

Certificate of Analysis

Product name: **Pilocarpini hydrochloridum**
Batch number / Weight: **21K12-B19-216778 / 1 G**
Analysed according to: **Ph.Eur.**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder or colorless crystals	Conform		
Identification	Conform	Conform		
Identification B	Conform	Conform		
Identification D	Conform	Conform		
Appearance of solution	Clear / $\leq Y7$	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	$\leq 1,5$	0,18	%	
Sum of impurities other than A and B	$\leq 0,5$	$< 0,2$	%	
Iron	≤ 10	Conform	ppm	
Loss on drying	$\leq 0,5$	0,07	%	
Sulphated ash	$\leq 0,1$	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

21-01-2022

Expiration: 23-10-2025

Conclusion: APPROVED

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