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. :	PN445A02	**A. R. No.:**	F20240926112
Mfg. Date :	Sep. 2024	**Pack Size:**	1x10 Tabs
Expiry date:	Aug. 2026	**Pack Type:**	Blister (Sale)
Batch Size :	100000 Tabs	**Sampled On:**	26/09/24
Product Code :	40068212	**Sample Quantity:**	90 Tabs
Specification No,Ver No.:	STS/FP/40068212-00	**Sampled By:**	RAMAN SINGH
Ref. STP No. , Ver No.:	STP/FP/0561	**Analyzed By:**	RAKESH VERMA
Manufactured For :	American Remedies Healthcare Pvt. Ltd.	**Date of Analysis:**	27/09/24
Manufactured By :	Pure & Cure Healthcare Pvt. Ltd.	**Analysis Completion Date:**	04/10/24

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	04/10/24	04/10/24	04/10/24
Name	UDAY	SACHIN CHAUHAN	YOGESH CHAUHAN
Designation	OPERATOR	DY. MANAGER	SR. MANAGER

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QA REVIEWED
Name : AVNEESH KUMAR ; Date : 04/10/2024

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S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
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 ± 0.2 mm. (9.5 mm to 9.9 mm)	Min. 9.63 mm Max. 9.67 mm
b.	Thickness	3.9 mm ± 0.4 mm. (3.5 mm to 4.3 mm)	Min. 3.91 mm Max. 3.97 mm
4	Average weight	292.0 mg ± 5.0 %.	290.75 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%.	-2.0% to +2.6%
6	Disintegration Time	Not more than 30 Minutes.	Passes (04 Minutes 54 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	95.71%, 97.64%, 95.16%, 97.36%, 97.09%, 98.46%

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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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S.No.	TEST	ACCEPTANCE CRITERIA		RESULTS
	Labetalol Hydrochloride IP - 100 mg/Tab	NLT 95.00mg/Tab to NMT 105.00mg/Tab (NLT 95.00% to NMT105.00% of label claimed)	NLT 97.00mg/Tab to NMT 105.00mg/Tab (NLT 97.00% to NMT105.00% of label claimed)	98.29mg 98.29%

CONCLUSION : The Finished Product complies as per IP Specifications.

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