

Certificate of Analysis

Productname: Calamina
Number of analysis/Inspection Code: 1 / KEUR-187965B
Batchnumber: 20J28-F02-375667
Reference code / No.: 1987 / 3092304
Analysed according to: BP2020+

Tests	Requirement	Result	Unit	Standard remark
Appearance	Amorphous, pink or reddish brown powder	Conform		
Identification A	Conform	Conform		Carbonate
Identification B1	Blue	Conform		Iron (III)
Identification B2	White, gelatinous	Conform		Zinc
Calcium	Conform	Conform		
Soluble bariumsalts	Conform	Conform		
Lead	<=150	<5	ppm	AAS
Chlorides	<=0,07	Conform	%	
Sulphates	<=0,6	Conform	%	
Alcohol-soluble coloring matter	Conform	Conform		
Substances insoluble in hydrochloric acid	<=10	0,4	mg	
Water-soluble coloring matter	Conform	Conform		
Residue on ignition	68,0 - 74,0	73,2	%	> 900°C
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	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

Analysis performed by the authorized laboratory Pharma Cosmetic + microbieel.

Release:
Paul Hofman
Pharmacist - Qualified Person

12/29/20

Expiration: 09-2023

Conclusion: APPROVED

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