

**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/25/018
Generic Name	Labetalol Injection IP 4ml	Sampled qty.	45 Ampoules
Batch No.	ARN2515A	Sampled by	Anuj Verma
Batch Size	30,200 Ampoules	Sampled on	13/09/2025
Mfg. Date	08/2025	Date of Testing	13/09/2025
Exp. Date	07/2027	Date of Release	28/09/2025

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) (By HPLC)	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. 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 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	4.03
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.	327.47/Ampoule 73.07/Ampoule Complies

Analysis by
NAME: RAMANJEET SINGHChecked by
NAME: SUFIYAN ANSARIApproved 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	5.062 mg	101.24%	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.

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