

# Pace

Add Pace To Health

# Pace Biotech

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

Title

:

Certificate of Analysis Finished Product

Product Name	Labecanol Injection	A.R. No.	NL/FP/24/477
Generic Name	Labetalol Injection IP 20mg/4ml	Sampled qty.	45 Ampoules
Batch No.	A24370A	Sampled by	Aakash
Batch Size	20,832 Ampoules	Sampled on	10/01/2025
Mfg. Date	01/2025	Date of Testing	10/01/2025
Exp. Date	12/2026	Date of Release	28/01/2025

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. The absorption spectrum of the test preparation should exhibit maxima at same wavelength with that obtained with similar preparation of working standard solution	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 the reference solution.	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	4.11
6.	Free carboxylic acid and other related substances (by TLC)	The area of any other secondary peak is not more intense than the spot in the chromatogram obtained with reference solution.	Complies
7.	Particulate Matter		
	(A.) Light Obscuration Particle Count Test 1. Particles $\geq 10 \mu\text{m}$ 2. Particles $\geq 25 \mu\text{m}$	NMT-6000/Ampoule NMT-600/Ampoule	32.8/Ampoule 0.8/Ampoule
	(B.) Visual	The solution is free from particles of foreign matter particles that can be observed on visual inspection.	Complies

Analysis by  
NAME: SANDHYA

Checked by  
NAME: SUFIYAN ANSARI

Approved by  
NAME: P. N. TRIPATHI



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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: Each ml Contains				
Ingredients		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Labetalol Hydrochloride IP		5 mg	4.986 mg	99.72%	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: SANDHYA

Checked by  
NAME: SUFIYAN ANSARI

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NAME: P.N. TRIPATHI

