ALVENTA PHARMA LIMITED

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

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Tamsuheal 0.4 mg	**A.R. No.**	FG/G/24A01190
Generic Name	Tamsulosin HCl Modified Release Tablets	**Sample Quantity**	100 Tablets
Batch No.	AGT40804	**Sample Received on**	23/08/2024
Batch Size	2.0 Lac	**Analysis Date**	23/08/2024
Mfg. Date	08/2024	**Release Date**	28/08/2024
Exp. Date	07/2026	**Page No.**	Page 1 of 1

Sr. No.	Test Parameter	Acceptance Criteria	Result
1.	**Description**	White colour, round shaped, biconvex, both side plain, film coated tablet.	White colour, round shaped, biconvex, both side plain, film coated tablet.
2.	**Identification**	In the assay, the retention time of 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**	173.00 mg ± 3%	174.056 mg
4.	**Uniformity of weight**	± 7.5 % of its average weight.	Min: 169.86 mg ; Max: 175.52 mg - 2.41% ; + 0.84%
5.	**Hardness**	NLT 4.0 Kg/cm^2	9.83 Kg/cm^2
6.	**Uniformity of content (Tamsulosin HCl)**	The acceptance value (AV) calculated using 10 dosage units must be less than or equal to 15 (L1 =15, L2 =25)	12.70
7.	**Dissolution:**		
	2nd hour	15.00% to 40.00%.	Min. 28.39%, Max. 38.33%, Mean 31.66%
	6th hour	50.00% to 70.00%.	Min. 54.82%, Max. 71.33%, Mean 61.21%
	12th hour	Not less than 80.00% of labeled amount of Tamsulosin	Min. 80.97%, Max. 104.09%, Mean 89.37%
8.	**Assay: Each film coated modified release tablet contains:**		

Tamsulosin Hydrochloride IP	Claim	Limit	mg	%
	0.4 mg	Between 90.00 % to 110.00 % of stated amount (Between 0.36 mg to 0.44 mg)	0.39085 mg	97.71%

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		Tanvej	
Date	28/08/24	28/8/2024	28/08/2024