



QUÍMICA LTDA

CERTIFICATE OF ANALYSIS

Pilocarpine Hydrochloride (USP, Ph. Eur.)			
Batch Number: 22CL02	DMF: 016873	Production Date: 09/Dec/2022	Expiration Date: 08/Dec/2027
Purchase Order Number: 16350822-105	CEP: R1-CEP 1997-034 Rev 04	Analysis Date: 12/Dec/2022	

Tests	Method	Specifications	Unit	Results
Identification				
Test A - Infrared Absorption	USP	Pass Test		Pass Test
Test B - Chloride	USP	Pass Test		Pass Test
Test B - Infrared Absorption	Ph.Eur. 10.8	Pass Test		Pass Test
Test D - Reaction of chlorides	Ph.Eur. 10.8	Pass Test		Pass Test
Character	Ph.Eur. 10.8	White or almost white crystalline powder or colorless crystals, hygroscopic		Pass Test
	USP	Colorless, translucent, and odorless. Is hygroscopic and affected by light.		Pass Test
Solubility	Ph.Eur. 10.8	Very soluble in water and freely soluble in ethanol (96 percent).		Pass Test
	USP	Very soluble in water, freely soluble in ethanol (96 percent), slightly soluble in chloroform and insoluble in ether		
Appearance of solution	Ph.Eur. 10.8	Clear and not more intensely coloured than reference solution Y?	-	Pass Test
Acidity	Ph.Eur. 10.8	pH 3.5 to 4.5	-	3.9
Melting range	Ph.Eur. 10.8	~ 203	°C	202-204
Specific optical rotation	USP	Between +88.5 and +91.5	°	+90.0
	Ph.Eur. 10.8	Between +89.0 and +93.0		+91.0
Loss on drying (105°C)	USP	NMT 3.0	%	0.11
	Ph.Eur. 10.8	NMT 0.5		
Related Substances				
Isopilocarpine	Ph.Eur. 10.8	NMT 1.0	%	0.2
Isopilocarpine + Pilocarpic acid		NMT 1.5		<0.2
Total other impurities		NMT 0.5		<0.2
Readily carb. Substances	USP	The solution has no more color than matching Fluid B	-	Pass Test
Other alkaloids	USP	No turbidity is produced in either solution	-	Pass Test
Iron	Ph.Eur. 10.8	Color in Test Solution NMT 10 ppm (standard)	-	Pass Test
Sulphated Ash	Ph.Eur. 10.8	NMT 0.1	%	0.04
Assay	Ph.Eur. 10.8	99.0 to 101.0 on a dry basis	%	100.6
	USP	98.0 to 102.0 on a dry basis		101.5
Related Substances				
Isopilocarpine (RRT = 0.94)	USP	NMT 1.0	%	0.1
Pilocarpic Acid (RRT = 1.15)		NMT 0.5		<0.05
Isopilocarpic Acid (RRT = 1.19)		NMT 0.1		<0.05
Any unspecified impurity		NMT 0.1		0.06
Total impurities		NMT 1.0		0.3
Sourcotech in-house, validated and non-compendial tests				
Character or Appearance	In House	White Crystalline powder or colorless crystals, hygroscopic	-	Pass Test
Assay (RRT = 1.0)	In House	99.0 to 101.0 on a dry basis	%	100.8
Residual solvents				
Chloroform	In House	NMT 60	ppm	<0.3
Ethanol		NMT 1000		83.9
Acetone		NMT 1000		33.7
Ethyl Ether		NMT 1000		<1000
Related Substances				
Isopilocarpine (RRT = 0.92)	In House	NMT 0.40	%	0.2
Pilocarpic Acid (RRT = 1.30)		NMT 0.10		<0.01
Isopilocarpic Acid (RRT = 1.62)		NMT 0.10		<0.01
Each Unknown Impurity		NMT 0.06		<0.01
Total Known & Unknown Impurities		NMT 1.00		0.2

Conclusion:	Approved	Date: December 12, 2022
Packaging and Storage:	Preserve in tight, light-resistant containers. Store at room temperature.	
Observation:	For ophthalmic usage only.	

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Quality Responsible

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Responsible Chemist