

Certificate of Analysis

Product name: **Cystinum**
Batch number / Weight: **22C17-B02-213899 / 25 G**
Analysed according to: **Ph.Eur.10.8**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification A	-224- -218	Conform		
Identification B	Conform	Conform		
Appearance of solution	Clear / $\leq Y7$	Conform		
Specific optical rotation	-224- -218	-219,2		
Ninhydrin-positive substances	Conform	Conform	%	
Any ninhydrin-positive substance	$\leq 0,2$	0,08	%	
Total	$\leq 0,5$	0,15	%	
Chlorides	≤ 200	< 200	ppm	
Sulphates	≤ 300	< 300	ppm	
Ammonium	$\leq 0,02$	Conform	%	
Iron	≤ 10	Conform	ppm	
Loss on drying	$\leq 0,5$	0,03	%	
Sulphated ash	$\leq 0,1$	0,05	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Cystine	98,5 - 101,0	99,89	%	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
Agnieszka Pszczółka
Qualified Person

13-07-2022

Expiration: 01-05-2024

Conclusion: APPROVED

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