

Certificate of Analysis

Product name: **Calamina**

Batch number / Weight: **23K16-B02-234607 / 50 G**

Analysed according to: **British Pharmacopoeia**

Number of analysis / Inspection Code **23K16-B02 / INS-24-0599**

Reference Code / No.: **V01183 / 3130805**

Tests	Requirement	Result	Unit	Standard remark
Appearance	Amorphous, pink or reddish brown powder depending on the variety and amount of iron(III) oxide present	Conform		
Appearance				
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Calcium	Conform	Conform		
Soluble bariumsalts	Conform	Conform		
Lead	<=150	<5	ppm	
Chlorides	<=0,07	<0,07	%	
Sulphates	<=0,6	<0,6	%	
Alcohol-soluble coloring matter	Conform	Conform		
Substances insoluble in hydrochl	<=10	1,2	mg	
Water-soluble coloring matter	Conform	Conform		
Residue on ignition	68,0 - 74,0	73,34	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		
Residual solvents	CPMP/ICH/82 260/06	Conform		
Ps. aeruginosa	Negative / g	Conform		
S. aureus	Negative / g	Conform		
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		

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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, CBMiA

Release:
Ewelina Gadzinowska
Qualified Person

08-02-2024

Expiration: 19-03-2026

Conclusion: APPROVED

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