/Ampoule NMT 600/Ampoule The solution is free from particles of foreign matter particles that can be observed on visual inspection. | 11/Ampoule 0/Ampoule Complies |

Analysis by 
NAME: RAMANJEET SINGH

Checked by 
NAME: SUFIYAN ANSARI

Approved by 
NAME: MRS. SWATI DHAWAN



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| | | | | | |
|----------------------------|--------------------------------------|---|---|---------------------|----------------------------|
| 8. | Sterility | No microbial growth should be observed. | Complies | | |
| 9. | Bacterial Endotoxins | NMT 1.2 EU/mg of Labetalol Hydrochloride. | Less than 1.2 EU/mg of Labetalol Hydrochloride. | | |
| 10. | Assay: (By HPLC) Each ml contains | | | | |
| Ingredients | | Labeled Claim | Found | % of labeled amount | Limits % of labeled amount |
| Labetalol Hydrochloride IP | | 5 mg | 5.226 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/THS.

| | | |
|--------------------------------------|------------------------------------|--|
| Analysis by NAME: RAMANJEET SINGH | Checked by NAME: SUFIYAN ANSARI | Approved by NAME: MRS. SWATI DHAWAN |
|--------------------------------------|------------------------------------|--|

