

Certificate of Analysis

Product name: **Silica colloidalis anhydrica**

Batch number / Weight: **22H23-B17-224367 / 100 G**

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

Number of analysis / Inspection Code **22H23-B17 / INS-22-7236**

Reference Code / No.: **V01288 / 152062914**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, light, fine, amorphous powder	Conform		
Identification	White	Conform		
pH	3,5 - 5,5	4,31		
Chlorides	<=250	<250	ppm	
Loss on ignition	<=5,0	2,48	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Silicon dioxide	99,0 - 100,5	99,99	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Total aerobic microbial count (TA)	<=10	<1	CFU/g	
Total yeasts and moulds (TYMC)	<=1	<1	CFU/g	

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:

Ewelina Gadzinowska

Qualified Person

21-10-2022

Expiration: 28-06-2024

Conclusion: APPROVED

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