

## Certificate of Analysis

**Product name:** **Tetracaini hydrochloridum**  
**Batch number / Weight:** **21I20-B04-213231 / 25 G**  
**Analysed according to:** **Ph. Eur.**

Tests	Requirement	Result	Unit	Standard remark
Appearance	White, crystalline powder, slightly hygroscopic	Conform		
Identification A	Conform	Conform		
Identification B	About 131	131,8	°C	
Identification D	White	Conform		
Appearance of solution	Clear and colourless	Conform		
pH	4,5 - 6,5	5,66		
Related substances	Conform	Conform		
Impurity A	<=0,05	0,00	%	
Impurity B	<=0,1	<0,05	%	
Impurity C	<=0,1	<0,05	%	
Unspecified impurities	<=0,10	0,057	%	
Total impurities	<=0,5	0,057	%	
Loss on drying	<=1,0	0,01	%	
Sulphated ash	<= 0,1	0,00	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Tetracaine hydrochloride	99,0 - 101,0	100,61	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:  
 Dominika Sołtysik  
 Qualified Person

15-12-2021

Expiration: 30-06-2026

Conclusion: APPROVED

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