

Certificate of Analysis

Product name: Dutasteride
Batch number: 20C25-B01-197313
Base unit: 1g
Expiration date: 31.12.2023
Quality: Ph. Eur.
Manufacturing date: 15.04.2020
Inspection report no.: INS-20-01462
Manufacturer: Swati Spentose Pvt. Ltd.
Manufacturer's batch number: DTR/120007

Parameter	Limit value	Result	Unit	Laboratory
Appearance	white or pale yellow powder	conform		Fagron Poland
Identification	acc. to Ph. Eur	conform		Fagron Poland
Specific optical rotation	+33,0 to (+39,0)	+35,6		Fagron Poland
Related substances	Method A:			
	Impurity F: $\leq 0,4 \%$	0,0		
	Impurity E: $\leq 0,3 \%$	<0,05		
	Impurity G: $\leq 0,3 \%$	<0,05		
	Impurity A: $\leq 0,2 \%$	<0,05		
	Impurity C: $\leq 0,2 \%$	0,0		
	Impurity B: $\leq 0,15 \%$	0,0		
	Method B:			
	Impurity I: $\leq 0,5 \%$	0,0		
	Impurity H: $\leq 0,3 \%$	0,0		
	Unspecified impurities: $\leq 0,10\%$	0,08		
	Unspecified impurities eluting after dutasteride: $\leq 0,10 \%$	0,07		
	Total impurities (Method A + Method B): $\leq 2,0 \%$	0,15		
Water	$\leq 0,2 \%$	0,04	%	data producer
Sulfated ash	$\leq 0,1 \%$	0,04	%	Fagron Poland
Assay (anhydrous substance)	97,0-102,0 %	99,45	%	Fagron Poland
Elementar impurities	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

Analysis performed by the laboratory: Fagron Poland.

Release:
 Dominika Sołtysik
 Qualified Person



Fagron sp. z o.o.
 Dominika Sołtysik
 osoba wykwalifikowana
 qualified person

Date of releasing: 29.04.2020
 Conclusion: Approved