

QUALITY CONTROL DEPARTMENT

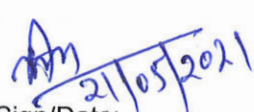
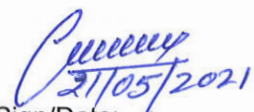

**CERTIFICATE OF ANALYSIS
(FINISHED PRODUCT)**

(Under Drugs &Cosmetics Act 1940 and Rules Made There Under)

Product Name	Dutanom	A.R. No.	: CF21-0532
Generic Name	Dutasteride Tablets 0.5 mg		
Batch No.	AT21467	Mfg. Date	: MAY.2021
Batch Size	3.0 Lac	Exp. Date	: APR.2023
Pack size	10 X 10 Tablets	Receipt Date	: 20/05/2021
Sample Qty.	50 Tablets	Release Date	: 21/05/2021
Manufactured for:	Naiom Healthcare		
Manufacturing Lic. No.	82/UA/2006		

Sr.No.	Tests	Specification	Results
1.	Description	White colour, round shape, biconvex, film coated tablets plane both side.	White colour, round shape, biconvex, film coated tablets plane both side.
2.	Identification	In the assay, the major peak in the chromatogram obtained with test-solution should be same retention time as that of the major peak in the chromatogram obtained with Dutasteride WS.	Complies
3.	Ave. weight of tablets	183 mg \pm 7.5%	183.56 mg
4.	Uniformity of weight	\pm 7.5% of the average weight	Within limit
5.	Uniformity of Content	NLT 85.0% to NMT 115.0%	93.41% to 104.56%
6.	Disintegration	Not more than 30 min	5 min
7.	ASSAY:		
Each film coated tablet contains:		Claim	Result
Dutasteride IP		0.5 mg	0.524 mg (104.80%)
			limit
			NLT 90% - NMT 110%

Opinion: in the opinion of the undersigned, the sample referred to above is of **STANDARD QUALITY** as per In-House Specification.

Analyzed by	Checked by:	Approved by
 Sign/Date: Officer QC	 Sign/Date: Executive QC	 Sign/Date: Manager QC

