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: 22/02085

Correction to the Test Report No.: 21/22148
Reason for correction: repeated measurement of Content activity Bromelaine

Customer

Customer: (name and address)	Fagron sp. z o.o. ul. Pasternik 26, 31354 Kraków	**Date of sample receipt :**	23.08.2021
Division:	Fagron Kraków	**Date of testing from:**	23.08.2021
Contract / order:	2021 19/0033/SLP/F	**to:**	15.02.2022
Order No.:	21-07690	**Date of Test Report issue:**	15.02.2022

Description of the Sample

Laboratory No.	**21-017931**
Type of the sample	**Pharmaceutical raw materials, drugs and auxiliary materials**
Name of the sample / Product	**Bromelain (>1200 GDU/g)**
Strength / Dosage form	-
Batch No.	21H12-B05
Expiry date	31.05.2023
Description of package	plastic cup
Size of package / Quantity	1 unit
Manufacturer / Trader	Fagron
Sampling / Delivery	Sample delivered by Customer
Purpose of testing	Batch release – Assessment of conformity with specification No.: INTERNAL
Specification / Test procedure	External documentation with specification No.: INTERNAL
Appearance of the sample	white powder

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

Test sample: Bromelain (>1200 GDU/g) **Batch:** 21H12-B05 **Manufacturer / Trader:** Fagron

Tested sample in performed tests is in compliance with the specifications presented in INTERNAL.

- 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.: INTERNAL.

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. Eva Pjatáková Palenčárová, PhD., Head of LFOA

Test Report will be delivered to: Fagron Kraków

Date: 15.02.2022

Approved by: Ing. Mária Gavláková, Qualified Person

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Test Report N°: 22/02085

Description of the Sample

Laboratory No.	21-017931
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Name of the sample / Product	Bromelain (>1200 GDU/g)
Strength / Dosage form	-
Batch No.	21H12-B05

Test Results

Physico-chemical testing: INTERNAL

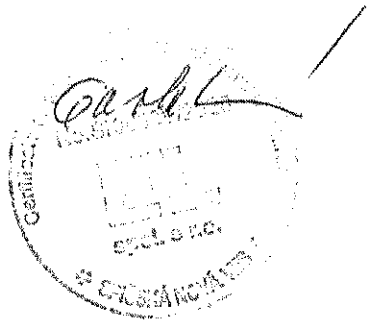
Test / parameter	Test method	Unit of measurement	Limit value	Result	Statement of Compliance	Start of the Test
Appearance of the substance	VI	-	white or creamy white powder	white powder	Compliance	21.10.2021
Identification A (UV spectrum)	UV/VIS	-	compliance	compliance	Compliance	21.10.2021
Identification B (content activity Bromelaine)	Test	-	compliance	compliance	Compliance	02.11.2021
Heavy metals	Test	ppm	≤50	<50	Compliance	21.10.2021
Sulfated ash	GA	%	≤5	1.5	Compliance	21.10.2021
Loss on drying	GA	%	≤5	2.7	Compliance	20.10.2021
Content activity Bromelaine	UV/VIS	GDU/g	about 1200	1203	Compliance	15.02.2022

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

Test Methods

Abbreviation	Method
GA	Gravimetric analysis
Test	Test
UV/VIS	Spectrophotometry
VI	Visual inspection

Date: 15.02.2022
Approved by: Ing. Mária Gavláková, Qualified Person



ZOZ CENTRUM BADAŃ MIKROBIOLOGICZNYCH I AUTOSZCZEPIONEK
imienia dr Jana Kobra Sp. z o.o.
31-016 Kraków, ul. Sławkowska 17, tel. 12 421 78 36, biuro@cbm.com.pl; www.cbm.com.pl
(wejście również z ul. Św. Jana 22)

Badanie czystości mikrobiologicznej preparatów farmaceutycznych
Badanie wykonano zgodnie z Ph. Eur. 10.0

Numer badania	**B/3109/F**
Przedmiot badania	**Bromelaina (>1200 GDU/g), 1 op. a' 21,57 g**
Miejsce pobrania	
Numer serii	**21H12-B05**
Data pobrania próbki	**2021-08-17**
Data dostarczenia próbki	**2021-08-17 13:25**
Data rozpoczęcia badania	**2021-08-17 14:30**
Data zakończenia badania	**2021-08-23 10:00**
Próbki pobrał i dostarczył	**"FAGRON" Sp. z o.o.** **ul. Pasternik 26** **31-354 Kraków**

WYNIKI BADAŃ :

L.P.	Rodzaj drobnoustroju / podłoża	Dopuszczalna ilość CFU w 1g lub 1ml	Wynik / Oznaczona ilość CFU w 1g lub 1ml
1	***Staphylococcus aureus*** podłoże: TSB, firma:Graso, seria: 20210224;Mannitol, firma:Graso, seria: 20210531	**nieobecne w 1g lub 1ml**	**nieobecne w 1g**
2	***Escherichia coli*** podłoże: TSB, firma: Graso, seria: 20210224;MCK bulion, firma:Graso, seria: 20210222;MCK, firma:Graso, seria:20210702	**nieobecne w 1g lub 1ml**	**nieobecne w 1g**
3	***Salmonella*** podłoże: TSB, firma:Graso, seria: 20210224;Rappap.-Vassiliad. bul., firma:Graso, seria: 20210219;XLD, firma:Graso, seria:20210614	**nieobecne w 10 g lub 10 ml**	**nieobecne w 10 g**
4	***Bakterie Gram-ujemne tolerujące żółć*** podłoże: TSB, firma: Graso, seria: 20210224;Mossela Bulion, firma: Graso, seria: 20210722;VRBGA, firma:Graso, seria: 20210615	$\leq 10^2$	**<10**
5	**Ogólna liczba drobnoustrojów tlenowych (TAMC)** podłoże: T.C.S., firma: Bio-Rad, seria: 64407256	$\leq 2 \times 10^4$	**<10**
6	**Ogólna liczba pleśni i drożdży (TYMC)** podłoże: Sabour. Dext. agar z chloramf., firma:Graso,seria: 20210630	$\leq 2 \times 10^2$	**<10**

Inne: NaCl buf.r-ór z pept. o pH=7,0, firma: Graso, seria: 20201119

Wyizolowane drobnoustroje: -

Spełnia wymogi Ph. Eur. 10.0

Potwierdzenie etapu wytwarzania produktu leczniczego.

Niniejszym potwierdzam, że etap wytwarzania obejmujący badania czystości mikrobiologicznej został przeprowadzony w pełnej zgodności z wymaganiami Dobrej Praktyki Wytwarzania i warunkami określonymi w umowie, zapewniającymi zgodność z wymaganiami pozwolenia i dokumentacji dotyczącej wprowadzenia do obrotu produktu leczniczego, jakie zostały przekazane przez Zleceniodawcę.

WYNIK ZATWIERDZIŁ:
2021-08-23
OSOBA WYKWALIFIKOWANA
mgr biol. Katarzyna Bucała-Śladowska
Diagnosta laboratoryjny