

Certificate of Analysis

Product name: **Magnesii subcarbonas levis**

Batch number / Weight: **22A14-B09-224288 / 1 KG**

Analysed according to: **Ph. Eur. 10.8**

Number of analysis / Inspection Code **22A14-B09 / INS-22-4083**

Reference Code / No.: **V01298 / 3099771-2**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white powder	Conform		
Identification A	$\leq 0,15$	0,126	g/ml	
Identification B	Conform	Conform		
Identification C	Conform	Conform		
Appearance of solution	$\leq B4$	Conform		
Soluble substances	$\leq 1,0$	0,31	%	
Substances insoluble in acetic a	$\leq 0,05$	0,030	%	
Chlorides	≤ 700	< 700	ppm	
Sulphates	$\leq 0,3$	$< 0,3$	%	
Calcium	$\leq 0,75$	Conform	%	
Iron	≤ 400	Conform	ppm	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay	40,0 - 45,0	43,00	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Total aerobic microbial count (TA)	10^3	< 10	CFU/g	
Total yeasts and moulds (TYMC)	10^2	< 10	CFU/g	
Arsenic	≤ 1	0,1	ppm	
Cobalt	≤ 1	$< 0,1$	ppm	
Nickel	≤ 50	< 5	ppm	
Vanadium	≤ 5	0,9	ppm	

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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

28-11-2022

Expiration: 16-12-2024

Conclusion: APPROVED

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