

CERTIFICATE OF ANALYSIS

Our Ref. : F23/0844-01

Our Sample Id. : 74913

FSA NV
Oostmalsebaan 1c unit 5
2960 Sint-Lenaarts
BELGIUM

Product : Pregnenolone

Lot number : 23C27-GS23041

Customer product number : N/A

Customer reference : PO05502

Date of application : 19/04/2023

Date of reception : 24/04/2023

Date start of analysis : 28/04/2023

Date of end of analysis : 24/05/2023

Test Method : ANA-Q-109/1

Spec Reference : N/A

PERFORMED ANALYSIS AND RESULTS

Analysis	Specification	Result
Aspect		
Appearance	White crystalline powder, practically insoluble in water, soluble in methylene chloride.	Complies
Identifications		
Identification (Ph.Eur.2.2.24 IR)	Similar spectra for sample and reference.	POSITIVE

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PERFORMED ANALYSIS AND RESULTS

Analysis	Specification	Result
Other tests		
Melting point	188 to 193 °C	191.2 °C
Specific optical rotation	+27.5 to +31.5°	+30.2
Loss on drying (Ph.Eur)	NMT 0.50%	0.13 %
Related substances (HPLC)		
Total impurity (HPLC)	NMT 1.0%	0.3 %
Single impurity (HPLC) / 1	NMT 0.50%	0.01 %
Single impurity (HPLC) / 2	NMT 0.50%	0.01 %
Single impurity (HPLC) / 3	NMT 0.50%	0.003 %
Single impurity (HPLC) / 4	NMT 0.50%	0.01 %
Single impurity (HPLC) / 5	NMT 0.50%	0.22 %
Single impurity (HPLC) / 6	NMT 0.50%	0.05 %
Single impurity (HPLC) / 7	NMT 0.50%	0.01 %
Single impurity (HPLC) / 8	NMT 0.50%	0.02 %
Residual solvents (GC)		
Klasse 2 Methanol (Ph.Eur.2.4.24 GC)	NMT 3000 ppm	393 ppm
Klasse 3 Ethanol (Ph.Eur.2.4.24 GC)	NMT 5000 ppm	496 ppm
Assays		
Assay Pregnenolone (HPLC)	98.5% to 101.5%	98.9 %
± CI (95% Confidence interval)		0.3 %

CONCLUSION : The sample complies with the specifications of the performed analysis.

Issued By: Ingrid Van den Broeck

Patsy Peeters

Office Manager/HR

Industrial Pharmacist, QP

Date of Issue: 24/05/2023

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