

Certificate of Analysis

Product name: **Finasteridum**

Batch number / Weight: **21K27-B02-215548 / 1 G**

Analysed according to: **Ph. Eur.**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white crystalline powder	Conform		
Identification	Conform	Conform		
Specific optical rotation	+12,0 - +14,0	+13,0		
Related substances	Conform	Conform		
Impurity A	<=0,3	0,052	%	
Impurity C	<=0,3	0,11	%	
Any other impurity	<=0,10	0,07	%	
Total impurities	<=0,5	0,27	%	
Loss on drying	<=0,5	0,03	%	
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Finasteride	98,0 - 102,0	101,03	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer

Analysis performed by the authorized lab.

Release:
Agnieszka Pszczółka
Qualified Person

05-01-2022

Expiration: 03-10-2026

Conclusion: APPROVED

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