

Certificate of Analysis

Productname: **Finasteridum**
Number of analysis/Inspection Code: 1 / KEUR-186580B
Batchnumber: **20J01-F05-374297**
Reference code / No.: 4385 / 20200801
Analysed according to: **PH.EUR10.2**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white crystalline powder	Conform		
Identification	Conform	Conform		IR-spectrum
Specific optical rotation	+12,0 - +14,0	+13,0		Dried
Related substances	Conform	Conform		HPLC
Impurity A	<=0,3	0,1	%	
Impurity C	<=0,3	0,1	%	
Any other impurity	<=0,10	0,05	%	
Total impurities	<=0,5	0,4	%	
Loss on drying	<=0,5	0,2	%	105 °C
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Finasteride	98,0 - 102,0	100,3	%m/m	Dried; HPLC
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:
Paul Hofman
Pharmacist - Qualified Person

11/13/20

Expiration: 08-2022

Conclusion: APPROVED

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