



Test Report No.: 21/23041

Page: 1 of 2
 Printout: 1 of 1

Correction to the Test Report No.: 21/22529

Reason for correction: correction -result Absorbance at about 287 nm

Customer

Customer: Fagron sp. z o.o.
 (name and address) ul. Pasternik 26, 31354 Kraków
Division: Fagron Kraków
Contract / order: 2021 19/0033/SLP/F
Order No.: 21-08557

Date of sample receipt : 14.09.2021
Date of testing from: 14.09.2021
to: 16.11.2021
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

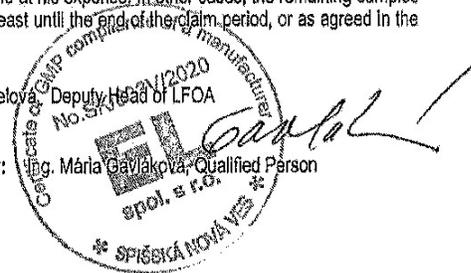
Test sample: Acidum flufenamicum	Batch: 21H10-B05	Manufacturer / Trader: Fagron
<p>Tested sample in performed tests is in compliance with the specifications presented in Flufenamic acid Specification : INTERNAL.</p>		
<ul style="list-style-type: none"> ▪ Statement of compliance / noncompliance is presented 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 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:
Test Report will be delivered to: Fagron Kraków
Date: 23.11.2021

Ing. Silvia Strelcová, Deputy Head of LFOA
 Approved by: Ing. Mária Gavlaková, Qualified Person





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Page: 2 of 2
Printout: 1 of 1

Description of the Sample

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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)	TitMet	%	99.0-101.0	100.7	Compliance	02.11.2021

Person responsible for results: Ing. Silvia Streľová, 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
TitMet	Titrimetric method
UV	UV spectrometry
UV/VIS	Spectrophotometry
VI	Visual inspection

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

