

Certificate of Analysis

Product name: **Calcii carbonas ponderous**

Batch number / Weight: **23D27-B09-229139 / 1 KG**

Analysed according to: **Ph.Eur.11.1**

Number of analysis / Inspection Code **23D27-B09 / INS-23-3866**

Reference Code / No.: **V01919 / 23002201**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white powder	Conform		
Density	0,550-1,000	0,9111	g/ml	
Apparent volume	About 0,8		g/ml	
Identification A	Conform	Conform		
Identification B	White	Conform		
Substances insoluble in acetic a	<=0,2	0,13	%	
Chlorides	<=330	<330	ppm	
Sulphates	<= 0,25	<0,25	%	
Iron	<=200	<200	ppm	
Magnesium and alkaline metals	<=1,5	0,15	%	
Loss on drying	<=2,0	0,12	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Calcium carbonate	98,5 - 100,5	99,63	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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

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:
Dominika Soltysik
Qualified Person

28-06-2023

Expiration: 31-03-2025

Conclusion: APPROVED

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

fagron.pl

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