



ALVENTA PHARMA LIMITED

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

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Dutaheal 0.5 mg	A.R. No.	FG/G/24A0109
Generic Name	Dutasteride Tablets 0.5 mg	Sample Quantity	60 Tablets
Batch No.	AGT40207	Sample Received on	09/02/2024
Batch Size	2.0 Lac	Analysis Date	09/02/2024
Mfg. Date	02/2024	Release Date	14/02/2024
Exp. Date	01/2026	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	174.0 mg ± 3%	176.693 mg		
4.	Uniformity of weight	± 7.5 % of its average weight.	Min: 173.01 mg ; Max: 178.33 mg - 2.08% ; + 0.93%		
5.	Hardness	NLT 4.0 Kg/cm ²	5.17 Kg/cm ²		
6.	Disintegration	Not more than 30 minutes.	02 minutes 48 seconds.		
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)	14.85		
8.	Assay:				
	Each film coated tablet contains:	Claim	Limit	mg	%
	Dutasteride IP	0.5 mg	Between 90.0 % to 110.0 % of stated amount (Between 0.45 mg to 0.55 mg)	0.5190 mg	103.80 %
9.	Microbial Limit Tests:				
i.	Total aerobic microbial count	NMT 1000 cfu/g	20 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	DURGESH KUMAR	Gautam Singh
Designation	Executive	QC Head	Head-BIA
Signature			
Date	14/02/2024	14/02/2024	14/02/2024