

## Certificate of Analysis

**Product name:** **Chinini hydrochloridum**

**Batch number / Weight:** **22D21-B05-219705 / 100 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	6,35		
Specific optical rotation	(-258)-(-245)	-250,5		
Related substances	Conform	Conform		
Impurity C	$\leq 10$	4,24	%	
Unspecified impurities	$\leq 5$	0,94		
Total impurities	$\leq 2,5$	$< 0,2$	%	
Sulphate	$\leq 500$	$< 500$	ppm	
Barium	$\leq 500$	Conform		
Loss on drying	6,0-10,0	6,82	%	
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	100,52	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Total aerobic microbial count (TA)		$< 10$	CFU/g	
Total yeasts and moulds (TYMC)		$< 10$	CFU/g	

Analysis performed by the authorized lab.

Release:

Ewelina Gadzinowska

Qualified Person

25-07-2022

Expiration: 24-01-2027

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.