

Certificate of Analysis

Product name: **Penicillaminum**

Batch number / Weight: **21K09-B02-215593 / 30 G**

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

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Identification D	Blue	Conform		
Appearance of solution	Clear / <= ref. colour 6	Conform		
pH	4,5 - 5,5	5,11		
Specific optical rotation	-61,0 - -65,0	-64,0	°	
Absorbance	<= 0,5	0,006	%	
Impurity A	<= 1	0,12	%	
Impurity B	<= 0,1	Conform	ppm	
Loss on drying	<= 0,5	0,02	%	
Sulphated ash	<= 0,1	0,06	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay D-Penicillamine	98,0 - 101,0	100,19	%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

17-12-2021

Expiration: 30-09-2023

Conclusion: APPROVED

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