Fagron

Certificate of Analysis

Productname:	**Cocaini hydrochloridum**
Number of analysis/Inspection Code:	1 / KEUR-198852B
Batchnumber:	**24A23-F01-386067**
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%m/V
Acidity	Conform	Conform		
Specific optical rotation	-70 - -73	-72		2.5% m/V; 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	%m/m	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	:	

Release:
Anthony Amoureus
Qualified Person

18-04-24

Expiration: 31-12-26

Conclusion: APPROVED

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