

Certificate of Analysis

Product name: **Calamina**
Batch number / Weight: **21G22-B02-213168 / 100 G**
Analysed according to: **BP**

Tests	Requirement	Result	Unit	Standard remark
Appearance	Amorphous, pink or reddish brown powder	Conform		
Identification A	Conform	Conform		
Identification B1	Blue	Conform		
Identification B2	White, gelatinous	Conform		
Calcium	Conform	Conform	ppm	
Soluble bariumsalts	Conform	Conform		
Lead	<=150	Conform	ppm	
Chlorides	<=0,07	Conform	%	
Sulphates	<=0,6	Conform	%	
Alcohol-soluble coloring matter	Conform	Conform		
Substances insoluble in hydrochloric	<=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

Analysis performed by the authorized lab.

Release:
 Ewelina Gadzinowska
 Qualified Person

09-12-2021

Expiration: 04-10-2023

Conclusion: APPROVED

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