

Certificate of Analysis

Product name: Silicii dioxidum praec. pond.

Batch number / Weight: 23D07-B05-229439 / 100 G

Analysed according to: Monograph

Number of analysis / Inspection Code 23D07-B05 / INS-23-3627

Reference Code / No.: V01577 / 0192060635

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, light, fine, amorphous powder	Conform		
Identification A	White	Conform		
рН	4,0 - 7,0	6,2		
Chlorides	<=0,1	0,02	%	
Sulphates	<=1	0,35	%	
Iron	<=300	<400	ppm	
Loss on ignition	<=20,0	7,3	%	
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Siliciumdioxide	98,0 - 100,5	99,7	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Apparent volume		35	g/100 ml	

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 EL Spol

Release:

Dominika Sołtysik Qualified Person

31-05-2023

Expiration: 05-06-2024

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.

fagron.pl Fagron Sp. z o.o.

ul. Armii Krajowej 3 32-540 Trzebinia, Poland e-mail:biuro@fagron.pl

fagron.pl Fagron sp. z o.o.

ul. Pasternik 26, 31-354 Kraków, Poland

tel.: +48 12 3343 512 e-mail: biuro@fagron.pl