

Certificate of Analysis

Product name: Pregnenolonum
Batch number / Weight: 25C17-B04-013334 / 10 g
Producer / Producer Batch Number: Jiangsu Jiaerke Pharmaceuticals Group Corp. Ltd / C07-240903
Analyzed according to: Internal
Number of Analysis / Certificate no.: 25C17-B04 / QO0020484

	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification	A	Conform		
Melting point	185 -194	190,4	°C	
Specific optical rotation	(+27) - (+30)	+28,0		
Loss on drying	<=0,50	0,057	%	
Related substances	Conform	Conform		
Individual impurities	<=0,50	0,201	%	
Total impurities	<= 1,0	0,55	%	
Assay	>= 99,0	99,45	% m/m	
Metallic residues	CHMP/ICH/353369/2013	Conform		
Residual solvents	CPMP/ICH/82 260/06	Conform		
TSE/BSE-statement:	EMA/410/01 guidance compliant – no contamination	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 FSNE

Release:

28-8-2025
 Ewelina Gadzinowska
 Qualified Person

Expiration: 8-9-2027

Conclusion: APPROVED

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