

Certificate of Analysis

Product name: **Chinini hydrochloridum**

Batch number / Weight: **23E17-B04-233668 / 100 G**

Analysed according to: **Ph.Eur.11.2**

Number of analysis / Inspection Code **23E17-B04 / INS-23-4499**

Reference Code / No.: **V01400 / 10264**

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	6,32		
Specific optical rotation	(-258)-(-245)	-252,0		
Related substances	Conform	Conform		
Impurity C	≤ 10	4,1	%	
Unspecified impurities	≤ 5	2,7	%	
Total impurities	$\leq 2,5$	0,00	%	
Sulphate	≤ 500	< 500	ppm	
Loss on drying	6,0-10,0	7,04	%	
Sulphated ash	$\leq 0,1$	0,03	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay	99,0 - 101,0	100,14	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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Fagron Services Northern Europe Sp. z o.o.
ul. Armii Krajowej 3
32-540 Trzebinia, Poland
e-mail: fsne@fagron.pl

fagron.pl

Fagron sp. z o.o.
ul. Pasternik 26, 31-354 Kraków, Poland
tel.: +48 12 3343 512
e-mail: biuro@fagron.pl

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

Release:
Ewelina Gadzinowska
Qualified Person

09-11-2023

Expiration: 17-11-2027

Conclusion: APPROVED

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Fagron Services Northern Europe Sp. z o.o.
ul. Armii Krajowej 3
32-540 Trzebinia, Poland
e-mail:fsne@fagron.pl