

Certificate of Analysis

Productname: Cocaini hydrochloridum
Number of analysis/Inspection Code: 1 / KEUR-180245B
Batchnumber: 19L19-F01-367594
Reference code / No.: 1242 / 19-00629
Analysed according to: PH.EUR10.0

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder or colourless crystals	Conform		Hygroscopic
Identification B	Conform	Conform		IR-spectrum
Identification D	White	Conform		Chloride
Appearance of solution	Clear and colourless	Conform		2% <i>m/V</i>
Acidity	Conform	Conform		
Specific optical rotation	-70 - -73	-72	°	2.5% <i>m/V</i> ; dried
Readily carbonisable substances	Conform	Conform		
Related substances	Conform	Conform		HPLC
Any impurity eluting after principal peak	<=0,1	n.d.	%	
Total impurities	<=0,5	0,3	%	
Loss on drying	<=0,5	0,2	%	105°C
Sulphated ash	<=0,1	<0,1	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Cocain hydrochloride	98,5 - 101,0	100,8	% <i>m/m</i>	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Proxylabs.

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

02/11/20

Expiration: 11-2023

Conclusion: APPROVED

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