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 :	BISOCOR 5 mg		
Generic Name :	Bisoprolol Fumarate Tablets USP		
Mfg. Lic. No. :	31/UA/2013	**Market:**	DOMESTIC
Batch No. :	PA2BG04	**A. R. No.:**	F20240119059
Mfg. Date :	Jan. 2024	**Pack Size:**	1x10 Tabs
Expiry date:	Dec. 2025	**Pack Type:**	Alu-Alu Blister (Sale)
Batch Size :	100000 Tabs	**Sampled On:**	19/01/24
Product Code :	40053741	**Sample Quantity:**	90 Tabs
Specification No,Ver No.:	STS/FP/40053741-00	**Sampled By:**	SOMESH UPADHAY
Ref. STP No. , Ver No.:	STP/FP/0221	**Analyzed By:**	ANKUSH KUMAR
Manufactured For :	Healing Pharma India Pvt. Ltd.	**Date of Analysis:**	19/01/24
Manufactured By :	Pure & Cure Healthcare Pvt. Ltd.	**Analysis Completion Date:**	20/01/24

S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
1	Description	Reddish brown coloured, round, biconvex & scored on one side and plain on other side film coated tablets. 10 tablets packed in an alu alu blister of printed aluminium foil & base aluminium foil.	Reddish brown coloured, round, biconvex & scored on one side and plain on other side film coated tablets. 10 tablets packed in an alu alu blister of printed aluminium foil & base aluminium foil.
2	Identification	By TLC: The RF value of the principal spot obtained from the test solution corresponds to that obtained from the Standard solution.	Complies
3	Dimension	As below	As below
a.	Diameter	7.1 mm ± 0.2 mm	Min. 7.05 mm Max. 7.09 mm
b.	Thickness	3.1 mm ± 0.4 mm	Min. 3.14 mm Max. 3.20 mm

	Prepared By QC	Reviewed By QC	Approved By QC
Date	20/01/24	20/01/24	20/01/24
Name	PRATEEK BHAGAT	SACHIN CHAUHAN	RAJESHWAR SINGH
Designation	ASST. OPERATOR	DY. MANAGER	DY. MANAGER

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QA REVIEWED
Name : AVNEESH KUMAR ; Date : 20/01/2024

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S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
4	Average weight	130.0 mg ± 7.5%	132.04 mg
5	Uniformity of weight	Not more than two of individual weight deviate from the average weight by more than 7.5% and none deviates by more than 15%.	-2.6% to +5.0%
6	Disintegration Time	Not more than 30 minutes	Passes (01 Minutes 11 Seconds)
7	Dissolution	Not less than 80% (Q) of the labeled amount of Bisoprolol Fumarate is dissolved in 20 Minutes.	92.70%, 98.54%, 98.33%, 102.76%, 100.26%, 97.72%

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S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
8	Uniformity of Dosage Units	The acceptance value of the first 10 dosage units shall be less than or equal to L1%. If the acceptance value is greater than L1%, test the next 20 units, and calculate the acceptance value. The requirements shall met if the final acceptance value of the 30 dosage units less than or equal to L1%, and no individual content of any dosage unit shall be less than [1-(0.01)(L2)] M not more than [1 + (0.01)(L2)] M Where, L1 is 15.0 and L2 is 25.0.	AV =8.6

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S.No.	TEST	ACCEPTANCE CRITERIA		RESULTS
9	**Assay - Each film coated tablet contains:**	**Shelf Life Limit**	**Release Limit**	
	Bisoprolol fumarate IP - 5 mg/Tab	NLT 4.500mg/Tab to NMT 5.250mg/Tab (NLT 90.00% to NMT105.00% of label claimed)	NLT 4.750mg/Tab to NMT 5.250mg/Tab (NLT 95.00% to NMT105.00% of label claimed)	4.871mg 97.42%

CONCLUSION : The Finished Product complies as per USP Specifications.

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