Certificate of Analysis

Product name: Dutasteride
Batch number / Weight: 25E23-B15-011649 / 1 g
Producer / Producer Batch Number: Shakti Lifescience Pvt. Ltd. / DT025001
Analyzed according to: Ph. Eur. 11.7
Number of Analysis / Certificate no.: 25E23-B15 / QO0017314

	Requirement	Result	Unit	Standard remark
Appearance	white or pale yellow powder	Conform		
Identification	A, B	Conform		
Specific optical rotation	(+33,0) - (+39,0)	+35,28		
Related substances	Conform	Conform		
Test A				
Impurity A	<=0,2	0,00	%	
Impurity B	<=0,15	0,000	%	
Impurity C	<=0,2	0,00	%	
Impurity E	<=0,3	0,00	%	
Impurity F	<=0,4	0,05	%	
Impurity G	<=0,3	<0,05	%	
Unspecified impurities	<=0,10	<0,05	%	
Test B				
Impurity I	<=0,5	0,00	%	
Impurity H	<=0,3	0,00	%	
Unspecified impurities	<=0,10	0,07	%	
Total impurities	<=1,5	0,12	%	
Water	<=0,2	0,1	%	
Sulfated ash	<=0,1	0,04	%	
Assay	97,0 - 102,0	98,57	% m/m	
Metallic residues	CHMP/ICH/353369/2013	Conform		DP
Residual solvents	CPMP/ICH/82 260/06	Conform		DP
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials during	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:

24-6-2025
Dominika Sołtysik
Qualified Person

Expiration: 28-2-2029

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Certificate of Analysis

	Requirement	Result	Unit	Standard remark

Conclusion: APPROVED

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

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