

Certificate of Analysis

Productname: Cocaini hydrochloridum
Number of analysis/Inspection Code: 1 / KEUR-198649B
Batchnumber: 24A23-F01-385717
Reference code / No.: 1242 / 22-00464
Analysed according to: PH.EUR11.3

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder or colourless crystals	Conform		
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	<0,1	%	
Total impurities	<=0,5	<0,1	%	
Loss on drying	<=0,5	0,1	%	105°C
Sulphated ash	<=0,1	Conform	%	
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	100,5	% <i>m/m</i>	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Nitrosamine impurities	Art. 5(3) of Reg. (EC) No 726/2004	Conform		Data producer

Analysis performed by the authorized laboratory Synergy Health Utrecht B.V.

Manufacturer / Country : MacFarlan Smith Ltd. / GB
CEP : R1-CEP 1996-051-Rev 05

Release:
Anthony Amoureux
Qualified Person

12-02-24

Expiration: 31-12-26

Conclusion: APPROVED

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