



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/26/118
Generic Name	Labetalol Injection IP 4ml	Sampled qty.	45 Ampoules
Batch No.	A26101B	Sampled by	Aakash
Batch Size	40,000 Ampoules	Sampled on	02/07/2026
Mfg. Date	06/2026	Date of Testing	03/07/2026
Exp. Date	05/2028	Date of Release	17/07/2026

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	4.06
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	28/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	Checked by	Approved by
NAME: FIROJ KHAN	NAME: SUFIYAN ANSARI	NAME: MRS. SWATI DHAWAN

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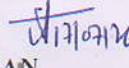
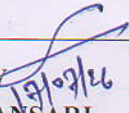
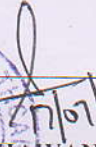
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Certificate of Analysis Finished Product

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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	5.06543 mg	101.31%	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: FIROJ KHAN	Checked by  NAME: SUFIYAN ANSARI	Approved by  NAME: MRS. SWATI DHAWAN
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