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: 22/06879

Customer

Customer: (name and address)	Fagron sp. z o.o. ul. Pasternik 26, 31354 Kraków	**Date of sample receipt :**	08.03.2022
Division:	Fagron Kraków	**Date of testing from:**	08.03.2022
Contract / order:	2022 19/0033/SLP/F	**to:**	05.05.2022
Order No.:	22-01870	**Date of Test Report issue:**	05.05.2022

Description of the Sample

Laboratory No.	**22-004093**
Type of the sample	**Pharmaceutical raw materials, drugs and auxiliary materials**
Name of the sample / Product	**Acidum flufenamicum**
Strength / Dosage form	-
Batch No.	22A14-B06
Expiry date	01.09.2024
Description of package	plastic cup
Size of package / Quantity	8 units -25 g
Manufacturer / Trader	Fagron
Sampling / Delivery	Sample delivered by Customer
Purpose of testing	Batch release – Assessment of conformity with specification No.: INTERNAL Flufenamic acid and Ph.Eur 10.6 07/2018:50400
Specification / Test procedure	External documentation with specification No.: INTERNAL Flufenamic acid and Ph.Eur 10.6 07/2018:50400
Appearance of the sample	Pale yellow, crystalline powder

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

Test sample: Acidum flufenamicum **Batch:** 22A14-B06 **Manufacturer / Trader:** Fagron

Tested sample in performed tests
is in compliance with
the specifications presented in INTERNAL Flufenamic acid and Ph.Eur 10.6 07/2018:50400.

- 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 Flufenamic acid and Ph.Eur 10.6 07/2018:50400.

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: 05.05.2022

Approved by: Ing. Mária Gaviaková, Qualified Person

EL spol. s r.o. SPIŠSKÁ NOVÁ VES

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: 22/06879

Description of the Sample

Laboratory No.	22-004093
Type of the sample	Pharmaceutical raw materials, drugs and auxiliary materials
Name of the sample / Product	Acidum flufenamicum
Strength / Dosage form	-
Batch No.	22A14-B06

Test Results

Physico-chemical testing: INTERNAL Flufenamic acid and Ph.Eur 10.6 07/2018:50400

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	13.04.2022
Identification A (Infrared absorption spectrophotometry)	IR	-	Compliance	Compliance	Compliance	30.03.2022
Identification B	UV	-	Compliance	Compliance	Compliance	25.04.2022
Absorbance at 287 nm	UV/VIS	-	0.55-0.59	0.58	Compliance	25.04.2022
Absorbance at 344 nm	UV/VIS		0.28-0.31	0.30	Compliance	25.04.2022
Copper	AAS-F	ppm	≤20	<2	Compliance	04.05.2022
Related substances	TLC chrom	%	≤0.2	<0.2	Compliance	26.04.2022
Loss on drying	GA	%	≤0.5	0.01	Compliance	13.04.2022
Sulfated ash	GA	%	≤0.1	<0.01	Compliance	27.04.2022
3-Aminobenzotrifluoride	Test	ppm	≤100	<100	Compliance	13.04.2022
Assay of Acidum flufenamicum (dried substance)	TitrMet	%	99.0-101.0	100.7	Compliance	13.04.2022
Residual solvents:						
N,N-dimethylformamide	GC/FID	ppm	≤890	<15	Compliance	12.04.2022
toluene	GC/FID	ppm	≤880	141	Compliance	12.04.2022

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

Test Methods

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

Date: 05.05.2022
Approved by: Ing. Mária Gavláková, Qualified Person

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 N°: 22/07387

Customer

Customer: (name and address)	Fagron sp. z o.o. ul. Pasternik 26, 31354 Kraków	Date of sample receipt :	10.05.2022
Division:	Fagron Kraków	Date of testing from:	10.05.2022
Contract / order:	2022 19/0033/SLP/F	to:	12.05.2022
Order No.:	22-03875	Date of Test Report issue:	12.05.2022

Description of the Sample

Laboratory No.	22-008607
Type of the sample	Pharmaceutical raw materials, drugs and auxiliary materials
Name of the sample / Product	Acidum flufenamicum
Strength / Dosage form	-
Batch No.	22A14-B06
Expiry date	01.09.2024
Description of package	plastic cup
Size of package / Quantity	8 units -25 g
Manufacturer / Trader	Fagron
Sampling / Delivery	Sample delivered by Customer
Purpose of testing	Batch release – Assessment of conformity with specification No.: INTERNAL Flufenamic acid
Specification / Test procedure	External documentation with specification No.: INTERNAL Flufenamic acid
Appearance of the sample	Pale yellow, crystalline powder

Test Results

Physico-chemical testing: INTERNAL Flufenamic acid

Test / parameter	Test method	Unit of measurement	Limit value	Result	Statement of Compliance	Start of the Test
Identification A (Infrared absorption spectrophotometry) Sample No.1 to Sample No. 8	IR	-	Compliance	Compliance	Compliance	12.05.2022
Identification B Sample No.1 to Sample No. 8	UV	-	Compliance	Compliance	Compliance	12.05.2022

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

Test Methods

Abbreviation	Method
IR	Infrared spectrometry
UV	UV spectrometry

Statements:

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- 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.
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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: 12.05.2022 **Approved by:** Ing. Mária Gavláková, Qualified Person