

Certificate of Analysis

Product name: **Calcii citras**

Batch number / Weight: **23J19-B02-233670 / 500 G**

Analysed according to: **USP**

Number of analysis / Inspection Code **23J19-B02 / INS-23-9083**

Reference Code / No.: **V01196 / THG2307008**

Tests	Requirement	Result	Unit	Standard remark
Appearance	White, crystalline powder	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Loss on drying	10,0 - 13,3	12,12	%	
Arsenic	<= 3	<3	ppm	
Limit of Fluoride	<= 0,003	0,0023	%	
Subst. insoluble in hydrochloric a	<= 0,2	0,04	%	
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	98,7	%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, EI Spol

Release:
Ewelina Gadzinowska
Qualified Person

22-12-2023

Expiration: 31-07-2025

Conclusion: APPROVED

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