

Certificate of Analysis

Product name: **Chinini sulfas**

Batch number / Weight: **22J11-B13-224546 / 1 KG**

Analysed according to: **Ph.Eur.10.8**

Number of analysis / Inspection Code **22J11-B13 / INS-22-8832**

Reference Code / No.: **V01400 / 10149**

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 D	Conform	Conform		
Identification E	Conform	Conform		
Appearance of solution	Conform	Conform		
pH	5,7 - 6,6	6,36		
Specific optical rotation	(-237) - (-245)	-239,6		
Related substances	Conform	Conform		
Impurity C	<=10	6,2	%	
Any impurity elut.bef.quinine	<=5	1,4	%	
Any other impurity	<=2,5	<0,2	%	
Loss on drying	3,0 - 5,0	4,61	%	
Sulphated ash	<=0,1	0,01	%	
Assay	99,0 - 101,0	100,53	%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
Residual solvents				
Toluene	<= 890 ppm	<890	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 Fagron PL lab,CBMiA

Release:

Agnieszka Pszczółka

Qualified Person

05-12-2022

Expiration: 28-02-2027

Conclusion: APPROVED

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