Certificate of Analysis

Product name: Finasteridum
Batch number / Weight: 25I16-B02-015713 / 10 g
Producer / Producer Batch Number: Hunan Yuxin Pharmaceutical Co., Ltd / FSD-20250401
Analyzed according to: Ph.Eur.11.8
Number of Analysis / Certificate no.: 25I16-B02 / QO0022821

	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white crystalline powder	Conform		
Identification	Conform	Conform		
Specific optical rotation	(+12,0) - (+14,0)	+12,8		
Related substances	Conform	Conform		
Impurity A	<=0,3	0,02	%	
Impurity C	<=0,3	0,02	%	
Any other impurity	<=0,10	0,03	%	
Total impurities	<=0,5	0,07	%	
Loss on drying	<=0,5	0,23	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		DP
Residual solvents	CPMP/ICH/82 260/06	Conform		DP
Assay	98,0 - 102,0	99,9	% m/m	
TSE/BSE-statement:	EMA/410/01 guidance compliant – no contamination	Conform		DP

All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab FSNE lab

Release:

20-10-2025
Dominika Sołtysik
Qualified Person

Expiration: 28-3-2030
Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.

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