

Certificate of Analysis

Product name: **Cysteyni hydrochloridum monoh.**

Batch number / Weight: **22A13-B16-215576 / 100 G**

Analysed according to: **Ph. Eur.**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder / crystals	Conform		
Identification A	+5,5 - +7,0	Conform		
Identification B	Conform	Conform		
Identification E	Conform	Conform	%	
Appearance of solution	Clear / colour <=BY6	Conform		
Specific optical rotation	+5,5 - +7,0	+6,6		
Ninhydrin-positive substances	Conform	Conform		
Impurity A at 570 nm	<=0,5	0,07	%	
Any ninhydrin-positive substance	<=0,2	<0,05	%	
Total	<=1,0	0,07	%	
Ammonium at 570 nm	<=0,02	<0,02	%	
Sulphates	<=300	<300	ppm	
Iron	<=20	Conform	ppm	
Loss on drying	8.0 - 12.0	10,10	%	
Sulphated ash	<=0,1	0,04	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay L-Cysteine hydrochloride	98,5 - 101,0	100,08	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
Agnieszka Pszczółka
Qualified Person

26-05-2022

Expiration: 16-05-2023

Conclusion: APPROVED

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