

Certificate of Analysis

Product name: Dutasteride
Batch number / Weight: 26B06-B08-020962 / 1 g
Producer / Producer Batch Number: Swati Spentose Pvt.Ltd. / DTR/124027
Analyzed according to: Ph. Eur. 12.1
Number of Analysis / Certificate no.: 26B06-B08 / QO0030294

	Requirement	Result	Unit	Standard remark
Appearance	white or pale yellow powder	Conform		
Identification	A, B	Conform		
Specific optical rotation	(+33,0) - (+39,0)	+36,23		
Related substances (test A)	Conform	Conform		
Impurity A	<= 0,2	< 0,05	%	
Impurity B	<= 0,15	0,000	%	
Impurity C	<= 0,2	0,00	%	
Impurity E	<= 0,3	< 0,05	%	
Impurity F	<= 0,4	0,00	%	
Impurity G	<= 0,3	< 0,05	%	
Unspecified impurities	<= 0,10	< 0,05	%	
Related substances (test B)	Conform	Conform		
Impurity I	<= 0,5	0,00	%	
Impurity H	<= 0,3	0,00	%	
Unspecified impurities eluting after dutasteride	<= 0,10	0,063	%	
Total impurities (for tests A and B)	<= 1,5	0,06	%	
Water	<= 0,2	0,05	%	
Sulfated ash	<= 0,1	0,09	%	
Assay	97,0 - 102,0	99,05	% 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:

25-3-2026
 Agnieszka Pszczółka
 Qualified Person

Expiration: 30-11-2029

Conclusion: APPROVED

Certificate of Analysis

Requirement	Result	Unit	Standard remark
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