

CERTIFICATE OF ANALYSIS

FINASTERIDE TABLETS IP 1 mg (FINPECIA TABLETS)

INSPECTION LOT NO. : 40000893291

DATE OF RELEASE : 29.12.2021

BATCH NO. : GH10844

MFG. DT. : Dec 2021

QTY : SAMPLE

EXP. DT. : Nov 2024

LIMS LOT NO. : 3586738

TEST	REFERENCE	UNIT	STANDARD	RESULT
DESCRIPTION	INHOUSE			Meets the requirement
Observation		-	White, circular, biconvex, film coated tablets, plain on both side.	Complies
IDENTIFICATION (BY HPLC)	IP_2.4.14			Meets the requirement
Observation		-	The retention time of the principal peak in the chromatogram of the Test solution corresponds to that in the chromatogram of the reference solution, as obtained in the test for Dissolution.	Complies
DISSOLUTION (BY HPLC)	IP_2.4.14			Meets the requirement
Dissolution		-		Pass
Minimum		%	Should meets the requirement of the final stage executed.	87
Maximum		%	Should meets the requirement of the final stage executed.	99
Average		%	Should meet the requirement of the final stage executed.	96
Stage 1		-	Each unit is not less than 75 % (D) + 5 % which is	Pass

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DISSOLUTION (BY HPLC)	IP_2.4.14			Meets the requirement
Stage 2		-	equivalent to 80 % of the labeled claim released in 45 minutes . Average of 12 units (S1 + S2) is equal to or greater than 75 % (D) . No unit is less than 60 % (D -15 %) .	Not Applicable
Stage 3		-	Average of 24 units (S1+ S2 + S3) is equal to or greater than 75 % (D). Not more than 2 units are less than 60 % (D-15 %) . No unit is less than 50 % (D- 25 %) .	Not Applicable
RELATED SUBSTANCES (BY HPLC)	IP_2.4.14			Meets the requirement
Impurity A		%	Not more than 0.3	0.1
Impurity B		%	Not more than 0.3	Not Detected
Impurity C		%	Not more than 0.3	0.1
Individual unknown impurity		%	Not more than 0.1	0.1
Total impurities		%	Not more than 0.6	0.2

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TEST	REFERENCE	UNIT	STANDARD	RESULT
UNIFORMITY OF CONTENT (BY HPLC)	IP_2.4.14			Meets the requirement
Range (10 units)		%		97 - 104
Average value (10 units)		%		101
Range (30 units)		%		Not Applicable
Average value (30 units)		%		Not Applicable
Observation		-	The tablets comply with the test if not more than one of the individual values from 10 tablets is outside the limits 85 % to 115 % of the average value and none is outside the limits 75 % to 125 %. If more than one of the individual values are outside the limits 85 % to 115 % of the average value repeat the determination using another 20 tablets. The tablets comply with the test if in the total sample of 30 tablets, not more than one of the individual values are outside the limits 85 % to 115 % and none is outside the	Complies

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TEST	REFERENCE	UNIT	STANDARD	RESULT
UNIFORMITY OF CONTENT (BY HPLC)	IP_2.4.14		limits 75 % to 125 % of the average value.	Meets the requirement
ASSAY (BY HPLC)	IP_2.4.14			Meets the requirement
Content of Finasteride		mg/tablet	Not less than 0.950 Not more than 1.050	0.992
Content of Finasteride		%	Not less than 95.0 Not more than 105.0	99.2
AVERAGE WEIGHT	INHOUSE			Meets the requirement
Average weight		g	Not less than 0.0751 Not more than 0.0830	0.0788
DISINTEGRATION	IP_2.5.1			Meets the requirement
Disintegration		MINUTES	Not more than 30	4

REMARK : COMPLIES WITH IP 2018 AND INHOUSE STANDARDS.

QUALITY CONTROL		QUALITY ASSURANCE	
Name	: Snehal Pawar (23076) (Head Unit Quality Control)	Name	: Arvind Lasune (33503) (Head Unit Quality Assurance)
Date	: 28.12.2021 17:31:38	Date	: 29.12.2021 18:46:21

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