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: 21/09704

Customer

Customer: (name and address)	Fagron sp. z o.o. ul. Pasternik 26, 31354 Kraków	**Date of sample receipt :**	04.05.2021
Division:	Fagron Kraków	**Date of testing from:**	04.05.2021
Contract / order:	2021 19/0033/SLP/F	**to:**	27.05.2021
Order No.:	21-03775	**Date of Test Report issue:**	27.05.2021

Description of the Sample

Laboratory No.	**21-008582**
Type of the sample	**Pharmaceutical raw materials, drugs and auxiliary materials**
Name of the sample / Product	**Lactosum monohyd. 200M**
Strength / Dosage form	-
Batch No.	21D20 - F02
Expiry date	-
Description of package	plastic cup
Size of package / Quantity	5 + 5 (units)
Manufacturer / Trader	Fagron, Krakow
Sampling / Delivery	Sample delivered by Customer
Purpose of testing	Batch release – Assessment of conformity with specification No.: Ph. Eur. 10.4 01/2021:0187
Specification / Test procedure	External documentation with specification No.: Ph. Eur. 10.4 01/2021:0187
Appearance of the sample	white, crystalline powder

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

Test sample: Lactosum monohyd. 200M **Batch:** 21D20 - F02 **Manufacturer / Trader:** Fagron, Krakow

Tested sample in performed tests is in compliance with the specifications presented in Ph. Eur. 10.4 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. 10.4 01/2021:0187.

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 Cerificate 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. Eva Pjatáková Palenčárová, PhD., Head of LFOA

Test Report will be delivered to: Fagron Kraków

Date: 27.05.2021 **Approved by:** Ing. Mária Gavláková, Qualified Person

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

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Description of the Sample

Laboratory No.	21-008582
Type of the sample	Pharmaceutical raw materials, drugs and auxiliary materials
Name of the sample / Product	Lactosum monohyd. 200M
Strength / Dosage form	-
Batch No.	21D20 - F02

Test Results

Physico-chemical testing: Ph. Eur. 10.4 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	10.05.2021
Identification: D (water)	PotTitr	-	Compliance	Compliance	Compliance	24.05.2021
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	26.05.2021
Specific optical rotation (anhydrous substance)	Polar	-	+54.4 to +55.9	+54.6	Compliance	27.05.2021
Acidity or alkalinity	VA	ml NaOH 0.1 M	≤0.4	0.25	Compliance	27.05.2021
Water	PotTitr	%	4.5-5.5	4.74	Compliance	24.05.2021
Sulfated ash	GA	%	≤0.1	0.07	Compliance	27.05.2021
Absorbance: proteins and light-absorbing impurities						
Absorbance (400 nm)	UV/VIS	-	≤0.04	0.02	Compliance	27.05.2021
Absorbance (210 - 220 nm)	UV/VIS	-	≤0.25	0.07	Compliance	27.05.2021
Absorbance (270- 300 nm)	UV/VIS	-	≤0.07	0.04	Compliance	27.05.2021

Person responsible for results: Ing. Eva Pjatáková Palenčárová, PhD., Head of LFOA

Microbiological testing: Ph. Eur. 10.4 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	05.05.2021
Escherichia coli	Cultivation	CFU/g	absent	absent	Compliance	05.05.2021

Person responsible for results: MVDr. Ferenčáková Eva, Head of LMMP

SPECIFICATIES GECONTROLEERD EN CONFORM
DATUM 01 06 21 PARAAF

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Accredited Testing Laboratory according to ISO/IEC 17025: 2017
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Test Report N°: 21/09704

Test Methods

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

Date: 27.05.2021
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

SPECIFICATIES GECONTROLEERD EN CONFORM
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