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

SPECIFICATIES GECONTROLEERD EN CONFORM
DATUM 10-02-21 PARAAF YS

Test Report Nº: 21/01389

Customer

Customer: (name and address)	Fagron sp. z o.o. ul. Pasternik 26, 31354 Kraków	**Date of sample receipt :**	19.01.2021
Division:	Fagron Kraków	**Date of testing from:**	19.01.2021
Contract / order:	2021 19/0033/SLP/F	**to:**	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	-
Batch No.	21A07-F01
Expiry date	-
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: Lactosum monohyd. 200M 120-35 **Batch:** 21A07-F01 **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 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 costumer 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 Strelová, Deputy Head of LFOA

Test Report will be delivered to: Fagron Kraków

Date: 03.02.2021 **Approved by:** Ing. Mária Gavláková, Qualified Person

Certificate of GMP compliance of the manufacturer No.SK/033V/2020 EL spol. s r.o. SPIŠSKÁ NOVÁ VES

Test Report N°: 21/01389

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:	-
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
Identification: D (water)	PotTitr	-	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:						
Absorbance at 400 nm	UV/VIS	-	≤0.04	0.003	Compliance	01.02.2021
Absorbance from 210 to 220 nm	UV/VIS	-	≤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.

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Abbreviations

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

Date: 03.02.2021
Approved by: Ing. Mária Gavláková, Qualified Person

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