



Certificate of Analysis

FARMADENT d.o.o.
Minarikova ul. 6
2000 Maribor
Prejel: FUJS DRAGO

Datum prejema: 12.6.2013
Pregledal: MAROLT Robert, mag. farm., spec.

Datum pregleda: 13.6.2013

Productname: **Pilocarpini hydrochloridum**
Number of analysis/Inspection Code: 1 / KEUR-63367B
Batchnumber: **10E03-B06** ✓
Reference code / No.: 2135 / 10 CB 04
Analysed according to: **PH.EUR 6.7**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		Hygroscopic t
Identification A	+89 - +93	Conform	°	Specific rotation
Identification B	Conform	Conform		IR-spectrum
Identification E	White	Conform		Chloride
Appearance of solution	Clear / \leq Y7	Conform		5% m/V
pH	3,5 - 4,5	3,9		5% m/V
Spezifische Drehung	+89 - +93	90	°	5% m/V; dried
Related substances	Conform	Conform		HPLC
Iron	\leq 10	Conform	ppm	
Loss on drying	\leq 0,5	\leq 0,1	%	105 °C
Sulphated ash	\leq 0,1	Conform	%	
Assay Pilocarpine hydrochloride	99,0 - 101,0	99,4	%m/m	Dried
Residual solvents	CPMP/ICH/283/95	Conform		
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		

Release:
Drs. M.V. Garcia Alia
Pharmacist - QA Manager / QP

09-06-10

Expiration: 05-2015 ✓

Conclusion: APPROVED

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