

Certificate of Analysis

Product name: Dutasteride
Batch number: 19K20-B03-195640
Base unit: 1g
Expiration date: 30.09.2023
Quality: Ph. Eur.
Manufacturing date: 09.12.2019
Inspection report no.: INS-19-05039
IIN: 105816-114-91

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:			Fagron Poland
	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: $\leq 0,10\%$	0,05		
	Unspecified impurities eluting after dutasteride: $\leq 0,10 \%$	<0,05		
	Total impurities (Method A + Method B): $\leq 2,0 \%$	0,05		
Water	$\leq 0,2 \%$	0,17	%	data producer
Sulfated ash	$\leq 0,1 \%$	0,03	%	Fagron Poland
Assay (anhydrous substance)	97,0-102,0 %	98,86	%	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: 25.02.2020

Conclusion: Approved