

## Certificate of Analysis

**Product name:** **Cystinum**  
**Batch number / Weight:** **22C17-B03-218888 / 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	-219,0		
Ninhydrin-positive substances	Conform	Conform	%	
Any ninhydrin-positive substance	$\leq 0,2$	0,08	%	
Total	$\leq 0,5$	0,08	%	
Chlorides	$\leq 200$	$< 200$	ppm	
Sulphates	$\leq 300$	$< 300$	ppm	
Ammonium	$\leq 0,02$	Conform	%	
Iron	$\leq 10$	Conform	ppm	
Loss on drying	$\leq 0,5$	0,07	%	
Sulphated ash	$\leq 0,1$	0,01	%	
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	100,08	%	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:  
Agnieszka Pszczółka  
Qualified Person

12-07-2022

Expiration: 13-05-2024

Conclusion: APPROVED

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