

Certificate of Analysis

Product name: Pilocarpini Hydrochloridum

Batch number: 20E28-B02-201930

Base unit: 1g

Expiration date: 14.02.2025

Quality: Ph.Eur.

Manufacturing date: 07.08.2020

Inspection report no.: INS-20-02326

IIN: 100913-114-91

Description	Claim	Result	Unit	Laboratory
Appearance	White or almost white, crystalline powder or colourless crystals, hygroscopic	conform		
Melting point	About 203 °C	202,5	°C	
Identification A	acc. to Ph. Eur.	conform		
Identification B	acc. to Ph. Eur.	conform		
Identification D	acc. to Ph. Eur.	conform		
Appearance of solution	acc. to Ph. Eur.	conform		
pH	3,5 - 4,5	3,56		
Specific optical rotation	+89 - +93	+91,0		
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 0,0	%	
Iron	max. 10 ppm	<10	ppm	
Loss on drying	max. 0,5%	0,03	%	
Sulfated ash	max. 0,1%	0,005	%	
Assay	99,0 – 101,0%	100,33	%	
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:

Dominika Sołtysik

Qualified Person



Fagron sp. z o.o.

Dominika Sołtysik

osoba wykwalifikowana
qualified person

Date of releasing: 13.08.2020

Conclusion: Approved