

Certificate of analysis no. 104/FSNL/2019

Description of the sample:

Name of the sample:	Calcii carbonas levis
Batch number:	19B14-B03
Expiration date:	-
Required specifications:	Ph.Eur. (01/2017:0014)

Test results:

Parameter	Limit value	Result	Statement of compliance
Appearance	White or almost white powder	Almost white powder	complies
Identification A	It gives the reaction of carbonates	conform x 5	complies
Identification B	0,2 ml of solution S gives reactions of calcium	conform x 5	complies
Substances insoluble in acetic acid	NMT 0,2 %	0,02 %	complies
Chlorides	NMT 330 ppm	< 330 ppm	complies
Sulfates	NMT 0,25 %	< 0,25 %	complies
Arsenic	NMT 4 ppm	< 4 ppm	complies
Barium	acc. to Ph. Eur.	conform	complies
Iron	NMT 200 ppm	< 200 ppm	complies
Magnesium and alkali metals	NMT 1,5 %	0,48 %	complies
Loss on drying	NMT 2,0 %	0,90 %	complies
Assay (dried substance)	98,5 – 100,5 %	99,67 %	complies
Apparent volume	About 0,33 g/ml	0,340 g/ml	complies
Microbial contamination	TAMC: NMT 5000 CFU/g Absence of Escherichia coli (per 1g)	< 10 CFU/g absence	complies

Date of analysis: 01-05.03.2019

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Fagron sp. z o.o.
ul. Pasternik 26, 31-354 Kraków, NIP: 679 002 64 73, Regon: 350013075, BDO-000031662 tel.: (+48) 12 3343 512,
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

Kraków, 06.03.2019

Statement of compliance:

The sample meet the requirements for performed tests.



Fagron sp. z o.o.

dr Adam Zięba *A. Zięba*
starszy specjalista ds. kontroli
jakości 06.03.2019

Approved by:

06.03.2019

Fagron sp. z o.o.
Rukhondio
ul. M. Skłodowska-Curie 10
31-354 Kraków

