

## Certificate of Analysis

**Product name:** **Lidocaini hydrochloridum x1H<sub>2</sub>O**  
**Batch number / Weight:** **21A12-B04-203405 / 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	4,27		
Related substances	Conform	Conform		
Impurity A	<=0,01	0,001	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=0,5	0,001	%	
Water (Karl Fischer)	5,5 - 7,0	6,38	%	
Sulphated ash	<= 0,1	0,06	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		
Residual solvents	CPMP/ICH/82 260/06	Conform		
Assay Lidocaine hydrochloride	99,0 - 101,0 (anhydrous substance)	100,62	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		

Analysis performed by the authorized lab.

Release:  
 Dominika Sołtysik  
 Qualified Person

15-02-2021

Expiration: 30-06-2025

Conclusion: APPROVED

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