EL spol. s r.o., Centre of Laboratory Services
Radlinského 17A, 052 01 Spišská Nová Ves, Slovakia

Accredited Testing Laboratories by ISO/IEC 17025, SNAS, Certificate of Accreditation No. S-025
Holder of GMP Certificate No. SK/021V/2018 ŠUKL

SPECIFICATIES GECONTROLEERD EN CONFORM
DATUM 04-12-20 PARAAF YS

Test Report Nº: 20/24675

Correction to the Test Report No.: 20/22657
Reason for correction: Correction of Appearance of the sample

Customer

Customer: (name and address)	Fagron sp. z o.o. ul. Pasternik 26, 31354 Kraków
Division:	Fagron Kraków
Contract / order:	2020 19/0033/SLP/F
Order No.:	20-09974

Date of sample delivery :	23.10.2020
Date of analysis from:	23.10.2020
to:	05.11.2020
Date of Test Report issue:	03.12.2020

Description of the Sample

Laboratory No.:	**20-024141**
Object of the test:	**Pharmaceutical raw materials, drugs and auxiliary materials**
Name of the sample / product:	**Amifampridinum Diaminopyridinum 3,4-DAC**
Power / form of the drug:	-
Batch No.:	20J13-F01
Expiration date:	-
Description of the packing:	plastic cup
Size of the packing:	1 unit
Contractor / producer:	Fagron
Way of the sampling / delivery:	Sample delivered by Customer
Purpose of the test:	Batch release – Assessment of conformity with specification No.: DAC 2020/1 AMIFAMPRIDIN
Required specifications:	DAC 2020/1 AMIFAMPRIDIN
Appearance of the sample / description:	White to slightly brownish, crystalline powder

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

Test sample: Amifampridinum Diaminopyridinum 3,4-DAC **Batch:** 20J13-F01 **Contractor / producer:** Fagron

Tested sample in performed tests is in compliance with specifications presented in DAC 2020/1 AMIFAMPRIDIN.

- 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 2020/1 AMIFAMPRIDIN.
- The comparison applies to results of the stated tests parameters of this sample only.

Statements

- **Testing Laboratory is a holder of the APPROVING DECREE SUKL No. Š-08/08, control laboratory for pharmaceutical testing.**
- **Tests are performed according to GMP Certificate No. SK/021V/2018 ŠUKL, quality control testing of medicinal products.**
- Testing Laboratory declares that the Test Results relate to the tested items only.
- This Test Report shall not be reproduced except in full, without written approval of the Testing Laboratory.
- The laboratory accreditation or its Test Report itself shall mean in no case approval of the product by the body granting the accreditation or by any other body.

Claiming and storage of samples remains

- It is possible to claim the test results up to 30 days from the date of the results sending to customer. Claims delivered in written form only are accepted and executed.
- Only samples whose original properties do not change over time will be retained - at least during the claim period or according to the particular customer agreement (e.g. until the expiration date).
- Return of samples remains - the samples will be returned to the costumer upon their written request and at their expense. In other cases the samples remains are discarded at customer expense after the expiry of storage period.

Test Report provided by and for Statement of Compliance is responsible: Ng. Silvia Strelová, Deputy Head of LFOA

Test Report will be delivered to: Fagron Kraków

Date: 03.12.2020 **Approved by:** Ing. Mária Gavláková, Head of Centre of laboratory Services

Certificate of GMP compliance of manufacturer No.SK/021V/2018 EL spol. s r.o. NOVÁ VES

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Test Report Nº: 20/24675

Description of the Sample

Laboratory No.:	20-024141
Object of the test:	Pharmaceutical raw materials, drugs and auxiliary materials
Name of the sample / product:	Amifampridinum Diaminopyridinum 3,4-DAC
Power / form of the drug:	-
Batch No.:	20J13-F01

Test Results

Physico-chemical testing: DAC 2020/1 AMIFAMPRIDIN

Test / parameter	Test method	Unit of measurement	Limit value	Result	Statement of Compliance	Start of the Test
Appearance	Test	-	White to slightly brownish, crystalline powder	White to slightly brownish, crystalline powder	Compliance	23.10.2020
Solubility	Test	-	Slightly soluble in water, soluble in methanol	Compliance	Compliance	23.10.2020
Identification (IR spectrum)	IR	-	Compliance	Compliance	Compliance	28.10.2020
Appearance of solution	Test	-	Solution is clear and not more intensely coloured than reference solution B5	Solution was clear and not more intensely coloured than reference solution B5	Compliance	02.11.2020
Related substances :						
Impurity A	HPLC_UVVIS	%	≤0.1	<0.01	Compliance	27.10.2020
Unspecified impurities	HPLC_UVVIS	%	≤0.10	<0.05	Compliance	27.10.2020
Total impurities	HPLC_UVVIS	%	≤0.5	<0.05	Compliance	27.10.2020
Water	PotTitr	%	≤1.0	0.13	Compliance	28.10.2020
Sulfated ash	GA	%	≤0.1	0.03	Compliance	02.11.2020
Assay of Amifampridinum (anhydrous substance)	PotTitr	%	99.0 - 101.0	100.3	Compliance	02.11.2020

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

Test equipment and instruments used for testing have been calibrated and verified according to valid metrological regulations.

Abbreviations

Abbreviation	Method
GA	Gravimetric analysis
HPLC_UVVIS	High-performance liquid chromatography with UV-visible detector
IR	Infrared spectrometry
PotTitr	Potentiometric titration
Test	Test

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Date: 03.12.2020
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