

Certificate of Analysis

Product name: Cysteyni hydrochloridum monoh.

Batch number / Weight: 22C17-B06-224255 / 25 G

Analysed according to: Ph. Eur. 10.8

Number of analysis / Inspection Code 22C17-B06 / INS-22-3523

Reference Code / No.: V01762 / 16HC1F2

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	+6,7		
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	9,48	%	
Sulphated ash	<=0,1	0,00	%	
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	99,79	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab Fagron PL, ElSpol

Release:

Ewelina Gadzinowska

Qualified Person

30-09-2022

Expiration: 14-10-2023

Conclusion: APPROVED

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