

Certificate of Analysis

Product name: Calcii citras

Batch number / Weight: 22D25-B07-224356 / 100 G

Analysed according to: USP

Number of analysis / Inspection Code 22D25-B07 / INS-22-4648

Reference Code / No.: V01196 / THG2112011

Tests	Requirement	Result	Unit	Standard remark
Appearance	White, crystaline powder	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Loss on drying	10,0 - 13,3	11,45	%	
Arsenic	<= 3	Conform	ppm	
Limit of Fluoride	<= 0,003	0,0006	%	
Subst. insoluble in hydrochloric a <= 0,2		0,01	%	
Lead	<= 10	<10	ppm	
Metallic residues	CHMP/ICH/353369/2013	Conform		
Residual solvents	CPMP/ICH/82 260/06	Conform		
Assay Calcium citrate	97,5 - 100,5	98,86	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		

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, ElSpol

Release:

Agnieszka Pszczółka Qualified Person

16-11-2022

Expiration: 31-12-2023

Conclusion: APPROVED

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fagron.pl Fagron Sp. z o.o.

ul. Armii Krajowej 3 32-540 Trzebinia, Poland e-mail:biuro@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