

Certificate of Analysis

Product name: **Pilocarpini hydrochloridum**
Batch number / Weight: **21E07-B04-213098 / 1 G**
Analysed according to: **Ph. Eur.**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder or colorless crystals	Conform		
Melting point	about 203 °C	203,5	°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	4,04		
Specific optical rotation	+89 - +93 (dried substance)	+89		
Related substances	Conform	Conform		
Impurity A	<=1	<0,2	%	
Sum of impurities A and B	<=1,5	<0,2	%	
Sum of impurities other than A and B	<=0,5	<0,2	%	
Iron	<=10	<=10	ppm	
Loss on drying	<=0,5	<0,01	%	
Sulphated ash	<=0,1	0,07	%	
Assay Pilocarpine hydrochloride	99,0 - 101,0 (dried substance)	99,7	%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
Total aerobic microbial count (TAMC)	<=10 ⁴	<1	CFU/g	
Total yeasts and moulds (TYMC)	<=10 ²	<1	CFU/g	

Analysis performed by the authorized lab.

Release:
 Ewelina Gadzinowska
 Qualified Person

11-08-2021

Expiration: 23-10-2025

Conclusion: APPROVED

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