

LUE 26-B01

Director Técnico



CERTIFICATE OF ANALYSIS

Pilocarpine Hydrochloride

Batch Number: 14CB01	Production Date: 08/Feb/2014	Expiration Date: 07/Feb/2019
Purchase Order Number: 540-5087377-UG-HEI	DMF: 16873	Analysis Date: 12/Feb/2014

Tests	Method	Specifications	Unit	Results
Identification				
Test A, B	USP	Pass	-	Pass test
Test B, D	Ph.Eur.	Pass	-	Pass test
Character	Ph.Eur.	White or almost white crystalline powder or colorless crystals, hygroscopic	-	Pass test
Appearance of solution	Ph.Eur.	Clear and not more intensely coloured than reference solution Y ₇	-	Pass test
Acidity	Ph.Eur.	pH 3.5 to 4.5	-	3.9
Melting range	Ph.Eur.	~ 203	-	202-204
Specific rotation	USP	Between +88.5 and +91.5	-	+90.0
Specific optical rotation	Ph.Eur.	Between +89.0 and +93.0	-	
Loss on drying (105°C)	USP	Dry at 105° for 2 hours: NMT 3% of its weight	%	0.05
Loss on drying (105°C)	Ph.Eur.	NMT 0.5		
Related Substances				
Isopilocarpine	Ph.Eur.	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.	NMT 10	ppm	Pass test
Sulphated Ash	Ph.Eur.	NMT 0.1	%	0.01
Assay				
	Ph.Eur.	99.0 to 101.0 on a dry basis	%	99.9
	USP	98.0 to 102.0 on a dry basis	%	100.5
Related Substances				
Isopilocarpine (RRT = 0.94)	USP	NMT 1.0	%	0.11
Pilocarpine Acid (RRT = 1.15)		NMT 0.5		<0.05
Isopilocarpine Acid (RRT = 1.19)		NMT 0.1		<0.05
Any unspecified impurity		NMT 0.1		<0.05
Total impurities		NMT 1.0		0.11

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	%	99.7
Residual solvents				
Chloroform	In House	NMT 60	ppm	<1.0
Ethanol		NMT 1000		7.5
Acetone		NMT 1000		1.1
Related Substances				
Isopilocarpine (RRT = 0.92)	In House	NMT 0.40	%	0.15
Pilocarpine Acid (RRT = 1.30)		NMT 0.10		<0.06
Isopilocarpine Acid (RRT = 1.62)		NMT 0.10		<0.06
Each Unknown Impurity		NMT 0.06		<0.06
Total Known & Unknown Impurities		NMT 1.00		0.15

Conclusion: Approved
Packaging and Storage: Preserve in tight, light-resistant containers. Store at room temperature (USP).
In an airtight container, protected from light (EP).
Solubility: Easy soluble at water and ethanol, practically insoluble at ether.

Responsible Chemist
CRQ n° 04116024

Jonas Oliveira de Mello
Responsible of Unit Quality
CRQ n° 04363753

Date of Approval: 19/MAR/2014

Anexo 04 do POP-87.08

Certificate of Analysis - Pilocarpine Hydrochloride (USP/Ph.Eur.)

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