

Certificate of Analysis

Product name: **Chinini hydrochloridum**

Batch number / Weight: **21K12-B04-216941 / 25 G**

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

Tests	Requirement	Result	Unit	Standard remark
Appearance	white or almost white, or colourless,	Conform		
Appearance	fine, silky needles, often in clusters			
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Identification C	Conform	Conform		
Identification D	Conform	Conform		
Identification E	Conform	Conform		
Appearance of solution	Clear / $\leq Y_6$	Conform		
pH	6,0 - 6,8	6,39		
Specific optical rotation	(-258)-(-245)	-246,6		
Related substances	Conform	Conform		
Impurity C	≤ 10	5,30	%	
Unspecified impurities	≤ 5	0,97	%	
Total impurities	$\leq 2,5$	$< 0,2$	%	
Sulphate	≤ 500	< 500	ppm	
Barium	≤ 500	Conform		
Loss on drying	6,0-10,0	6,34	%	
Sulphated ash	$\leq 0,1$	0,02	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay	99,0 - 101,0	100,34	%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

09-03-2022

Expiration: 22-09-2026

Conclusion: APPROVED

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