

spoles r.o., Radlinského 17A, 052 01 Spišská Nová Ves, Slovakia dited Testing Laboratory according to ISO/IEC 17025: 2017

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

GECONTROLEERD EN CONFORM Test Report Nº: 21/01389

DATUM

10-02-21

PARAAF

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Customer

Date of sample receipt :

19.01.2021

( name and address ) Division:

Customer:

Fagron sp. z o.o. ul. Pasternik 26, 31354 Kraków Fagron Kraków

Date of testing from:

19.01.2021

Contract / order:

2021 19/0033/SLP/F

03.02.2021

Order No.:

21-00373

Date of Test Report issue:

03.02.2021

## Description of the Sample

Laboratory No.	21-000818
Type of the sample	Pharmaceutical raw materials, drugs and auxiliary materials
Name of the sample / Product	Lactosum monohyd. 200M 120-35
Strength / Dosage form	The second secon
Batch No.	21A07-F01
Expiry date	A CONTROL OF THE PROPERTY OF T
Description of package	palstic cup
Size of package / Quantity	5 + 5 (micro) units
Manufacturer / Trader	Fagron, Krakow
Sampling / Delivery	Sample delivered by Customer
Purpose of testing	Batch release – Assessment of conformity with specification No.: Ph.Eur. 10.3 01/2021:0187
Specification / Test procedure	External documentation with specification No.: Ph.Eur. 10.3 01/2021:0187
Appearance of the sample	white crystalline powder

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

Test sample:

L'actosum monohyd. 200M 120-35

21A07-F01 Batch:

Manufacturer / Trader: Fagron, Krakow

Tested sample in performed tests is in compliance with the specifications presented in Ph.Eur. 10.3 01/2021:0187.

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. 10.3 01/2021:0187.

The comparison applies to results of the stated tests parameters of this sample only.

### 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).

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

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 costumer upon their written request and at their expense of their expense of their expense after the expiry of storage period. s the samples

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

Ing. Silvia Strelová, Deputy Head o

Test Report will be delivered to:

Fagron Kraków

Date: 03.02.2021 Approved by:

Ing. Mária Gavláková,

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KvK 350 22 503

IBAN NL78INGB0674 2801 48 BIC INGBNL2A Version: 14.12.20

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The Netherlands

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Description of the Sample

Laboratory No.:	21-000818
Type of the sample:	Pharmaceutical raw materials, drugs and auxiliary materials
Name of the sample / product:	Lactosum monohyd, 200M 120-35
Strength / Dosage form:	Control of the Contro
Batch No.:	21A07-F01

#### Test Results

Physico-chemical testing: Ph.Eur. 10.3 01/2021:0187

Test / parameter	Test method	Unit of measurement	Limit value	Result	Statement of Compliance	Start of the Test
Identification: A ( infrared absorption spectrophotometry) Sample-1 Sample-2 Sample-3 Sample-4 Sample-5	IR:	#	Compliance	Compliance	Compliance	21.01.2021
entification: D (water) PotT		1	Compliance Compliance		Compliance	25.01.2021
Appearance of solution	Test		Solution S is clear and not more intensely coloured than reference solution BY7.	Solution S was clear and not more intensely coloured than reference solution BY7.	Compliance	01.02.2021
Specific optical rotation (anhydrous substance)	Polar		+54,4 to +55,9	+54.4	Compliance	01.02.2021
Acidity or alkalinity	VA	ml NaOH 0.1 M	≤0.4	0.35	Compliance	01.02.2021
Water	PotTitr	%	4.5-5.5	4.8	Compliance	25.01.2021
Sulphated ash	GA	%	≤0.1	0.08	Compliance	01.02.2021
Absorbance: proteins and light- absorbing impurities:	200. ** 200. *					
Absorbance at 400 nm	UV/VIS	*	≤0.04	0.003	Compliance	01.02.2021
Absorbance from 210 to 220 nm	UVIVIS		≤0.25	0.038	Compliance	01.02.2021
Absorbance from 270 to 300 nm	UV/VIS		≤0.07	0.011	Compliance	01.02.2021

Person responsible for results:

Ing. Silvia Strelová, Deputy Head of LFOA

Microbiological testing: Ph.Eur. 10.3 01/2021:0187

Test / parameter	Test method	Unit of measurement	Limit value	Result	Statement of Compliance	Start of the Test
Total aerobic microbial count	Cultivation	CFU/g	≤100	<10	Compliance	20.01.2021
Escherichia coli '	Cultivation	CFU/g	absence	absence	Compliance	20.01.2021

Person responsible for results:

MVDr. Ferenčáková Eva, Head of LMMP

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

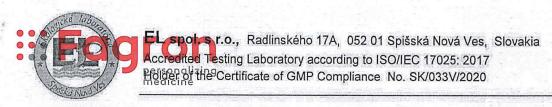
SPECIFICATIES GECONTROLEERD EN CONFORM

DATUM

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10-02-21

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Abbreviations

Method Abbreviation Cultivation Cultivation method GA Gravimetric analysis IR Infrared spectrometry Polar Polarimetry Potentiometric titration PotTitr Test Test

VA Volumetric analysis

Date: Approved by: us.02.2021
Ing. Mária Gavláková, Qualifie Person

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