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°: 22/05445

Customer

Customer: (name and address)	Fagron sp. z o.o. ul. Pasternik 26, 31354 Kraków
Division:	Fagron Kraków
Contract / order:	2022 19/0033/SLP/F
Order No.:	22-02696

Date of sample receipt :	04.04.2022
Date of testing from:	04.04.2022
to:	13.04.2022
Date of Test Report issue:	13.04.2022

Description of the Sample

Laboratory No.	**22-006027**
Type of the sample	**Pharmaceutical raw materials, drugs and auxiliary materials**
Name of the sample / Product	**Aminopyridinum** V
Strength / Dosage form	-
Batch No.	22C25-B07 V
Expiry date	23.02.2025 V
Description of package	plastic cup
Size of package / Quantity	1 unit- 10 g V
Manufacturer / Trader	Fagron V
Sampling / Delivery	Sample delivered by Customer
Purpose of testing	Batch release – Assessment of conformity with specification No.: INTERNAL Fagron Aminopyridinum V
Specification / Test procedure	External documentation with specification No.: INTERNAL Fagron Aminopyridinum
Appearance of the sample	white crystalline powder — prosba o kontrolu 13.04.2022

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

Test sample: Aminopyridinum **Batch:** 22C25-B07 **Manufacturer / Trader:** Fagron

Tested sample in performed tests is in compliance with the specifications presented in INTERNAL Fagron Aminopyridinum.

- 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 Fagron Aminopyridinum.

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: 13.04.2022

Approved by: Ing. Mária Gavláková, Qualified Person

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Description of the Sample

Laboratory No.	22-006027
Type of the sample	Pharmaceutical raw materials, drugs and auxiliary materials
Name of the sample / Product	Aminopyridinum
Strength / Dosage form	-
Batch No.	22C25-B07

Test Results

Physico-chemical testing: INTERNAL Fagron Aminopyridinum

Test / parameter	Test method	Unit of measurement	Limit value	Result	Statement of Compliance	Start of the Test
Identification B. (Infrared absorption spectrophotometry)	IR	-	Compliance	Compliance	Compliance	11.04.2022
Appearance of solution	VI	-	The solution is clear and not more intensely colored than reference solution BY5.	The solution was clear and not more intensely colored than reference solution BY5.	Compliance	11.04.2022
Related substances:						
impurity A (4-Cyanpyridine)	HPLC	%	≤0.1	<0.01	Compliance	08.04.2022
impurity B (Isonicotinamide)	HPLC	%	≤0.1	<0.01	Compliance	08.04.2022
unspecified impurities	HPLC	%	≤0.10	<0.01	Compliance	08.04.2022
total impurities	HPLC	%	≤0.5	<0.01	Compliance	08.04.2022
Sulfated ash	GA	%	≤0.1	0.04	Compliance	11.04.2022
Assay Aminopyridinum (4-) (anhydrous substance)	PotTitr	%	99.0-101.0	100.2	Compliance	11.04.2022
Water	PotTitr	%	≤0.5	0.36	Compliance	11.04.2022

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

Test Methods

Abbreviation	Method
GA	Gravimetric analysis
HPLC	High-performance liquid chromatography
IR	Infrared spectrometry
PotTitr	Potentiometric titration
VI	Visual inspection

Date: 13.04.2022
Approved by: Ing. Mária Gavláková, Qualified Person