

## Certificate of Analysis

**Productname:** **Calcii carbonas levis**  
**Number of analysis/Inspection Code:** 1 / KEUR-180631B  
**Batchnumber:** **19L30-F05-367887**  
**Reference code / No.:** 4392 / EBPM047691  
**Analysed according to:** **PHEUR10.0+**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white powder	Conform		
Apparent volume	About 0,33	0,42	g / ml	Untapped
Identification A	Conform	Conform		Carbonate
Identification B	White	Conform		Calcium
Substances insoluble in acetic acid	<=0,2	Conform	%	
Chlorides	<=330	Conform	ppm	
Sulphates	<=0,25	Conform	%	
Arsenic	<=4	Conform	ppm	
Barium	Conform	Conform		
Iron	<=200	Conform	ppm	
Magnesium and alkaline metals	<=1,5	0,0	%	
Loss on drying	<=2,0	1,1	%	200 °C
Assay Calcium carbonate	98,5 - 100,5	98,9	%m/m	Dried
Total aerobic microbial count (TAMC)	<=5000	Conform	CFU / g	
E. coli	Negative / gram	Conform		
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic + microbiel.

Release:  
dr. M.J. Vincenten - van Maanen  
Pharmacist - Qualified Person

02/21/20

Expiration: 10-2023

Conclusion: APPROVED

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