

F&A PHARMA

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CERTIFICATE OF ANALYSIS



Product(品名): Pregnenolone

Batch No.(批号): YXCTA250101

Quantity(数量): 10kg

Specification(规定): in house

Mfg. date(生产日期): 2025.01.02

Retest date(复验日期): 2028.01.01

Item (项目)	Specifications (标准)	Results (结果)
Description (性状)	White or Almost white crystalline powder	Almost white crystalline powder
Identification (鉴别)	IR spectroscopy	Conform
Melting range (熔点)	185°C~194°C	187.0°C-190.5°C
Loss on drying (干燥失重)	≤0.5%	0.11%
Specific optical rotation (比旋度)	+ 27°~ + 31°	+29.1°
Related substances (有关物质)	Single impurity ≤0.5%	0.26%
	Total impurities ≤1.0%	0.38%
Residual solvent (残留溶剂)	Methanol ≤3000ppm	367ppm
	Ethanol ≤5000ppm	22ppm
	Dichloromethane ≤600ppm	Not detected
Purity (纯度)	≥99.0%	99.6%
Assay (含量)	98.0%~102.0%	99.4%
Microbial control (微生物)	Total Plate Count ≤1,000cfu/g	<1,000cfu/g
	Yeasts & Moulds ≤100cfu/g	<100cfu/g

Conclusion: Complies with the requirements of In house

Report person: 李

Date: 2025.06.12

QP: 侯海波

Date: 2025.06.12

METAPHARMACEUTICAL

N DE LOTE:

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02/07/2025