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: 21/23041

Correction to the Test Report No.: 21/22529
Reason for correction: correction -result Absorbance at about 287 nm

Customer

Customer: (name and address)	Fagron sp. z o.o. ul. Pasternik 26, 31354 Kraków	**Date of sample receipt :**	14.09.2021
Division:	Fagron Kraków	**Date of testing from:**	14.09.2021
Contract / order:	2021 19/0033/SLP/F	**to:**	16.11.2021
Order No.:	21-08557	**Date of Test Report issue:**	23.11.2021

Description of the Sample

Laboratory No.	**21-020445**
Type of the sample	**Pharmaceutical raw materials, drugs and auxiliary materials**
Name of the sample / Product	**Acidum flufenamicum**
Strength / Dosage form	-
Batch No.	21H10-B05
Expiry date	31.10.2023
Description of package	plastic cup
Size of package / Quantity	2 units
Manufacturer / Trader	Fagron
Sampling / Delivery	Sample delivered by Customer
Purpose of testing	Batch release – Assessment of conformity with specification No.: Flufenamic acid Specification : INTERNAL
Specification / Test procedure	External documentation with specification No.: Flufenamic acid Specification : INTERNAL
Appearance of the sample	Pale yellow, crystalline powder

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

Test sample: Acidum flufenamicum **Batch:** 21H10-B05 **Manufacturer / Trader:** Fagron

Tested sample in performed tests
is in compliance with
the specifications presented in Flufenamic acid Specification : 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.: Flufenamic acid Specification : 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 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. Silvia Strelová, Deputy Head of LFOA

Test Report will be delivered to: Fagron Kraków

Date: 23.11.2021

Approved by: Ing. Mária Gavláková, Qualified Person

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

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Test Report Nº: 21/23041

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Name of the sample / Product	Acidum flufenamicum
Strength / Dosage form	-
Batch No.	21H10-B05

Test Results

Physico-chemical testing: Flufenamic acid Specification : INTERNAL

Test / parameter	Test method	Unit of measurement	Limit value	Result	Statement of Compliance	Start of the Test
Appearance of the substance	VI	-	Pale yellow, crystalline powder	Pale yellow, crystalline powder	Compliance	02.11.2021
Identification A (Infrared absorption spectrophotometry) Sample-1 Sample-2	IR	-	Compliance	Compliance	Compliance	22.09.2021
Identification B Sample-1 Sample-2	UV	-	Compliance	Compliance	Compliance	02.11.2021
Absorbance at about 287 nm	UV/VIS	-	0.55-0.59	0.58	Compliance	02.11.2021
Absorbance at about 344 nm	UV/VIS	-	0.28-0.31	0.31	Compliance	02.11.2021
Copper	AAS-F	ppm	≤20	<2	Compliance	12.11.2021
Related substances	TLC chrom	%	≤0.2	<0.2	Compliance	02.11.2021
Loss on Drying	GA	%	≤0.5	0.03	Compliance	02.11.2021
Sulfated ash	GA	%	≤0.1	<0.1	Compliance	02.11.2021
3-Aminobenzotrifluoride	Test	ppm	≤100	<100	Compliance	02.11.2021
Assay of Acidum flufenamicum (dried substance)	TitrMet	%	99.0-101.0	100.7	Compliance	02.11.2021

Person responsible for results: Ing. Silvia Strelová, Deputy Head of LFOA

Test Methods

Abbreviation	Method
AAS-F	Atomic absorption spectrometry with flame atomization
GA	Gravimetric analysis
IR	Infrared spectrometry
TLC chrom	Thin layer chromatography
Test	Test
TitrMet	Titrimetric method
UV	UV spectrometry
UV/VIS	Spectrophotometry
VI	Visual inspection

Date: 23.11.2021
Approved by: Ing. Mária Gavláková, Qualified Person