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: 21/03061

Customer

Customer: (name and address)	Fagron sp. z o.o. ul. Pasternik 26, 31354 Kraków	**Date of sample receipt :**	04.02.2021
Division:	Fagron Kraków	**Date of testing from:**	04.02.2021
Contract / order:	2021 19/0033/SLP/F	**to:**	24.02.2021
Order No.:	21-00950	**Date of Test Report issue:**	24.02.2021

Description of the Sample

Laboratory No.	**21-002157**
Type of the sample	**Pharmaceutical raw materials, drugs and auxiliary materials**
Name of the sample / Product	**Phytomenadionum racemicum**
Strength / Dosage form	-
Batch No.	21A28-F03
Expiry date	-
Description of package	dark glass bottle
Size of package / Quantity	2 units
Manufacturer / Trader	Krakow
Sampling / Delivery	Sample delivered by Customer
Purpose of testing	Batch release – Assessment of conformity with specification No.: Ph.Eur 10.3 01/2020:3011
Specification / Test procedure	External documentation with specification No.: Ph.Eur 10.3 01/2020:3011
Appearance of the sample	clear, intense yellow, viscous, oily liquid.

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

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DATUM 01 03 21 PARAAF

Test sample: Phytomenadionum racemicum **Batch:** 21A28-F03 **Manufacturer / Trader:** Krakow

Tested sample in performed tests is in compliance with the specifications presented in Ph.Eur 10.3 01/2020:3011.

- 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.: Ph.Eur 10.3 01/2020:3011.
- The comparison applies to results of the stated tests parameters of this sample only.

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).**
- 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: Ing. Silvia Strelová, Deputy Head of LFQA

Test Report will be delivered to: Fagron Kraków

Date: 24.02.2021 **Approved by:** Ing. Mária Gavláková, Qualified Person

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Description of the Sample

Laboratory No.:	21-002157
Type of the sample:	Pharmaceutical raw materials, drugs and auxiliary materials
Name of the sample / product:	Phytomenadionum racemicum
Strength / Dosage form:	-
Batch No.:	21A28-F03

Test Results

Physico-chemical testing: Ph.Eur 10.3 01/2020:3011

Test / parameter	Test method	Unit of measurement	Limit value	Result	Statement of Compliance	Start of the Test
Indentification A: Optical rotation Sample-1 Sample-2	Polar	°	-0.05 to +0.05	Compliance	Compliance	18.02.2021
Indentification B: Ultraviolet and visible absorption spectrophotometry Sample-1 Sample-2	UV/VIS	-	Compliance	Compliance	Compliance	19.02.2021
Indentification C: Assay	HPLC/DAD	-	the principal peak in the chromatogram obtained with the test solution is similar in retention time and size to the principal peak in the chromatogram obtained with reference solution (d)	the principal peak in the chromatogram obtained with the test solution was similar in retention time and size to the principal peak in the chromatogram obtained with reference solution (d)	Compliance	22.02.2021
Appearance of solution	Test	-	The solution is clear	The solution was clear	Compliance	18.02.2021
Optical rotation Sample-1 Sample-2	Polar	°	-0.05 to +0.05	-0.03 -0.03	Compliance	18.02.2021
Acid Value	VA	-	≤2.0	0.3	Compliance	18.02.2021
Impurity A	TLC chrom	%	≤0.2	<0.2	Compliance	18.02.2021
Related substances :						
Impurity B	HPLC/DAD	%	≤0.2	<0.05	Compliance	22.02.2021
unspecified impurities	HPLC/DAD	%	≤0.15	<0.05	Compliance	22.02.2021
Total	HPLC/DAD	%	≤1.0	<0.05	Compliance	22.02.2021
Sulfated ash	GA	%	≤0.1	<0.01	Compliance	18.02.2021
Assay of Phytomenadione racemic :						
trans-phytomenadione isomers	HPLC/DAD	%	≥ 85.0	86.9	Compliance	22.02.2021
sum of trans-phytomenadione and cis-phytomenadione isomers	HPLC/DAD	%	97.0 - 103.0	102.3	Compliance	22.02.2021

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.

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Test Report Nº: 21/03061

Abbreviations

Abbreviation	Method
GA	Gravimetric analysis
HPLC/DAD	High-performance liquid chromatography with diode-array detector
Polar	Polarimetry
TLC chrom	Thin layer chromatography
Test	Test
UV/VIS	Spectrophotometry
VA	Volumetric analysis

Date: 24.02.2021
Approved by: Ing. Mária Gavláková, Qualified Person

Certificate of GMP compliance of a manufacturer No.SK/033V/2020 EL spol. s r.o. SPIŠSKÁ NOVÁ VES

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