

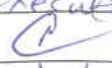
Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Tamsuheal 0.4 mg	A.R. No.	FG/G/24A0462
Generic Name	Tamsulosin HCl Modified Release Tablets	Sample Quantity	120 Tablets
Batch No.	AGT40596	Sample Received on	03/06/2024
Batch Size	2.0 Lac	Analysis Date	03/06/2024
Mfg. Date	05/2024	Release Date	10/06/2024
Exp. Date	04/2026	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 $\pm$ 3%	171.78 mg		
4.	Uniformity of weight	$\pm$ 7.5 % of its average weight.	Min: 168.45 mg ; Max: 176.33 mg - 1.97 ; + 2.65%		
5.	Hardness	NLT 4.0 Kg/cm ²	10.42 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)	4.65		
7.	Dissolution:				
	2 nd hour	15.00% to 40.00%.	Min. 23.87%, Max. 30.85%, Mean 29.06%		
	6 th hour	50.00% to 70.00%.	Min. 59.12%, Max. 67.90%, Mean 63.92%		
	12 th hour	Not less than 80.00% of labeled amount of Tamsulosin	Min. 81.31%, Max. 90.98%, Mean 86.87%		
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)	0.39221 mg	98.05%
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	Braveen Kumar	DURGESH KUMAR	Gautam Singh
Designation	Executive	QC Head	Head-QA
Signature			
Date	10/06/2024	10/06/2024	10/06/2024