



ALVENTA PHARMA LIMITED

VILL. KISHANPURA, BADDI- NALAGARH ROAD, DISTT.- SOLAN-174101 (H.P.)

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Ivasmart 5 mg	A.R. No.	FG/G/24A1116
Generic Name	Ivabradine Tablets 5 mg	Sample Quantity	150 Tablets
Batch No.:	AGT407120	Sample Received on	03/08/2024
Batch Size:	1.0 Lac	Analysis Date	03/08/2024
Mfg. Date.	07/2024	Release Date	12/08/2024
Exp. Date	06/2026	Page No.:	Page 1 of 1

Sr. No.	Test Parameter	Acceptance Criteria	Result		
1.	Description	White colour, round shaped, biconvex, having both side plain, film coated tablet.	White colour, round shaped, biconvex, having both side plain, film coated tablet.		
2.	Identification	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.	Complies		
3.	Average weight	143.00 mg ± 3.0%.	143.558 mg		
4.	Uniformity of weight	± 7.5% of its average weight.	Min: 138.38 mg ; Max: 147.96 mg -3.61% ; +3.07%		
5.	Disintegration	Not more than 30 minutes.	02 minutes 10 seconds.		
6.	Hardness	Not less than 4.0 Kg/cm ²	11.75 Kg/cm ²		
7.	Uniformity of content	The acceptance value (AV) calculated using 10 dosage units must be less than or equal to 15 (L1 =15, L2 =25)	3.08		
8.	Assay:				
	Each film coated tablet contains:	Claim	Limit	mg	%
	Ivabradine Hydrochloride Eq. to Ivabradine	5 mg	Between 90.0 % to 110.0 % of labeled amount. (Between 4.5 mg to 5.5 mg)	4.8708 mg	97.42 %
9.	Microbial Limit Tests:				
i.	Total aerobic microbial count	NMT 1000 cfu/g		30 cfu/g	
ii.	Total yeast and mould count	NMT 100 cfu/g		Less than 10 cfu/g	
iii.	Pathogens: Escherichia coli	Should be absent/g		Absent/g	

Remarks: The above test parameters are complies/ not complies as per IP/BP/USP & In-House Specification.

Particulars	Prepared By	Checked By	Approved By
Name	Praveen Kumar	Tanvej	Gautam Singh
Designation	Executive	Sr. Executive	Head-QA
Signature			
Date	12/08/2024	12/08/2024	12/08/2024