

**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/26/070
Generic Name	Labetalol Injection IP 4ml	Sampled qty.	45 Ampoules
Batch No.	ARN2660A	Sampled by	Rakesh
Batch Size	58,000 Ampoules	Sampled on	28/08/2026
Mfg. Date	08/2026	Date of Testing	29/08/2026
Exp. Date	07/2028	Date of Release	12/09/2026

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	4.34
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 $\geq 10 \mu\text{m}$	NMT 6000/Ampoule	30/Ampoule
	2. Particles $\geq 25 \mu\text{m}$	NMT 600/Ampoule	1/Ampoule
	(B.) Visual	The solution is free from particles of foreign matter particles that can be observed on visual inspection.	Complies

Analysis by 21/09/26
NAME: FIROJ KHANChecked by 21/09/26
NAME: SURJEET KAURName : Mrs. Swati Dhawan
Designation : QC MODQuantified by 21/09/26 Clinical Microbiology
Registr. No. : 580106039503
NAME: MRS. SWATI DHAWAN
Punjab Technical University, Jalandhar

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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	5.01783 mg	100.36%	90.0% to 110.0%

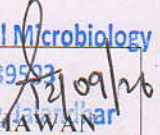
Remarks: In the opinion of the undersigned the sample referred to above is/is ~~not~~ of the standard quality as The Drug & Cosmetic Act 1940 and the rules made there under. Complies/~~not~~ complies as per ~~IP/BP/USP/HHS~~.

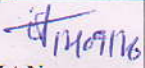
Name : Mrs. Swati Dhawan

Designation : QC HOD

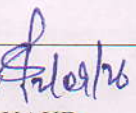
Qualification : M.Sc. Clinical Microbiology

Registration No. 586106339592

Approved by 
NAME: MRS. SWATI DHAWAN

Analysis by 

NAME: FIROJ KHAN

Checked by 

NAME: SURJEET KAUR