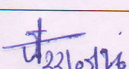
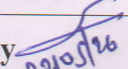


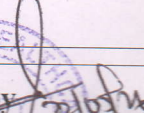
Title : Certificate of Analysis Finished Product

Product Name	LABECANOL Injection	A.R. No.	ARN/FP/26/011
Generic Name	Labetalol Injection IP 4ml	Sampled qty.	45 Ampoules
Batch No.	ARN2602A	Sampled by	Rakesh
Batch Size	50,000 Ampoules	Sampled on	07/05/2026
Mfg. Date	04/2026	Date of Testing	08/05/2026
Exp. Date	03/2028	Date of Release	22/05/2026

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) (By HPLC)	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. 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 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	4.07
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.	12/Ampoule 0/Ampoule Complies

Analysis by 
NAME: FIROJ KHAN

Checked by 
NAME: SUFIYAN ANSARI

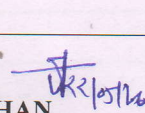
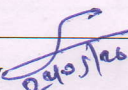
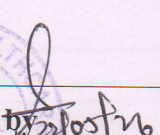
Approved by 
NAME: MRS. SWATI DHAWAN

Title : Certificate of Analysis Finished Product

Product Name	LABECANOL Injection	A.R. No.	ARN/FP/26/011
Generic Name	Labetalol Injection IP 4ml	Sampled qty.	45 Ampoules
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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	5.25334 mg	105.07%	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.

Analysis by  NAME: FIROJ KHAN	Checked by  NAME: SUFIYAN ANSARI	Approved by  NAME: MRS. SWATI DHAWAN
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