

# Pace

Add Pace To Health

# Pace Biotech

Surajpur, Paonta sahib Dist. Sirmour (H.P)

**Title : Certificate of Analysis Finished Product**

<b>Product Name</b>	LABECANOL Injection	<b>A.R. No.</b>	NL/FP/25/335
<b>Generic Name</b>	Labetalol Injection IP 4ml	<b>Sampled qty.</b>	45 Ampoules
<b>Batch No.</b>	A25396I	<b>Sampled by</b>	Anuj Verma
<b>Batch Size</b>	40,000 Ampoules	<b>Sampled on</b>	12/02/2026
<b>Mfg. Date</b>	02/2026	<b>Date of Testing</b>	13/02/2026
<b>Exp. Date</b>	01/2028	<b>Date of Release</b>	01/03/2026

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	4.10
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.	6/Ampoule 0/Ampoule Complies

Name : Mrs. Swati Dhawan  
Designation : QC HOD  
Qualification : M.Sc. Clinical Microbiology  
Registrar

Analysis by

Checked by

Approved by

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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				
<b>Ingredients</b>		<b>Labeled Claim</b>	<b>Found</b>	<b>% of labeled amount</b>	<b>Limits % of labeled amount</b>
Labetalol Hydrochloride IP		5 mg	4.98793 mg	99.76%	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/IHS.

Name : Mrs. Swati Dhawan  
Designation : QC HOD  
Qualification : M.Sc. Clinical Microbiology  
Registra Approved by 01/03/26  
NAME: MRS. SWATI DHAWAN

<b>Analysis by</b>  NAME: FIROJ KHAN	<b>Checked by</b>  NAME: SUFIYAN ANSARI	<b>Approved by</b>  NAME: MRS. SWATI DHAWAN
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