

## Certificate of Analysis

**Product name:** **Dutasteride**  
**Batch number / Weight:** **22A15-B03-223359 / 1 G**  
**Analysed according to:** **Ph. Eur. 10.8**  
**Number of analysis / Inspection Code** **22A15-B03 / INS-22-5000**  
**Reference Code / No.:** **V01382 / DT210703**

Tests	Requirement	Result	Unit	Standard remark
Appearance	white or pale yellow powder	Conform		
Identification	Conform	Conform		
Specific optical rotation	(+33,0) - (+39,0)	+37,8		
Related substances	Conform	Conform		
Test 1			%	
Impurity A	$\leq 0,2$	0,09	%	
Impurity B	$\leq 0,15$	$< 0,05$	%	
Impurity C	$\leq 0,2$	$< 0,05$	%	
Impurity E	$\leq 0,3$	0,11	%	
Impurity F	$\leq 0,4$	0,18	%	
Impurity G	$\leq 0,3$	$< 0,05$	%	
Unspecified impurities	$\leq 0,10$	$< 0,05$	%	
TEST B				
Impurity I	$\leq 0,5$	$< 0,05$	%	
Impurity H	$\leq 0,3$	$< 0,05$	%	
Unspecified impurities	$\leq 0,10$	$< 0,05$		
Total impurities	$\leq 1,5$	0,38	%	
Water	$\leq 0,2$	$< 0,1$		
Sulphated ash	$\leq 0,1$	$< 0,01$	%	
Assay	97,0 - 102,0	99,8	%m/m	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents				
Acetonitrile	$\leq 410$	25	ppm	
Ethanol	$\leq 5000$	2224	ppm	
Dichlorometane	$\leq 600$	$< 10$	ppm	

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Methanol	<=3000	<25	ppm
Dioxane	<=380	<25	ppm
Pyridine	<=200	<4	ppm
Toluene	<=890	<12,5	ppm

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 ElSpol, Eurofins

Release:

Ewelina Gadzinowska

Qualified Person

09-09-2022

Expiration: 18-07-2024

Conclusion: APPROVED

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