

## Certificate of Analysis

**Product name:** Chinini sulfas  
**Batch number / Weight:** 21I07-B02-213972 / 1 KG  
**Analysed according to:** Ph. Eur.

Tests	Requirement	Result	Unit	Standard remark
Appearance	white or almost white crystalline powder or fine,	Conform		
Appearance	colourless needles			
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Identification C	Conform	Conform		
Identification	Conform	Conform		
Identification E	Conform	Conform	%	
Appearance of solution	Conform	Conform		
pH	5,7 - 6,6	6,39		
Specific optical rotation	(-237) - (-245)	-241,8		
Related substances	Conform	Conform		
Impurity C	<=10	6,54	%	
Any impurity elut.bef.quinine	<=5	1,26	%	
Any other impurity	<=2,5	<0,2	%	
Loss on drying	3,0 - 5,0	4,54	%	
Sulphated ash	3,0 - 5,0	0,02	%	
Assay	99,0 - 101,0	99,60	%m/m	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:  
 Ewelina Gadzinowska  
 Qualified Person

28-11-2021

Expiration: 20-05-2026

Conclusion: APPROVED

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