

## Certificate of Analysis

**Productname:** Cocaini hydrochloridum  
**Number of analysis/Inspection Code:** 1 / KEUR-197148B  
**Batchnumber:** 23B23-F03-384319  
**Reference code / No.:** 1242 / 22-00297  
**Analysed according to:** PH.EUR11.0

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	-71		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	<0,05	%	
Total impurities	<=0,5	<0,05	%	
Loss on drying	<=0,5	0,1	%	105°C
Sulphated ash		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	99,4	% <i>m/m</i>	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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

**Manufacturer / Country** : MacFarlan Smith Ltd. / GB  
**CEP** :

Release:  
 Anthony Amoureux  
 Qualified Person

03/13/23

Expiration: 30-11-26

Conclusion: APPROVED

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