



Certificate of Analysis

FARMADENT d.o.o. Minarikova ul. 6 2000 Maribor Prejel: FUJS DRAGO	
ZA: A	
Datum prejema:	9.4.14
Pregledal:	MABOLT Roberž, mag. farm., spec.
Datum pregleda:	9.4.2014

Productname: Lidocaini hydrochloridum
Number of analysis/Inspection Code: 1 / KEUR-94011B
Batchnumber: 12L28-B02-280114
Reference code / No.:
Analysed according to: PH.EUR 7.6

Tests	Requirement	Result	Unit	Standard remark
Appearance	White, crystalline powder	Conform		
Identification D	White	Conform		IR-spectrum
Identification D	White	Conform		Chloride
Appearance of solution	Clear and colourless	Conform		5% <i>m/V</i>
pH	4,0 - 5,5	4,9		0.5% <i>m/V</i>
Related substances	Conform	Conform		HPLC
Impurity A	<=0,01	0,01	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=0,5	<0,05	%	
Heavy metals	<= 5	Conform	ppm	
Water (Karl Fischer)	5,5 - 7,0	6,4	%	
Sulphated ash	<= 0,1	Conform	%	
Residual solvents	CPMP/ICH/283/95	Conform		
Assay Lidocaine hydrochloride	99,0 - 101,0	99,1	% <i>m/m</i>	Anhydrous
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analyse performed by the authorized lab Synergy Health.

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

25-03-13

Expiration: 10-2017

Conclusion: APPROVED

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