

## Certificate of analysis no. 20/07495

Description of the sample:

<b>Name of the sample:</b>	Silicii dioxidum praec. pond.
<b>Batch number:</b>	20C23-F01
<b>Expiration date:</b>	-
<b>Required specifications:</b>	Ph. Eur. 10.1 01/2017:0738

Test results:

Parameter	Limit value	Result	Statement of compliance
Appearance	white or almost white, light, fine, amorphous powder	white, light, fine, amorphous powder	complies
Identification: sample 1	It gives the reaction of silicates.	conform	complies
Identification: sample 2	It gives the reaction of silicates.	conform	complies
Assay (ignited substance)	98.0% to 100.5%	99.2%	complies
Loss of ignition	NMT 20.0%	6.4%	complies
pH	4.0 to 7.0	4.3	complies
Water-absorption capacity	The mixture remains powdery.	The mixture remained powdery.	complies
Substances soluble in hydrochloric acid	NMT 2.0%	1.9%	complies
Chlorides	NMT 0.1%	< 0.1%	complies
Sulfates	NMT 1%	< 1%	complies
Iron	NMT 300 ppm	< 300ppm	complies
Heavy metals	NMT 10 ppm	< 10 ppm	complies
Bulk density	20-60 g/100ml	44 g/100ml	complies

Date of analysis: 04.04.2020 – 29.04.2020

Statement of compliance:

Fagron sp. z o.o.  
*Małgorzata Ostrowska-Sława*  
chemik-analityk 30.04.2020

The samples meet the requirements for performed tests.

SPECIFICATIES  
GECONTROLEERD  
EN CONFORM

DATUM  
060520  
PARAAF  
RW

Approved by:

30.04.2020  
Fagron sp. z o.o.  
*Magdalena Rutkowska*  
dr Magdalena Rutkowska  
kierownik kontroli jakości

fagron.pl

Fagron sp. z o.o.  
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e-mail: biuro@fagron.pl Konto - ING Bank Śląski S.A. nr 36 1050 0086 1000 0090 3014 8499  
Sąd Rejonowy dla Krakowa-Śródmieścia XI Wydział Gospodarczy KRS 0000405946 Wysokość kapitału  
zakładowego: 5050,00 PLN



**EL spol. s r.o.**, Centre of Laboratory Services  
Radlinského 17A, 052 01 Spišská Nová Ves, Slovakia

Accredited Testing Laboratories by ISO/IEC 17025, SNAS, Certificate of Accreditation No. S-025  
Holder of GMP Certificate No. SK/021V/2018 ŠUKL

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### Customer

**Customer:** Fagron sp. z o.o.  
(name and address) ul. Pasternik 26, 31354 Kraków  
**Division:** Fagron Kraków  
**Contract / order:** 2020 19/0033/SLP/F  
**Order No.:** 20-03042

**Date of sample delivery :** 08.04.2020  
**Date of analysis from:** 08.04.2020  
**to:** 29.04.2020  
**Date of Test Report issue:** 29.04.2020

### Description of the Sample

<b>Laboratory No.:</b>	20-007122
<b>Object of the test:</b>	Pharmaceutical raw materials, drugs and auxiliary materials
<b>Name of the sample / product:</b>	Silicii dioxidum
<b>Power / form of the drug:</b>	-
<b>Batch No.:</b>	20C23-F01
<b>Expiration date:</b>	-
<b>Description of the packing:</b>	plastic cup
<b>Size of the packing:</b>	2 units
<b>Contractor / producer:</b>	Fagron
<b>Way of the sampling / delivery:</b>	Sample delivered by Customer
<b>Purpose of the test:</b>	Batch release – Assessment of conformity with specification No.: Ph.Eur 10.1 01/2017:0738 and Ph.Eur 10.1 04/2019:20934
<b>Required specifications:</b>	Ph.Eur 10.1 01/2017:0738 and Ph.Eur 10.1 04/2019:20934
<b>Appearance of the sample / description:</b>	white powder

### Statement of Compliance / Non-compliance of the Test Results with requirements / specifications

SPECIFICATIES  
GECONTROLEERD  
EN CONFORM

**Test sample:** Silicii dioxidum

**Batch:** 20C23-F01 **Contractor / producer:** Fagron

DATUM 06.05.20  
PARAAF RW

Tested sample in performed tests  
is in compliance with  
specifications presented in Ph.Eur 10.1 01/2017:0738 and Ph.Eur 10.1 04/2019:20934.

- Statement of compliance / noncompliance is presented according to customer requirements.
- Statement of compliance / noncompliance of the results with requirements is based on comparison of the test results presented in this Test Report with values presented in external document No.: Ph.Eur 10.1 01/2017:0738.
- The comparison applies to results of the stated tests parameters of this sample only.

#### Statements

- Testing Laboratory is a holder of the APPROVING DECREE ŠUKL No. Š-08/08, control laboratory for pharmaceutical testing.
- Tests are performed according to GMP Certificate No. SK/021V/2018 ŠUKL, quality control testing of medicinal products.
- Testing Laboratory declares that the Test Results relate to the tested items only.
- This Test Report shall not be reproduced except in full, without written approval of the Testing Laboratory.
- The laboratory accreditation or its Test Report itself shall mean in no case approval of the product by the body granting the accreditation or by any other body.

#### Claiming and storage of samples remains

- It is possible to claim the test results up to 30 days from the date of the results sending to customer. Claims delivered in written form only are accepted and executed.
- Only samples whose original properties do not change over time will be retained - at least during the claim period or according to the particular customer agreement (e.g. until the expiration date).
- Return of samples remains - the samples will be returned to the customer upon their written request and at their expense. In other cases the samples remains are discarded at customer expense after the expiry of storage period.

**Test Report provided by and for Statement of Compliance is responsible:** Ing. Silvia Strelková, Head of UEOA  
**Test Report will be delivered to:** Fagron Kraków  
**Date:** 29.04.2020  
**Approved by:** Ing. Marija Gavlaková, Head of laboratory Services



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## Test Report N°: 20/07495

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### Description of the Sample

Laboratory No.:	20-007122
Object of the test:	Pharmaceutical raw materials, drugs and auxiliary materials
Name of the sample / product:	Silicli dioxidum
Power / form of the drug:	-
Batch No.:	20C23-F01

### Test Results

Physico-chemical testing: Ph.Eur 10.1 01/2017:0738 and Ph.Eur 10.1 04/2019:20934

Test / parameter	Test method	Unit of measurement	Limit value	Result	Statement of Compliance	Start of the Test
Identificacón: Sample-1 Sample-2	Test	-	About 20 mg gives the reaction of silicates	It gave reaction of silicates	Compliance	04.04.2020
pH	Potent.	-	4.0 - 7.0	4.3	Compliance	04.04.2020
Water-absorption capacity	Test	-	The mixture remains powdery	The mixture remained powdery.	Compliance	04.04.2020
Substances soluble in hydrochloric acid	GA	%	≤2.0	1.9	Compliance	22.04.2020
Chlorides	Test	%	≤0.1	<0.1	Compliance	22.04.2020
Sulfates	Test	%	≤1	<1	Compliance	22.04.2020
Iron	Test	ppm	≤300	<300	Compliance	22.04.2020
Bulk density	GA	g/100 ml	20 - 60	44	Compliance	21.04.2020
Heavy metals	Test	ppm	≤10	<10	Compliance	27.04.2020
Assay of SiO <sub>2</sub> (Ignited substance)	GA	%	98.0-100.5	99.2	Compliance	24.04.2020
Loss on ignition	GA	%	<20.0	6.4	Compliance	24.04.2020

Person responsible for results:

Ing. Silvia Strelková, Head of LFOA

Test equipment and Instruments used for testing have been calibrated and verified according to valid metrological regulations.

### Abbreviations

Abbreviation	Method
GA	Gravimetric analysis
Potent.	Potentiometry
Test	Test

Date:

29.04.2020

Approved by:

Ing. Mária Gavráková, Head of Centre of laboratory Services

