

Certificate of Analysis

Product name: **Aluminii magnesii silicas**

Batch number / Weight: **23E23-B02-234533 / 100 G**

Analysed according to: **Ph.Eur.11.2**

Number of analysis / Inspection Code **23E23-B02 / INS-23-4894**

Reference Code / No.: **V01879 / 2021391491**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(almost) white coarse powder, granules or flakes	Conform		
Identification A	White	Conform		
Identification B	White	Conform		
Identification C	White	Conform		
Identification F	Conform	Conform		
pH	9,0 - 10,0	9,80		
Viscosity	225 - 600	404	mPa.s	
Acid demand	<=4,0	2,74		
Arsenic	<= 3	<3	ppm	
Lead	<= 15	8,6	ppm	
Loss on drying	<= 8,0	3,1	%	110°C
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Aluminium	About 5	4,21	%m/m	
Assay Magnesium	About 6	6,35	%m/m	
Ratio Al / Mg	0,5 - 1,2	0,7	%m/m	
Total aerobic microbial count (TA)	<=1000	<10	CFU / g	
Total yeasts and moulds (TYMC)	<=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, EI Spol, CBMiA

Release:

Ewelina Gadzinowska

Qualified Person

10-01-2024

Expiration: 03-10-2026

Conclusion: APPROVED

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