

## Certificate of Analysis

**Product name:** **Calcii carbonas levis**

**Batch number / Weight:** **23J31-B01-233697 / 1 KG**

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

**Number of analysis / Inspection Code** **23J31-B01 / INS-23-8600**

**Reference Code / No.:** **V02168 / 80258**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white powder	Conform		
Apparent volume	About 0,33	0,310	g / ml	
Identification A	Conform	Conform		
Identification B	White	Conform		
Substances insoluble in acetic a	<=0,2	0,02	%	
Chlorides	<=330	<330	ppm	
Sulphates	<=0,25	<0,2	%	
Iron	<=200	<200	ppm	
Magnesium and alkaline metals	<=1,5	1,36	%	
Loss on drying	<=2,0	0,53	%	
Assay Calcium carbonate	98,5 - 100,5	99,33	%m/m	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
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

28-12-2023

Expiration: 16-08-2025

Conclusion: APPROVED

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