

Certificate of Analysis

Product name: **Finasteridum**

Batch number / Weight: **22B14-B09-219781 / 100 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	+12,9		
Related substances	Conform	Conform		
Impurity A	<=0,3	0,12	%	
Impurity C	<=0,3	<0,05	%	
Any other impurity	<=0,10	<0,05	%	
Total impurities	<=0,5	0,12	%	
Loss on drying	<=0,5	0,07	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Finasteride	98,0 - 102,0	99,24	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents:				
Methanol	<= 0,3	<0,0025	%	
Ethanol	<= 0,5	<0,0025	%	
Acetone	<= 0,5	<0,0025	%	
Ethylacetate	<= 0,5	<0,0025	%	
Tetrahydrofuran	<= 0,072	<0,0025	%	
Chloroform	<= 0,006	<0,0006	%	
1.4-dioxane	<= 0,038	<0,0025	%	
Toluene	<= 0,089	<0,00125	%	

Analysis performed by the authorized lab.

Release:

Agnieszka Pszczółka

Qualified Person

30-05-2022

Expiration: 01-11-2024

Conclusion: APPROVED

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