

## Certificate of Analysis

**Product name:** **Pregnenolonum**  
**Batch number / Weight:** **22I19-B02-226344 / 1 KG**  
**Analysed according to:** **Monograph**  
**Number of analysis / Inspection Code** **22I19-B02 / INS-22-8801**  
**Reference Code / No.:** **V01951 / C07-220306**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Melting point	about 193	192	°C	
Identification A	Conform	Conform		
Identification B	+24 - +32	+29		
Specific optical rotation	+24 - +32	+29		
Loss on drying	<=1,0	0,02	%	
Related Substances	Conform	Conform		
Individual impurities	<=0,50	<0,2	%	Producer method
Total impurities	<=1,0	<0,2	%	Producer method
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Pregnenolone	97,0 - 103,0	100,0	%m/m	Producer method
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Ethanol	<=5000	<5000	ppm	
Methanol	<=3000	<3000	ppm	

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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

Release:

Agnieszka Pszczółka

Qualified Person

27-12-2022

Expiration: 09-03-2025

Conclusion: APPROVED

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