eurofins | BioPharma Product Testing

Certificate of Analysis

Analytical Report: AAU57413
Eurofins Batch Number JJ22AA0916
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 JJ22AA0916-1	
Original Received Date:	22-Feb-2022
Description:	Pregnenolonum; 505548
Lot Number:	22B17-F03
Containers Submitted:	1 container

Analysis/Sample	Specification	Result	Unit
Ph Eur Characters Appearance			
JJ22AA0916-1	White or almost white, crystalline powder	Meets Requirements-White crystalline powder	----
Method: Current Ph Eur Analysis Date 03-Mar-2022 to 03-Mar-2022 for JJ22AA0916-1			
Identity A			
JJ22AA0916-1	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) Analysis Date 03-Mar-2022 to 03-Mar-2022 for JJ22AA0916-1			
Identity B			
JJ22AA0916-1	+24 to +32	29	°
Method: Current Ph Eur (2.2.7) Analysis Date 03-Mar-2022 to 03-Mar-2022 for JJ22AA0916-1			
Loss on drying			
JJ22AA0916-1	NMT 1.0	0.1	%
Method: Current Ph Eur (2.2.32) Analysis Date 21-Mar-2022 to 21-Mar-2022 for JJ22AA0916-1			

SPECIFICATIES
GECONTROLEERD
IN ORDE
DATUM 22/3/22 PARAAF

eurofins | BioPharma Product Testing

Certificate of Analysis

Analytical Report: AAU57413
Eurofins Batch Number JJ22AA0916
Version: 1

Analysis/Sample	Specification	Result	Unit
Assay			
JJ22AA0916-1	97.0 to 103.0	97.5	%
Method: Prüfvorschrift Pregnenolon v.01 Analysis Date 08-Mar-2022 to 09-Mar-2022 for JJ22AA0916-1			
Ph Eur Identification and Control of Residual Solvents Class 1,2 Procedure i and ii, System A			
JJ22AA0916-1			
Methanol	NMT 3000	52	ppm
Method: Current EP 2.4.24 Analysis Date 07-Mar-2022 to 14-Mar-2022 for JJ22AA0916-1			
Ph Eur Residual Solvents			
JJ22AA0916-1			
Ethanol	NMT 5000	104	ppm
Method: Current Ph Eur (2.4.24) Analysis Date 07-Mar-2022 to 14-Mar-2022 for JJ22AA0916-1			

Sample Compliance Assessment
Samples JJ22AA0916-1 meet the requirement(s) for all listed test(s) where specifications were applied.

Contracted Company: PROXY Laboratories Chemistry and Biochemistry
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.

SPECIFICATIES GECONTROLEERD EN CONFORM

DATUM	PARAAF
22/3/22	

Reviewed and electronically signed for Quality Assurance Approval by
Julia Melnikova, Analytical Review Officer
for Eurofins PROXY Laboratories B.V., on 22-Mar-2022 08:40:06 UTC+01:00

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: 22/03774

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.: 22-01516

SPECIFICATIES GECONTROLEERD EN CONFORM
DATUM 22/3/22 PARAAF

Date of sample receipt : 22.02.2022
Date of testing from: 22.02.2022
to: 15.03.2022
Date of Test Report issue: 15.03.2022

Description of the Sample

Laboratory No.	**22-003351**
Type of the sample	**Pharmaceutical raw materials, drugs and auxiliary materials**
Name of the sample / Product	**Pregnenolonum**
Strength / Dosage form	-
Batch No.	22B17-F03
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	15.03.2022

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 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: 15.03.2022

Approved by: Ing. Mária Gavláková, Qualified Person