

Certificate of Analysis

Product name: Lidocaini hydrochloridum x1H₂O
Batch number / Weight: 19J16-B02-196614 / 500 MG
Analysed according to: Ph. Eur.

Tests	Requirement	Result	Unit	Standard remark
Identification B	Conform	Conform		
Identification D	White	Conform		
Appearance of solution	Clear and colourless	Conform		
pH	4,0 - 5,5	5,19		
Related substances	Conform	Conform		
Impurity A	<=0,01	0,0003	%	
Unspecified impurities	<=0,10	0,02	%	
Total impurities	<=0,5	0,02	%	
Water (Karl Fischer)	5,5 - 7,0	6,23	%	
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)	100,59	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		

Analysis performed by the authorized lab.

Release:
Dorota Sutkowska
Qualified Person

03-01-2020

Expiration: 31-08-2024

Conclusion: APPROVED

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