

# 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)

<b>Product Name :</b>	IVAFOX 5 Tablets		
<b>Generic Name :</b>	Ivabradine Hydrochloride Tablets 5 mg		
<b>Mfg. Lic. No. :</b>	31/UA/2013	<b>Market:</b>	DOMESTIC
<b>Batch No. :</b>	PN445B02	<b>A. R. No.:</b>	F20241210126
<b>Mfg. Date :</b>	Nov. 2024	<b>Pack Size:</b>	1x10 Tabs
<b>Expiry date:</b>	Oct. 2026	<b>Pack Type:</b>	Blister (Sale)
<b>Batch Size :</b>	100000 Tabs	<b>Sampled On:</b>	10/12/24
<b>Product Code :</b>	40068211	<b>Sample Quantity:</b>	90 Tabs
<b>Specification No, Ver No.:</b>	STS/FP/40068211-00	<b>Sampled By:</b>	GAURAV KUMAR
<b>Ref. STP No. , Ver No.:</b>	STP/FP/0374	<b>Analyzed By:</b>	SHAHID
<b>Manufactured For :</b>	American Remedies Healthcare Pvt. Ltd.	<b>Date of Analysis:</b>	11/12/24
<b>Manufactured By :</b>	Pure & Cure Healthcare Pvt. Ltd.	<b>Analysis Completion Date:</b>	12/12/24

S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
1	Description	Orange coloured, round, biconvex, both side plain film coated tablet. 10 tablets packed in a blister of clear PVC film and printed aluminium foil.	Orange coloured, round, biconvex, both side plain film coated tablet. 10 tablets packed in a blister of clear PVC film and printed aluminium foil.
2	Identification	Positive for Ivabradine Hydrochloride.	Complies
3	Dimension	As below	As below
a.	Diameter	6.1 mm $\pm$ 0.2 mm. (5.9 mm to 6.3 mm)	Min. 6.05 mm Max. 6.10 mm
b.	Thickness	3.1 mm $\pm$ 0.4 mm. (2.7 mm to 3.5 mm)	Min. 2.97 mm Max. 3.04 mm

	Prepared By QC	Reviewed By QC	Approved By QC
<b>Date</b>	12/12/24 13:35:13	12/12/24 15:19:45	12/12/24 15:55:17
<b>Name</b>	NITIN BHATT	Arvind Kumar	UPENDRA KUMAR
<b>Designation</b>	ASST. OPERATOR	MANAGER	MANAGER

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QA REVIEWED  
Name : SHRI NIVAS ; Date : 12/12/2024 17:00:05

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4	Average weight	95.0 mg $\pm$ 7.5%	95.22 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%.	-3.7% to +4.7%
6	Disintegration Time	Not more than 30 minutes	Passes (05 Minutes 36 Seconds)

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7	Uniformity of content	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	99.68% to 100.47%

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		determination using another 20 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.		
8	Assay - Each film coated tablet contains:	Shelf Life Limit	Release Limit	

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S.No.	TEST	ACCEPTANCE CRITERIA		RESULTS
	Ivabradine Hydrochloride Eq. to Ivabradine - 5 mg/Tab	NLT 4.50mg/Tab to NMT 5.50mg/Tab  (NLT 90.00% to NMT110.00% of label claimed)	NLT 4.75mg/Tab to NMT 5.50mg/Tab  (NLT 95.00% to NMT110.00% of label claimed)	4.88mg 97.60%

**CONCLUSION :** The Finished Product complies as per IH Specifications.

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