

Certificate of analysis



Article	5526	Pilocarpinhydrochlorid, API	
Synonym		Pilocarpini hydrochloridum	
Synonym		Pilocarpine hydrochloride, API	
Batch	23000207		
Specification	Ph.Eur.10.0		
Production date	12.2022	Retest date	12.2027

Test	Specification	Result	
Characters	According to specification	Complies	
Appearance	According to specification	Complies	
Solubility	According to specification	Complies	
Identification	According to specification	Complies	
A	According to specification	Complies	
IR spectrophotometry	According to specification	Complies	
D	According to specification	Complies	
Tests	According to specification	Complies	
Appearance of solution	According to specification	Complies	
pH-Value	3,5 ... 4,5	4,0	
Specific optical rotation	89 ... 93	91	
Related substances	According to specification	Complies	#
Impurity A	Max. 1 %	< 1 %	#
Sum of impurities A a. B	Max. 1,5 %	0,2 %	#
Sum of all impurities except A and B	Max. 0,5 %	< 0,2 %	#
Iron	Max. 10 ppm	< 10 ppm	#
Loss on drying	Max. 0,5 %	0,2 %	
Sulphated ash	Max. 0,1 %	< 0,1 %	#
Assay	99,0 ... 101,0 %	100,4 %	
Correction factor weighing (f, NRF)		0,998	
Complies specification		Yes	

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Production date	12.2022	Retest date	12.2027

Release date	06.03.2023	Released by	Frau Apoth. Dr. Schücker, QP
Manufacturer	SOURCETECH QUIMICA LTDA		
Manufacturer batch	22CL04		
Manufacturer street	Rodovia Vereador Abel Fabricio Dias 3430		
Manufacturer city	12402-020 Pindamonhangaba, Sao Paulo		
Manufacturer country	Föderative Republik Brasilien		

GMP-compliant production and testing of the active pharmaceutical ingredients

Results marked with # were taken from the manufacturer's certificate.

The batch 23000207 complies specification.

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