

## Certificate of Analysis

**Product name:** **Pregnenolonum**

**Batch number / Weight:** **23E29-B02-231043 / 1 KG**

**Analysed according to:** **Monograph**

**Number of analysis / Inspection Code** **23E29-B02 / INS-23-4237**

**Reference Code / No.:** **V01951 / C07-230213**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification	Conform	Conform		
Melting point	185 - 194	194	°C	
Specific optical rotation	+27 to +30	+27,2		
Loss on drying	<=0,50	0,03	%	
Related Substances	Conform	Conform		
Any impurity	<=0,50	0,22	%	
Total impurities	<=1,0	0,22	%	
Assay	>= 99,0	99,5	%m/m	
Metallic residues	CHMP/ICH/353369/2013	Conform		
Residual solvents	CPMP/ICH/82 260/06	Conform		
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		

All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab EL Spol

Release:  
Dominika Sołtysik  
Qualified Person

26-06-2023

Expiration: 27-02-2026

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.

fagron.pl      Fagron Sp. z o.o.  
ul. Armii Krajowej 3  
32-540 Trzebinia, Poland  
e-mail:biuro@fagron.pl

**fagron.pl**      Fagron sp. z o.o.  
ul. Pasternik 26, 31-354 Kraków, Poland  
tel.: +48 12 3343 512  
e-mail: biuro@fagron.pl