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: 22/05895

Correction to the Test Report No.: 22/05893
Reason for correction: correction Appearance of the sample and result **Solubility**

Customer

Customer: (name and address)	Fagron sp. z o.o. ul. Pasternik 26, 31354 Kraków	**Date of sample receipt :**	18.02.2022
Division:	Fagron Kraków	**Date of testing from:**	18.02.2022
Contract / order:	2022 19/0033/SLP/F	**to:**	21.04.2022
Order No.:	22-01416	**Date of Test Report issue:**	22.04.2022

Description of the Sample

Laboratory No.	**22-003145**
Type of the sample	**Pharmaceutical raw materials, drugs and auxiliary materials**
Name of the sample / Product	**Amifampridinum**
Strength / Dosage form	-
Batch No.	22A22-B04
Expiry date	02.12.2024
Description of package	plastic cup
Size of package / Quantity	1 unit 10 g
Manufacturer / Trader	Fagron
Sampling / Delivery	Sample delivered by Customer
Purpose of testing	Batch release – Assessment of conformity with specification No.: DAC 2019 Fagron INTERNAL Amifampridin and Ph.Eur 10.6 07/2018:50400
Specification / Test procedure	External documentation with specification No.: DAC 2019 Fagron INTERNAL Amifampridin and Ph.Eur 10.6 07/2018:50400
Appearance of the sample	pale brown crystalline powder

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

Test sample: Amifampridinum **Batch:** 22A22-B04 **Manufacturer / Trader:** Fagron

Tested sample in performed tests is in compliance with the specifications presented in DAC 2019 Fagron INTERNAL Amifampridin 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.: DAC 2019 Fagron INTERNAL Amifampridin 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. Silvia Strelová, Deputy Head of LFOA

Test Report will be delivered to: Fagron Kraków

Date: 22.04.2022

Approved by: Ing. Mária Gavláková, Qualified Person

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Test Report N°: 22/05895

Description of the Sample

Laboratory No.	22-003145
Type of the sample	Pharmaceutical raw materials, drugs and auxiliary materials
Name of the sample / Product	Amifampridinum
Strength / Dosage form	-
Batch No.	22A22-B04

Test Results

Physico-chemical testing: DAC 2019 Fagron INTERNAL Amifampridin 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	Vis color	-	White to pale brown, crystalline powder	pale brown crystalline powder	Compliance	19.04.2022
Solubility	Test	-	Soluble in methanol, slightly soluble in water, sparingly soluble in acetone, practically insoluble in ether tert-butyl-methyl	Soluble in methanol, slightly soluble in water, sparingly soluble in acetone, practically insoluble in ether tert-butyl-methyl	Compliance	19.04.2022
Identification (IR spectrum)	IR	-	Compliance	Compliance	Compliance	13.04.2022
Appearance of solution	Test	-	Solution is clear and not more intensely coloured than reference solution B5	The solution was clear and not more intensely coloured than reference solution B5	Compliance	19.04.2022
Absorbance maximum at 224 nm	UV/VIS	-	about 1810	1737	Compliance	19.04.2022
Absorbance maximum at 286 nm	UV/VIS	-	about 780	739	Compliance	19.04.2022
Related substances :						
Impurity A	HPLC_UVVIS	%	≤0.1	<0.01	Compliance	30.03.2022
Unspecified impurities	HPLC_UVVIS	%	≤0.10	<0.05	Compliance	30.03.2022
Total impurities	HPLC_UVVIS	%	≤0.5	<0.05	Compliance	30.03.2022
Water	PotTitr	%	≤1.0	0.08	Compliance	14.04.2022
Sulfated ash	GA	%	≤0.1	<0.01	Compliance	20.04.2022
Assay of Amifampridinum (anhydrous substance)	PotTitr	%	99.0 - 101.0	100.0	Compliance	19.04.2022
Residual solvents:						
Methanol	GC/FID	ppm	≤3000	55	Compliance	03.03.2022
		%	≤0.3	0.006	Compliance	03.03.2022

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

Test Methods

Abbreviation	Method
GA	Gravimetric analysis
GC/FID	Gas chromatography with flame ionization detector
HPLC_UVVIS	High-performance liquid chromatography with UV-visible detector
IR	Infrared spectrometry
PotTitr	Potentiometric titration
Test	Test
Vis color	Visual colorimetry

Date: 22.04.2022
Approved by: Ing. Mária Gavláková, Qualified Person

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Test Report Nº: 22/05893

Description of the Sample

Laboratory No.	22-003145
Type of the sample	Pharmaceutical raw materials, drugs and auxiliary materials
Name of the sample / Product	Amifampridinum
Strength / Dosage form	-
Batch No.	22A22-B04

Test Results

Physico-chemical testing: DAC 2019 Fagron INTERNAL Amifampridin 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	Vis color	-	White to pale brown, crystalline powder	pale brown crystalline powder	Compliance	19.04.2022
Solubility	Test	-	Soluble in methanol, slightly soluble in water, sparingly soluble in acetone, practically insoluble in ether tert-butyl-methyl	soluble in methanol, slightly soluble in water, sparingly soluble in acetone	Compliance	19.04.2022
Identification (IR spectrum)	IR	-	Compliance	Compliance √	Compliance	13.04.2022
Appearance of solution	Test	-	Solution is clear and not more intensely coloured than reference solution B5	The solution was clear and not more intensely coloured than reference solution B5 √	Compliance	19.04.2022
Absorbance maximum at 224 nm	UV/VIS	-	about 1810	1737	Compliance	19.04.2022
Absorbance maximum at 286 nm	UV/VIS	-	about 780	739	Compliance	19.04.2022
Related substances :						
Impurity A	HPLC_UVVIS	%	≤0.1	<0.01 √	Compliance	30.03.2022
Unspecified impurities	HPLC_UVVIS	%	≤0.10	<0.05 √	Compliance	30.03.2022
Total impurities	HPLC_UVVIS	%	≤0.5	<0.05 √	Compliance	30.03.2022
Water	PotTitr	%	≤1.0	0.08 √	Compliance	14.04.2022
Sulfated ash	GA	%	≤0.1	<0.01 √	Compliance	20.04.2022
Assay of Amifampridinum (anhydrous substance)	PotTitr	%	99.0 - 101.0	100.0 √	Compliance	19.04.2022
Residual solvents:						
Methanol	GC/FID	ppm	≤3000	55 √	Compliance	03.03.2022
		%	≤0.3	0.006 √	Compliance	03.03.2022

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

Test Methods

Abbreviation	Method
GA	Gravimetric analysis
GC/FID	Gas chromatography with flame ionization detector
HPLC_UVVIS	High-performance liquid chromatography with UV-visible detector
IR	Infrared spectrometry
PotTitr	Potentiometric titration
Test	Test
Vis color	Visual colorimetry

Date: 21.04.2022
Approved by: Ing. Mária Gavláková, Qualified Person

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Test Report Nº: 22/05893

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Specification / Test procedure	External documentation with specification No.: DAC 2019 Fagron INTERNAL Amifampridin and Ph.Eur 10.6 07/2018:50400
Appearance of the sample	white crystalline powder

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

Test sample: Amifampridinum **Batch:** 22A22-B04 **Manufacturer / Trader:** Fagron

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Test Report will be delivered to: Fagron Kraków

Date: 21.04.2022 **Approved by:** Ing. Mária Gavláková, Qualified Person

wydano próbę o koncie CoA

Fagron sp. z o.o.
Starszy specjalista ds. kontroli jakości
21.04.2022