

Pure & Cure Healthcare Pvt. Ltd.

Plot No. 26A-30, Sector-8A, I.I.E., SIDCUL, Ranipur
Haridwar-249403, Uttarakhand, INDIA.

QUALITY CONTROL

CERTIFICATE OF ANALYSIS

(FINISHED PRODUCT)

Product Name :	LABECANOL 100		
Generic Name :	Labetalol Hydrochloride Tablets IP 100 mg		
Mfg. Lic. No. :	31/UA/2013	Market:	DOMESTIC
Batch No. :	PN445A03	A. R. No.:	F20250107061
Mfg. Date :	Dec. 2024	Pack Size:	1x10 Tabs
Expiry date:	Nov. 2026	Pack Type:	Blister (Sale)
Batch Size :	200000 Tabs	Sampled On:	07/01/25
Product Code :	40068212	Sample Quantity:	90 Tabs
Specification No, Ver No.:	STS/FP/40068212-00	Sampled By:	DEOVRAT
Ref. STP No. , Ver No.:	STP/FP/0561	Analyzed By:	RAKESH VERMA
Manufactured For :	American Remedies Healthcare Pvt. Ltd.	Date of Analysis:	07/01/25
Manufactured By :	Pure & Cure Healthcare Pvt. Ltd.	Analysis Completion Date:	09/01/25

S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
1	Description	White to off white coloured, round, biconvex, both sides plain film coated tablets. 10 tablets packed in a blister of amber colour PVC film and printed aluminium foil	White coloured, round, biconvex, both sides plain film coated tablets. 10 tablets packed in a blister of amber colour PVC film and printed aluminium foil

	Prepared By QC	Reviewed By QC	Approved By QC
Date	09/01/25 22:13:38	09/01/25 22:27:45	09/01/25 22:44:09
Name	NITIN BHATT	MUKESH PRIYA	SHRAVAN
Designation	ASST. OPERATOR	SR. EXECUTIVE	ASST. MANAGER

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Name : SHUBHANK SINHA ; Date : 09/01/2025 22:51:49

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2	Identification	A. By IR : Compare the spectrum with that obtained with Labetalol Hydrochloride WS/RS treated in the same manner or with the reference spectrum of Labetalol. B. By HPLC: In the Assay, the principle peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.	Complies
3	Dimension	As below	As below

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S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
a.	Diameter	9.7 mm \pm 0.2 mm. (9.5 mm to 9.9 mm)	Min. 9.68 mm Max. 9.73 mm
b.	Thickness	3.9 mm \pm 0.4 mm. (3.5 mm to 4.3 mm)	Min. 3.99 mm Max. 4.09 mm
4	Average weight	292.0 mg \pm 5.0 %.	291.09 mg
5	Uniformity of weight	Not more than two of individual weight deviate from the average weight by more than 5% and none deviates by more than 10%.	-1.7% to +2.6%
6	Disintegration Time	Not more than 30 Minutes.	Passes (09 Minutes 40 Seconds)

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S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
7	Dissolution	Level S1 (No. of tablets Tested 6 units): Each unit is not less than 80 % (Q) which is equivalent to 85 % of the labelled amount is released. Level S2 (No. of tablets tested 6 units): Average of 12 units (S1 + S2) is equal to or greater than 80 % and no unit is less than 65 % (Q – 15 %). Level S3 (No. of tablets tested 12 units): Average of 24 units (S1 + S2 + S3) is equal to or greater than 80 % not more than 2 units are less than 65	96.19%, 95.08%, 95.08%, 99.22%, 91.50%, 94.53%
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S.No.	TEST	ACCEPTANCE CRITERIA		RESULTS
		% (Q – 15 %) and No unit is less than 55 % (Q – 25 %).		
8	Related Substances By TLC	Any secondary spot in the chromatogram obtained with the test solution is not more intense than the spot in the chromatogram obtained with reference solution (a) (1.0 per cent) and not more than one such spot is more intense than the spot in the chromatogram obtained with reference solution (b) (0.5 per cent)		Complies
9	Assay - Each film coated tablet contains:	Shelf Life Limit	Release Limit	

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	Labetalol Hydrochloride IP - 100 mg/Tab	NLT 95.00mg/Tab to NMT 105.00mg/Tab (NLT 95.00% to NMT 105.00% of label claimed)	NLT 97.00mg/Tab to NMT 105.00mg/Tab (NLT 97.00% to NMT 105.00% of label claimed)	99.67mg 99.67%

CONCLUSION : The Finished Product complies as per IP Specifications.

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