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

Test Report Nº: 20/00274

Customer

Customer: (name and address)	Fagron sp. z o.o. ul. Pasternik 26, 31354 Kraków
Division:	Fagron Kraków
Contract / order:	2019 19/0033/SLP/F
Order No.:	19-11829

Date of sample delivery :	17.12.2019
Date of analysis from:	17.12.2019
to:	15.01.2020
Date of Test Report issue:	15.01.2020

Description of the Sample

Laboratory No.:	**19-029832**
Object of the test:	**Pharmaceutical raw materials, drugs and auxiliary materials**
Name of the sample / product:	**Pregnenolonum**
Power / form of the drug:	-
Batch No.:	19L09-F01
Expiration date:	-
Description of the packing:	plastic cup
Size of the packing:	two packs
Contractor / producer:	Fagron
Way of the sampling / delivery:	Sample delivered by Customer
Purpose of the test:	Batch release – Assessment of conformity with specification No.: INTERN:Pregnenolone
Required specifications:	INTERN:Pregnenolone
Appearance of the sample / description:	white crystals

Test Results

Physico-chemical testing: INTERN:Pregnenolone

Test / parameter	Test method	Unit of measurement	Limit value	Result	Statement of Compliance	Start of the Test
Related Substances	TLC chrom	-	None of other spots in the chromatogram obtained with the test solution is more intense than the spot of the chromatogram obtained with reference solution.	None of other spots in the chromatogram obtained with the test solution was more intense than the spot of the chromatogram obtained with reference solution.	Compliance	14.01.2020

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

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DATUM 17-01-20 PARAAF YS

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

Abbreviations

Abbreviation	Method
TLC chrom	Thin layer chromatography

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.

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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 LFOA

Test Report will be delivered to: Fagron Kraków

Date: 15.01.2020

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

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DATUM 17-01-20 PARAAF YS