Cipla

CERTIFICATE OF ANALYSIS

FINASTERIDE TABLETS IP 1 mg (Finpecia tablets)

INSPECTION LOT NO. : 40000653222
BATCH NO. : GH90931
QTY : SAMPLE

DATE OF RELEASE : 21.10.2019
MFG. DT. : Aug 2019
EXP. DT. : Jul 2022
LIMS LOT NO. : 3187157

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			**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			**Meets the requirement**
Dissolution		-		**Pass**
Minimum		%	Should meets the requirement of the final stage executed.	**90**
Maximum		%	Should meets the requirement of the final stage executed.	**96**
Average		%	Should meet the requirement of the final stage executed.	**93**
Stage 1		-	Each unit is not less than 75 % (D) + 5 % which is	**Pass**

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TEST	REFERENCE	UNIT	STANDARD	RESULT
DISSOLUTION (BY HPLC)	IP			**Meets the requirement**
			equivalent to 80 % of the labeled claim released in 45 minutes .	
Stage 2		-	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			**Meets the requirement**
Impurity A		%	NMT 0.3	**Not Detected**
Impurity B		%	NMT 0.3	**Not Detected**
Impurity C		%	NMT 0.3	**0.2**
Individual unknown impurity		%	NMT 0.1	**0.1**
Total impurities		%	NMT 0.6	**0.3**

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TEST	REFERENCE	UNIT	STANDARD	RESULT
UNIFORMITY OF CONTENT (BY HPLC)	IP			**Meets the requirement**
Range (10 units)		%		**97 - 104**
Average value (10 units)		%		**100**
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		limits 75 % to 125 % of the average value.	**Meets the requirement**
ASSAY (BY HPLC)	IP			**Meets the requirement**
Content of Finasteride (in mg per tablet)		mg/tablet	NLT 0.950 NMT 1.050	**1.011**
Content of Finasteride (in %)		%	NLT 95.0 NMT 105.0	**101.1**
AVERAGE WEIGHT	INHOUSE			**Meets the requirement**
Average Value		g	NLT 0.0751 NMT 0.0830	**0.0794**
DISINTEGRATION	INHOUSE			**Meets the requirement**
Disintegration		MINUTES	NMT 30	**3**
MICROBIOLOGICAL EXAMINATION OF NON STERILE PRODUCTS	INHOUSE (HARMONISED METHOD)			**Meets the requirement**
Microbiological Examination of Non Sterile Products		-	Should meets the requirement	**Complies**
MICROBIAL ENUMERATION TESTS				**Meets the requirement**
Total Aerobic Microbial Count		CFU/g	NMT 10^3	**< 10**

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TEST	REFERENCE	UNIT	STANDARD	RESULT
MICROBIAL ENUMERATION TESTS				**Meets the requirement**
Total Combined Yeasts and Molds Count		CFU/g	NMT 10^2	**< 10**
TESTS FOR SPECIFIED MICROORGANISMS				**Meets the requirement**
Escherichia coli		-	Should be Absent per g	**Absent**

REMARK : COMPLIES WITH IP 2018 AND INHOUSE STANDARDS.

QUALITY CONTROL

Name : Rajaram jarande (22983)
(Head Unit Quality Control)
Date : 21.10.2019 09:22:24

QUALITY ASSURANCE

Name : Arvind Lasune (33503)
(Head Unit Quality Assurance)
Date : 21.10.2019 14:18:41

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