

Certificate of Analysis

Product name: **Calcii hydroxidum**

Batch number / Weight: **22L02-B07-226352 / 50 G**

Analysed according to: **Ph.Eur.11.0**

Number of analysis / Inspection Code **22L02-B07 / INS-23-0151**

Reference Code / No.: **V00621 / 97695**

Tests	Requirement	Result	Unit	Standard remark
Appearance	white to almost white, fine powder	Conform		
Identification A	acc.to Ph. Eur.	Conform		
Identification B	acc. to Ph. Eur.	Conform		
Matter insoluble in HCl	<= 0,5	0,01	%	
Carbonates	<= 5,0	1,00	%	
Chlorides	<= 330	<330	ppm	
Sulfates	<= 0,4	<0,4	%	
Cadmium	<=1	<0,1	ppm	
Lead	<=1	0,3	ppm	
Magnesium and alkali metals	<= 4,0	0,11	%	
Assay	95,0 - 100,5	97,17	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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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, ElSpol

Release:
Ewelina Gadzinowska
Qualified Person

26-01-2023

Expiration: 30-09-2027

Conclusion: APPROVED

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