

Certificate of Analysis

Product name: **Lidocaini hydrochloridum x1H2O**

Batch number / Weight: **23D25-B11-230508 / 5 G**

Analysed according to: **Ph.Eur.11.1**

Number of analysis / Inspection Code **23D25-B11 / INS-23-3624**

Reference Code / No.: **V01277 / LDH/123007**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification B	Conform	Conform		
Identification D	White	Conform		
Appearance of solution	Clear and colourless	Conform		
pH	4,0 - 5,5	4,94		
Related substances	Conform	Conform		
Impurity A	<=0,01	<0,01	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=0,5	0,00	%	
Water (Karl Fischer)	5,5 - 7,0	6,47	%	
Sulphated ash	<= 0,1	0,00	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		
Residual solvents	CPMP/ICH/82 260/06	Conform		
Assay Lidocaine hydrochloride	99,0 - 101,0 (anhydrous substance)	100,95	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab FAGRON PL lab

Release:
Ewelina Gadzinowska
Qualified Person

19-06-2023

Expiration: 31-12-2027

Conclusion: APPROVED

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