



BioPharma
Product Testing

Certificate of Analysis

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Analytical Report: AAV11327
Eurofins Batch Number JJ22AA1214
Version: 1

Fagron Services B.V.
Molenwerf 13
Uitgeest, 1911 DB
NL

Client Account Number: A00497292BNI
Eurofins Quote Number: IOQ6PH19016882

General Method Reference: CERTA Pregnenolone and Prüfvorschrift Pregnenolon

Eurofins Sample Number JJ22AA1214-1	
Original Received Date:	17-Mar-2022
Description:	Pregnenolonum; 505548
Lot Number:	22C14-F04
Containers Submitted:	1 Container(s)
Client Sample ID:	M001

Analysis/Sample	Specification	Result	Unit
Ph Eur Characters Appearance			
JJ22AA1214-1	White or almost white, crystalline powder	Meets Requirements-Almost white crystalline powder	----
Method: Current Ph Eur for JJ22AA1214-1 Analysis Date 24-Mar-2022 to 24-Mar-2022 for JJ22AA1214-1			
Identity A			
JJ22AA1214-1	The transmission minima (or absorption maxima) in the spectrum obtained with the substance to be examined correspond in position and relative size to those of the reference.	Meets Requirements	----
Method: Current Ph Eur (2.2.24) for JJ22AA1214-1 Analysis Date 24-Mar-2022 to 24-Mar-2022 for JJ22AA1214-1			
Identity B			
JJ22AA1214-1	+24 to +32	29	°
Method: Current Ph Eur (2.2.7) for JJ22AA1214-1 Analysis Date 24-Mar-2022 to 24-Mar-2022 for JJ22AA1214-1			
Loss on drying			
JJ22AA1214-1	NMT 1.0	0.0	%
Method: Current Ph Eur (2.2.32) for JJ22AA1214-1 Analysis Date 21-Mar-2022 to 21-Mar-2022 for JJ22AA1214-1			

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Analysis/Sample	Specification	Result	Unit
Assay			
JJ22AA1214-1	97.0 to 103.0	99.8	%
Method: Prüfvorschrift Pregnenolon v.01 for JJ22AA1214-1 Analysis Date 21-Mar-2022 to 22-Mar-2022 for JJ22AA1214-1			
Ph Eur Identification and Control of Residual Solvents Class 1,2 Procedure i and ii, System A			
JJ22AA1214-1			
Methanol	NMT 3000	32	ppm
Method: Current EP 2.4.24 for JJ22AA1214-1 Analysis Date 05-Apr-2022 to 06-Apr-2022 for JJ22AA1214-1			
Ph Eur Residual Solvents			
JJ22AA1214-1			
Ethanol	NMT 5000	74	ppm
Method: Current Ph Eur (2.4.24) for JJ22AA1214-1 Analysis Date 01-Apr-2022 to 05-Apr-2022 for JJ22AA1214-1			
Sample Compliance Assessment			
Samples JJ22AA1214-1 meet the requirement(s) for all listed test(s) where specifications were applied.			

Contracted Company: Eurofins PROXY Laboratories
Archimedesweg 25, 2333 CM, Leiden, The Netherlands
PROXYcustomer@eurofins.com

Questions about this report should be directed to your project manager or the general email listed above.

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Reviewed and electronically signed for Quality Assurance Approval by
Gonnie den Dekker, Supervisor QA Operations
for Eurofins PROXY Laboratories B.V., on 14-Apr-2022 11:40:25 UTC+02:00

Certificate of analysis no. 22/04871

Description of the sample:

Name of the sample:	Pregnenolonum
Batch number:	22C14-F04
Expiration date:	-
Required specifications:	INTERN

Test results:

Parameter	Limit value	Result	Statement of compliance	Testing laboratory
Related substances	TLC	conform	complies	EISpol

Date of analysis: 17.03.2022 – 31.03.2022

Statement of compliance:

The sample meets the requirements for performed tests.

Approved by:

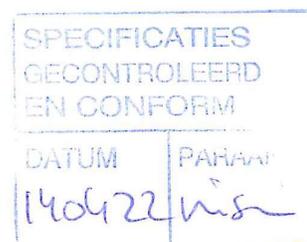
Fagron sp. z o.o.

[Signature]
Faz

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01.04.2022

Fagron sp. z o.o.

[Signature]
Izabela Kumor
stażystka
01.04.2022
jakość





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

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Test Report No: 22/04871

Customer

Customer: Fagron sp. z o.o.
(name and address) ul. Pasternik 26, 31354 Kraków
Division: Fagron Kraków
Contract / order: 2022 19/0033/SLP/F
Order No.: 22-02193

Date of sample receipt : 17.03.2022
Date of testing from: 17.03.2022
to: 31.03.2022
Date of Test Report issue: 31.03.2022

Description of the Sample

Laboratory No.	22-004850
Type of the sample	Pharmaceutical raw materials, drugs and auxiliary materials
Name of the sample / Product	Pregnenolonum
Strength / Dosage form	-
Batch No.	22C14-F04
Expiry date	-
Description of package	plastic cup
Size of package / Quantity	1 unit
Manufacturer / Trader	Fagron
Sampling / Delivery	Sample delivered by Customer
Purpose of testing	Batch release – Assessment of conformity with specification No.: INTERNAL Pregnenolone
Specification / Test procedure	External documentation with specification No.: INTERNAL Pregnenolone
Appearance of the sample	white crystalline powder

Test Results

Physico-chemical testing: INTERNAL Pregnenolone

Test / parameter	Test method	Unit of measurement	Limit value	Result	Statement of Compliance	Start of the Test
Related substances	TLC chrom	-	Compliance	Compliance	Compliance	31.03.2022

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

Test Methods

Abbreviation	Method
TLC chrom	Thin layer chromatography

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 Certificate 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: 31.03.2022

Approved by: Ing. Mária Gavláková, Qualified Person