

## Certificate of Analysis

**Product name:** **Amylocaini hydrochloridum**  
**Batch number / Weight:** **19A30-B03-219972 / 10 G**  
**Analysed according to:** **Monograph**

Tests	Requirement	Result	Unit	Standard remark
	or colourless crystals	C		
Appearance	White, crystalline powder	Conform		
Identification A	174 - 176	175	°C	
Identification B	Conform	Conform		
Identification C	120 - 124	120	°C	
Identification D	Conform	Conform		
Appearance of solution	Clear / colourless	Conform		2%m/V
pH	4,5 - 5,5	4,5		1%m/V
Readily carbonisable substances	<=BY5	Conform		
Diazotisable substances	Conform	Conform		
Sulphates	<=200	C	ppm	
Loss on drying	<=0,5	0,3	%	2 h 105 °C
Sulphated ash	<=0,1	0,1	%	
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Metallic residues	CHMP/ICH/353369/2013	Conform		
Assay Amylocaine hydrochloride	99,0 - 101,0	99,9	%m/m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:  
 Ewelina Gadzinowska  
 Qualified Person

06-06-2022

Expiration: 31-12-2023

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.