

## Certificate of Analysis Finished Product

<b>Title</b>	:		
<b>Product Name</b>	Labecanol Injection	<b>A.R. No.</b>	NL/FP/24/454
<b>Generic Name</b>	Labetalol Injection IP 20mg/4ml	<b>Sampled qty.</b>	45 Ampoules
<b>Batch No.</b>	A24330D	<b>Sampled by</b>	Rakesh
<b>Batch Size</b>	9000 Ampoules	<b>Sampled on</b>	24/12/2024
<b>Mfg. Date</b>	12/2024	<b>Date of Testing</b>	24/12/2024
<b>Exp. Date</b>	11/2026	<b>Date of Release</b>	08/01/2025

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	4.46
6.	Free carboxylic acid and other related substances (by TLC)		Not detected
	5-[1-hydroxy-2-(1-methyl-3-Phenylpropylamino) ethyl] Salicylic acid	NMT- 2.0%	
	Any other secondary peak	NMT- 0.5%	Not detected
7.	Particulate Matter	NMT-6000/Ampoule NMT-600/Ampoule	122/Ampoule 0/Ampoule
	(A.) Light Obscuration Particle Count Test 1. Particles $\geq 10 \mu\text{m}$ 2. Particles $\geq 25 \mu\text{m}$		
	(B.) Visual	The solution is free from particles of foreign matter particles that can be observed on visual inspection.	Complies



<b>Analysis by</b> NAME: SANDHYA	<b>Checked by</b> NAME: SUFIYAN ANSARI	<b>Approved by</b> 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	5.109 mg	102.18%	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: SUFIYAN ANSARI	Checked by NAME: SANDHYA	Approved by NAME: P. N. TRIPATHI
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