Fagron

Certificate of Analysis

Product name: Dutasteride
Batch number: 21H12-B02-214492
Base unit: 1g
Expiration date: 12.07.2024
Quality: Ph. Eur.
Manufacturing date: 29.09.2021
Inspection report no.: INS-21-4247
Manufacturer: Hubei Gedian Humanwell Pharmaceutical Co., Ltd.
Manufacturer's batch number: DT210702

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)	+36,3		Fagron Poland
Related substances	Method A: Impurity F: ≤ 0,4 % Impurity E: ≤ 0,3 % Impurity G: ≤ 0,3 % Impurity A: ≤ 0,2 % Impurity C: ≤ 0,2 % Impurity B: ≤ 0,15 % Method B: Impurity I: ≤ 0,5 % Impurity H: ≤ 0,3 % Unspecified impurities: ≤ 0,10% Unspecified impurities eluting after dutasteride: ≤ 0,10 % Total impurities (Method A + Method B): ≤ 2,0 %	 0,12 0,05 0,00 0,10 0,00 <0,05 <0,05 0,00 <0,05 <0,05 0,27	%	Fagron Poland
Water	≤ 0,2 %	0,1	%	Eurofins
Sulfated ash	≤ 0,1 %	0,01	%	Fagron Poland
Assay (anhydrous substance)	97,0-102,0 %	99,33	%	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 and Eurofins.

Release:
Dominika Sołtysik
Qualified Person

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

Date of releasing: 27.10.2021
Conclusion: Approved