



EL spol. s r.o., Radlinského 17A, 052 01 Spišská Nová Ves, Slovakia

Accredited Testing Laboratory according to ISO/IEC 17025: 2017

Holder of the Certificate of GMP Compliance No. SK/033V/2020

Test Report No.: 21/21942

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Correction to the Test Report No.: 21/21146

Reason for correction: addition Test - Assay of carboxylic acid (-CO₂H) groups

Customer

Customer: Fagron sp. z o.o.
(name and address) ul. Pasternik 26, 31354 Kraków
Division: Fagron Kraków
Contract / order: 2021 19/0033/SLP/F
Order No.: 21-07947

Date of sample receipt : 30.08.2021
Date of testing from: 30.08.2021
to: 26.10.2021
Date of Test Report issue: 08.11.2021

Description of the Sample

Laboratory No.	21-018518
Type of the sample	Pharmaceutical raw materials, drugs and auxiliary materials
Name of the sample / Product	Carbomerum 974P
Strength / Dosage form	-
Batch No.	21G14-B03
Expiry date	04.12.2022
Description of package	plastic cup
Size of package / Quantity	1 unit
Manufacturer / Trader	Fagron Krakow
Sampling / Delivery	Sample delivered by Customer
Purpose of testing	Batch release - Assessment of conformity with specification No.: Ph.Eur 10.5 04/2021:1299
Specification / Test procedure	External documentation with specification No.: Ph.Eur 10.5 04/2021:1299
Appearance of the sample	white hygroscopic powder

Statement of Compliance / Non-compliance with the requirements / specifications

Test sample: Carbomerum 974P

Batch: 21G14-B03 Manufacturer / Trader: Fagron Krakow

Tested sample in performed tests
is in compliance with
the specifications presented in Ph.Eur 10.5 04/2021:1299.

- 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 10.5 04/2021:1299.

Statements:

- EL spol. s r.o. performs pharmaceutical quality control testing on the basis of the Manufacturer's Authorisation No. V-23/2020, issued by the State Institute for Drug Control (ŠÚKL).
- This Certificate of Analysis shall not be reproduced except in full without approval of the Laboratory.
- Laboratory is not responsible for sampling, the results apply to the sample as received.
- Test results relate only to the sample tested and do not substitute the approval of the test item by the competent authority.
- Test equipment and instruments have been calibrated and verified in accordance with applicable metrological regulations.
- Test results can be claimed within 30 days of their sending to the customer. Claims delivered in written form only are accepted and executed.
- Return of sample remains - samples will be returned to the customer upon his written request and at his expense. In other cases, the remaining samples are discarded at the customer's expense after the expiration of the storage period (which is at least until the end of the claim period, or as agreed in the contract with a specific customer).

Test Report issued by and for Statement of Compliance is responsible:

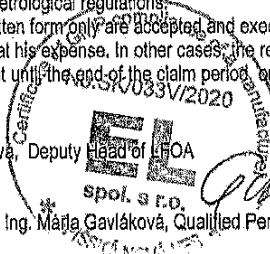
Ing. Silvia Strelková, Deputy Head of LHOA

Test Report will be delivered to:

Fagron Kraków

Date: 08.11.2021

Approved by: Ing. Mária Gavriláková, Qualified Person





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Test Results

Physico-chemical testing: Ph.Eur 10.5 04/2021:1299

Test / parameter	Test method	Unit of measurement	Limit value	Result	Statement of Compliance	Start of the Test
Identification A (Infrared absorption spectrophotometry)	IR	-	Compliance	Compliance	Compliance	03.09.2021
Free acrylic acid	HPLC_UVVIS	%	≤0.25	<0.05	Compliance	20.09.2021
Benzene	GC/FID	ppm	≤2	<2	Compliance	07.09.2021
Loss on drying	GA	%	≤3.0	2.7	Compliance	21.10.2021
Assay of carboxylic acid (-CO ₂ H) groups (dried substance)	PotTitr	%	56.0-68.0	56.7	Compliance	21.10.2021
Viscosity	Test	mPa.s	29400-39400	36543	Compliance	22.09.2021
Sulfated ash	GA	%	≤4.0	1.4	Compliance	22.10.2021
Ethylacetat	GC/FID	%	≤0.5	0.3	Compliance	13.09.2021

Person responsible for results:

Ing. Silvia Strelková, Deputy Head of LFOA

Test Methods

Abbreviation	Method
GA	Gravimetric analysis
GC/FID	Gas chromatography with flame ionization detector
HPLC_UVVIS	High-performance liquid chromatography with UV-visible detector
IR	Infrared spectrometry
PotTitr	Potentiometric titration
Test	Test

Date:

08.11.2021

Approved by:

Ing. Mária Čavňáková, Qualified Person

