

Certificate of Analysis

Product name: **Magnesii trisilicas**
Batch number / Weight: **23B14-B18-231639 / 100 G**
Analysed according to: **Ph.Eur.11.2**
Number of analysis / Inspection Code **23B14-B18 / INS-23-1687**
Reference Code / No.: **V01801 / MF2149**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white powder	Conform		
Apparent volume	350-500	485,85	g / l	
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Alcalinity	Conform	Conform		
Water soluble salts	<=1,5	Conform	%	
Chlorides	<=500	<500	ppm	
Sulphates	<=0,5	<0,5	%	
Arsenic	<=4	<4	ppm	
Loss on ignition	17 - 34	26,13	%	900 °C
Acid-absorbing capacity	>=100,0	111,63	ml / g	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Magnesium oxide	>=29,0	30,80	%m/m	
Assay Silicium dioxide	>=65,0	65,46	%m/m	
Total aerobic microbial count (TA)	<=100	<10	CFU / g	
E. coli	Negative / gram	Conform		
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 lab,CBMiA

Release:

Agnieszka Pszczółka

Qualified Person

18-10-2023

Expiration: 09-12-2024

Conclusion: APPROVED

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