

## Certificate of Analysis

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

**Batch number / Weight:** **21K12-B19-218784 / 1 G**

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

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder or colorless crystals	Conform		
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	3,83		
Specific optical rotation	+89 - +93 (dried substance)	+90,9		
Related substances	Conform	Conform		
Impurity A	<=1	0,18	%	
Sum of impurities A and B	<=1,5	0,18	%	
Sum of impurities other than A a	<=0,5	<0,2	%	
Iron	<=10	Conform	ppm	
Loss on drying	<=0,5	0,07	%	
Sulphated ash	<=0,1	0,05	%	
Assay Pilocarpine hydrochloride	99,0 - 101,0 (dried substance)	100,7	%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

Analysis performed by the authorized lab.

Release:  
Ewelina Gadzinowska  
Qualified Person

30-03-2022

Expiration: 23-10-2025

Conclusion: APPROVED

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