Certificate of Analysis

Product name: **Dutasteride**

Number of analysis: T0007324

Batch number / Weight: **22E13-H07-00823 / 1g**

Producer / Producer Batch Number: Hetero Labs (Unit-I)/DR2103005

Analysed according to: **USP 43**

Tests	Requirement	Result	Unit	Standard remark
Appearance	White or pale yellow powder	Conform		
Identification A	Conform	Conform		IR-spectrum
Identification B	Conform	Conform		HPLC
Residue on ignition	<= 0,1	0,1	%	HPLC
Residual solvents	Conform	Conform		GC
Acetonitrile	<= 0,3	0,0	%	GC
Ethyl acetate	<= 0,2	0,2	%	GC
1,4-Dioxane	<= 0,1	0,0	%	GC
Heptane	<= 0,5	0,4	%	GC
Pyridine	<= 0,2	0,0	%	GC
Toluene	<= 0,2	0,0	%	GC
Organic impurities	Conform	Conform		HPLC; Procedure 1
Dutasteride dimethylamide	<= 0,2	0,0	%	HPLC; Procedure 1
Dutasteride methyl ester	<= 0,15	0,0	%	HPLC; Procedure 1
Dutasteride ethyl ester	<= 0,2	0,0	%	HPLC; Procedure 1
Dutasteride 17-a-5-ene	<= 0,2	0,0	%	HPLC; Procedure 1
Dutasteride 17a-epimer	<= 0,3	0,0	%	HPLC; Procedure 1
Chlorodutasteride	<= 0,4	0,0	%	HPLC; Procedure 1
Dutasteride 5-ene	<= 0,3	0,0	%	HPLC; Procedure 1
Any other individual unspecified impurity	<= 0,1	0,0	%	HPLC; Procedure 1
Organic impurities	Conform	Conform		HPLC; Procedure 2
Dihydrodutasteride	<= 0,15	0,0	%	HPLC; Procedure 2
Dutasteride a-dimer	<= 0,3	0,0	%	HPLC; Procedure 2
Dutasteride b-dimer	<= 0,5	0,0	%	HPLC; Procedure 2
Any other individual unspecified impurity	<= 0,1	0,0	%	HPLC; Procedure 2
Total impurities	<= 2,0	0,0	%	HPLC; Procedure 1 & 2
Water	<= 0,5	0,15	%	
Specific optical rotation	15,0 - 25,0	20,0	°	
Assay	97,0 - 102,0	99,5	%m/m	HPLC
TSE/BSE-statement	Conform	Conform		DP

Analysis performed by the authorized internal lab and by Fagron Inc.

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16/05/2022

Expiration: 02-2026

Conclusion: APPROVED

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