

## **Certificate of Analysis**

Product name: Silica colloidalis anhydrica

Batch number / Weight: 23C27-B01-229340 / 100 G

Analysed according to: Ph.Eur.11

Number of analysis / Inspection Code 23C27-B01 / INS-23-3077

Reference Code / No.: V01288 / 233020520

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, light, fine, amorphous powder	Conform		
Identification	White	Conform		
pH	3,5 - 5,5	4,20		
Chlorides	<=250	<250	ppm	
Loss on ignition	<=5,0	1,44	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Silicium dioxide	99,0 - 100,5	99,35	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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

Release:

Dominika Sołtysik Qualified Person

11-05-2023

Expiration: 04-02-2025

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

ul. Pasternik 26, 31-354 Kraków, Poland

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