

## Certificate of Analysis

**Product name:** **Pilocarpini hydrochloridum**

**Batch number / Weight:** **22H16-B10-222952 / 1 G**

**Analysed according to:** **Ph.Eur.10.8**

**Number of analysis / Inspection Code** **22H16-B10 / INS-22-7356**

**Reference Code / No.:** **V01667 / VC-2004**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder or colorless crystals	Conform		
Melting point	about 203 °C	203,96	°C	
Identification	Conform	C		
Identification A	+89 - +93 (dried substance)	Conform		
Identification B	Conform	Conform		
Identification D	Conform	Conform		
Appearance of solution	Clear / <= Y7	Conform		
pH	3,5 - 4,5	3,91		
Specific optical rotation	+89 - +93 (dried substance)	+91,0		
Related substances	Conform	Conform		
Impurity A	<=1	0,13	%	
Sum of impurities A and B	<=1,5	0,13	%	
Sum of impurities other than A and B	<=0,5	<0,2	%	
Iron	<=10	<10	ppm	
Loss on drying	<=0,5	0,13	%	
Sulphated ash	<=0,1	0,03	%	
Assay Pilocarpine hydrochloride	99,0 - 101,0 (dried substance)	100,42	%m/m	
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
Residual solvents				
Methanol	<=600	<600	ppm	
Toluene	<=100	<100	ppm	
Dichloromethane	<=500	<500	ppm	
Acetone	<=500	<500	ppm	

fagron.pl

Fagron Sp. z o.o.  
 ul. Armii Krajowej 3  
 32-540 Trzebinia, Poland  
 e-mail: biuro@fagron.pl

**fagron.pl**

Fagron sp. z o.o.  
 ul. Pasternik 26, 31-354 Kraków, Poland  
 tel.: +48 12 3343 512  
 e-mail: biuro@fagron.pl

All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab Fagron PL lab

Release:

Agnieszka Pszczółka

Qualified Person

21-10-2022

Expiration: 10-10-2025

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.

fagron.pl

Fagron Sp. z o.o.  
ul. Armii Krajowej 3  
32-540 Trzebinia, Poland  
e-mail:biuro@fagron.pl