

Certificate of Analysis

Productname: Amylocaini hydrochloridum
Number of analysis/Inspection Code: 1 / KEUR-179660B
Batchnumber: 19A30-B03-365579
Reference code / No.: 2617 / 3635-18-01/O
Analysed according to: PBVI/MONOG

Tests	Requirement	Result	Unit	Standard remark
Appearance	White, crystalline powder or colourless crystals	Conform 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	Conform	ppm	
Heavy metals	<=20	Conform	ppm	
Loss on drying	<=0,5	0,3	%	2 h 105 °C
Sulphated ash	<=0,1	0,1	%	
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
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 laboratory Eurofins.

Release:
dr. M.J. Vincenten - van Maanen
Pharmacist - Qualified Person

01/15/20

Expiration: 12-2023

Conclusion: APPROVED

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