

## Certificate of Analysis

**Product name:** **Calamina**

**Batch number / Weight:** **21G22-B03-220887 / 100 G**

**Analysed according to:** **British Pharmacopoeia**

**Number of analysis / Inspection Code** **21G22-B03 / INS-21-4421**

**Reference Code / No.:** **V01183 / 3092304**

Tests	Requirement	Result	Unit	Standard remark
Appearance	Amorphous, pink or reddish brown powder	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Identification C	White, gelatinous	Conform		
Calcium	Conform	Conform	ppm	
Soluble bariumsalts	Conform	Conform		
Lead	$\leq 150$	Conform	ppm	
Chlorides	$\leq 0,07$	Conform	%	
Sulphates	$\leq 0,6$	Conform	%	
Alcohol-soluble coloring matter	Conform	Conform		
Substances insoluble in hydrochl	$\leq 10$	0,4	mg	
Water-soluble coloring matter	Conform	Conform		
Residue on ignition	68,0 - 74,0	72,80	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Ps. aeruginosa	Negative / g	Conform		
S. aureus	Negative / g	Conform		
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:  
Ewelina Gadzinowska  
Qualified Person

07-10-2022

Expiration: 04-10-2023

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