

Certificate of Analysis

Product name: Pilocarpine Hydrochloride
Batch number: 19E20-B13-190791
Base unit: 1g
Expiration date: 15.03.2024
Quality: Ph.Eur.
Manufacturing date: 07.06.2019
Inspection report no.: INS-19-02013
IIN: 100913-114-91

Description	Claim	Result	Unit	Laboratory
Appearance	White or almost white, crystalline powder or colourless crystals, hygroscopic	conform		Fagron Poland
Melting point	About 203 °C	203,3	°C	Fagron Poland
Identification A	acc. to Ph. Eur.	conform		Fagron Poland
Identification B	acc. to Ph. Eur.	conform		Fagron Poland
Identification D	acc. to Ph. Eur.	conform		Fagron Poland
Appearance of solution	acc. to Ph. Eur.	conform		Fagron Poland
pH	3,5 - 4,5	3,94		Fagron Poland
Specific optical rotation	+89 - +93	+91,98		Fagron Poland
Related substances	Impurity A: max. 1% Sum of impurity A and B: max. 1,5% Sum of impurities other than A and B: max. 0,5%	<0,2 <0,2 <0,2	%	Fagron Poland
Iron	max. 10 ppm	<10	ppm	Fagron Poland
Loss on drying	max. 0,5%	0,02	%	Fagron Poland
Sulfated ash	max. 0,1%	0,01	%	Fagron Poland
Assay Pilocarpine Hydrochloride	99,0 – 101,0%	100,39	%	Fagron Poland
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

Analysis performed by the laboratory: Fagron Poland.

Release:
 Dorota Sutkowska
 Qualified Person



Fagron sp. z o.o.
Dorota Sutkowska
Dorota Sutkowska
 osoba wykwalifikowana
 qualified person

Date of releasing: 18.06.2019

Conclusion: Approved