

Certificate of Analysis

Product name: **Lidocaini hydrochloridum x1H₂O**
Batch number / Weight: **20E28-B04-201245 / 5 G**
Analysed according to: **Ph. Eur.**

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	5,04		
Related substances	Conform	Conform		
Impurity A	<=0,01	0,0005	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=0,5	0,0005	%	
Water (Karl Fischer)	5,5 - 7,0	6,33	%	
Sulphated ash	<= 0,1	0,01	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		
Residual solvents	CPMP/ICH/82 260/06	Conform		
Assay Lidocaine hydrochloride	99,0 - 101,0 (anhydrous substance)	100,60	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		

Analysis performed by the authorized lab.

Release:
 Dominika Sołtysik
 Qualified Person

17-07-2020

Expiration: 28-02-2025

Conclusion: APPROVED

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