

Certificate of Analysis

Product name: **Pilocarpini hydrochloridum**

Batch number / Weight: **22L06-B04-225269 / 1 G**

Analysed according to: **Ph.Eur.11.0**

Number of analysis / Inspection Code **22L06-B04 / INS-22-10325**

Reference Code / No.: **V01667 / VC-2106**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder or colorless crystals	Conform		
Identification A	+89 - +93 (dried substance)	91,0		
Identification B	Conform	Conform		
Identification D	Conform	Conform		
Melting point	about 203 °C	203,5	°C	
Appearance of solution	Clear / <= Y7	Conform		
pH	3,5 - 4,5	3,95		
Specific optical rotation	+89 - +93 (dried substance)	+91,0		
Related substances	Conform	Conform		
Impurity A	<=1	0,24	%	
Sum of impurities A and B	<=1,5	0,24	%	
Sum of impurities other than A and B	<=0,5	0,00	%	
Iron	<=10	<10	ppm	
Loss on drying	<=0,5	0,13	%	
Sulphated ash	<=0,1	0,00	%	
Assay Pilocarpine hydrochloride	99,0 - 101,0 (dried substance)	99,60	%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
Toluene	<=100	<100	ppm	
Dichloromethane	<=500	<500	ppm	
Acetone	<=500	<500	ppm	

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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,CBMiA

Release:

Agnieszka Pszczółka

Qualified Person

12-01-2023

Expiration: 28-06-2027

Conclusion: APPROVED

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