

## CERTIFICATE OF ANALYSIS

### Pilocarpine Hydrochloride, USP, EP

Batch Number: **10 CD 04**

Purchase Order Number: **13416**

Analysis Date: **16/04/10**


DMF: **16873**


Tests	Specifications	Units	Results
Character	White or almost white crystalline powder or colorless crystals [EP]		Pass test
Identity	Complies with tests [EP]		Pass test
Appearance of solution	Clear and not more intensely coloured than reference solution Y <sub>7</sub> [EP]		Pass test
Acidity	pH 3.5 to 4.5 [EP]		4.0
Melting range	Between 199° and 205 [USP] ~ 203 [EP]	°C	203-205
Specific optical rotation	Between +88.5° and +91.5° [USP] Between +89.0° and +93.0° [EP]	°	+90.0
Loss on drying	NMT 3.0 [USP] NMT 0.5 [EP]	%	0.08
Related Substances:			
Isopilocarpine	≤ 1 [EP]	%	0.07
Isopilocarpine + Pilocarpic acid	≤ 1.5 [EP]	%	0.07
Total other impurities	≤ 0.5 [EP]	%	n.d.
Readily carbonizable substances	The solution has no more color than matching Fluid B [USP]		Pass test
Chloride reaction	Reaction [USP, EP]		Pass test
Other alkaloids	No turbidity is produced in either solution [USP]		Pass test
Iron	NMT 10 [EP]	ppm	Pass test
Sulphated Ash	NMT 0.1 [EP]	%	0.03
Assay	98.5 to 101.0 on a dry basis [USP] 99.0 to 101.0 on a dry basis [EP]	%	99.9 99.9
<b>Sourcotech in-house, validated and non-compendial tests</b>			
Residual solvents (OVI)	Chloroform: NMT 60 Ethanol: NMT 0.1 Acetone: NMT 0.01	ppm % %	n.d. 0.003 0.0001
HPLC Impurities	Pilocarpine HCl (RRT = 1.0) Known Impurity: Isopilocarpine (RRT = 0.92); NMT 0.40 Pilocarpine Acid (RRT = 1.30); NMT 0.10 Isopilocarpine Acid (RRT = 1.62); NMT 0.10 Each Unknown Impurity: NMT 0.05 Total Known & Unknown Impurities: NMT 1.00	%	99.9 0.07 n.d. n.d. n.d. 0.07

Conclusion: **Approved**

Production Date: **16/04/2010**

Validity: **5 years from production date, under good storage conditions.**

  
**Ricardo Kooli Teramoto**  
Responsible Chemist  
CRQ n° 04116024

  
**Demetrio da Mota Lima**  
Responsible of Q.C.  
CRQ n° 04200249