

Certificate of Analysis

Product name: **Penicillaminum**
Batch number / Weight: **22G06-B05-220926 / 30 G**
Analysed according to: **Ph. Eur. 10.8**
Number of analysis / Inspection Code **22G06-B05 / INS-22-5832**
Reference Code / No.: **V01511 / 29000729**

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	5,18		
Specific optical rotation	-61,0 - -65,0	-61,8	°	
Absorbance	<= 0,5	<0,5	%	
Impurity A	<= 1	0,12	%	
Impurity B	<= 0,1	0,1	ppm	
Loss on drying	<= 0,5	0,12	%	
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 D-Penicillamine	98,0 - 101,0	100,46	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents				
Methanol	<=3000	<50	ppm	
n-Butyl acetate	<=5000	<50	ppm	

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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 Own lab

Release:
Ewelina Gadzinowska
Qualified Person

26-09-2022

Expiration: 31-05-2024

Conclusion: APPROVED

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