

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 IP 5 mg		
Mfg. Lic. No. :	31/UA/2013	Market:	DOMESTIC
Batch No. :	PA2BG06	A. R. No.:	F20240921015
Mfg. Date :	Sep. 2024	Pack Size:	1x10 Tabs
Expiry date:	Aug. 2026	Pack Type:	Alu-Alu Blister (Sale)
Batch Size :	100000 Tabs	Sampled On:	21/09/24
Product Code :	40053741	Sample Quantity:	90 Tabs
Specification No, Ver No.:	STS/FP/40053741-01	Sampled By:	HARSHIT JOSHI
Ref. STP No. , Ver No.:	STP/FP/0221	Analyzed By:	Shiv Prakash Singh
Manufactured For :	Healing Pharma India Pvt. Ltd.	Date of Analysis:	21/09/24
Manufactured By :	Pure & Cure Healthcare Pvt. Ltd.	Analysis Completion Date:	23/09/24

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	As below	As below
a.	By TLC	The principal spot in the chromatogram obtained with the test solution corresponds to the chromatogram obtained with the reference solution.	Complies

	Prepared By QC	Reviewed By QC	Approved By QC
Date	23/09/24	23/09/24	23/09/24
Name	NITIN BHATT	SACHIN CHAUHAN	RAJESHWAR SINGH
Designation	ASST. OPERATOR	DY. MANAGER	DY. MANAGER

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QA REVIEWED

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b.	By HPLC	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 (a).	Complies
3	Dimension	As below	As below
a.	Diameter	7.1 mm $\pm$ 0.2 mm (6.9 mm to 7.3 mm)	Min. 7.11 mm Max. 7.16 mm
b.	Thickness	3.1 mm $\pm$ 0.4 mm (2.7 mm to 3.5 mm)	Min. 3.17 mm Max. 3.20 mm
4	Average weight	130.0 mg $\pm$ 7.5%	130.81 mg

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5	Uniformity of weight	Not more than two of individual weight deviate from the average weight by more than $\pm 7.5\%$ and none deviates by more than $\pm 15\%$.	-1.3% to +1.8%
6	Disintegration Time	Not more than 30 minutes	Passes (50 Seconds)

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7	Uniformity of content (By HPLC)	The preparation complies with the test if each individual content is 85 to 115 per cent of the average content. The preparation fails to comply with the test if more than one individual content is outside these limits or if one individual content is outside the limits of 75 to 125 per cent of the average content. If one individual content is outside the limits of 85 to 115 per cent of the average content but within the limits of 75 to 125 per cent, repeat the determination using another 20	96.93% to 102.90%

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		dosage units. The preparation complies with the test if not more than one of the individual contents of the total sample of 30 dosage units is outside 85 to 115 per cent of the average content and none is outside the limits of 75 to 125 per cent of the average content.	

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8	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 % (Q – 15 %) and No unit is less than	1=99.18%, 2=98.48%, 3=99.67%, 4=98.48%, 5=98.23%, 6=99.23%, Min.98.23%, Max.99.67%, Mean 98.88%

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		55 % (Q – 25 %).		
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 NMT 105.00% of label claimed)	NLT 4.750mg/Tab to NMT 5.250mg/Tab (NLT 95.00% to NMT 105.00% of label claimed)	4.961mg 99.22%

CONCLUSION : The Finished Product complies as per IP Specifications.

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