

Certificate of Analysis

Product name: **Amylocaini hydrochloridum**

Batch number / Weight: **22A25-B06-222317 / 10 G**

Analysed according to: **Monograph**

Number of analysis / Inspection Code **22A25-B06 / INS-22-4944**

Reference Code / No.: **V01862 / 3635-21-02/O**

Tests	Requirement	Result	Unit	Standard remark
Appearance	White, crystalline powder or colourless crystals	Conform		
Identification A	174 - 176	176	°C	
Identification B	Conform	Conform		
Identification C	120 - 124	122	°C	
Identification D	Conform	Conform		
Appearance of solution	Clear / colourless	Conform		2% <i>m/V</i>
pH	4,5 - 5,5	5,40		1% <i>m/V</i>
Readily carbonisable substances	<=BY5	Conform		
Diazotisable substances	Conform	Conform		
Sulphates	<=200	<200	ppm	
Heavy metals		<20	ppm	
Loss on drying	<=0,5	0,18	%	2 h 105 °C
Sulphated ash	<=0,1	0,04	%	
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Metallic residues	CHMP/ICH/353369/2013	Conform		
Assay Amylocaine hydrochloride	99,0 - 101,0	100,6	% <i>m/m</i>	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Acetone		738	ppm	

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab EL Spol

Release:
Ewelina Gadzinowska
Qualified Person

24-08-2022

Expiration: 11-03-2026

Conclusion: APPROVED

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