

# Hubei Zhuxi Humanwell Pharmaceutical Co., Ltd.

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## CERTIFICATE OF ANALYSIS

Product(品名): Pregnenolone

Batch No.(批号): YXCTA210101W

Quantity(数量): 10kg

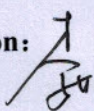
Specification(规定): in house

Mfg. date(生产日期): 2021.01.26

Retest date(复验期): 2023.01.25

Item	Specifications	Results	Test method
Appearance	White crystalline micronized powder	Conforms	Visual
Identifiacation	1): Melting Point 185~194°C	188.5°C-191.5°C	USP
	2) : IR spectroscopy	Conform	USP
Assay	99.0%Min	99.6%	HPLC
Loss on drying	≤0.5%	0.05%	USP
Residue on ignition	≤0.5%	0.03%	USP
Related substances	Any impurity: 0.5%Max	0.12%	HPLC
	Total impurities: 1.0%Max	0.12%	
Residual solvent	Methanol ≤3000ppm	141ppm	GC
	Ethanol ≤5000ppm	Not detected	
	Dichloromethane ≤600ppm	Not detected	
Specific optical rotation	+27.0°~+31.0°	+28.7°	USP
Heavy metal	<10ppm	Conforms	USP
Particle size	100% through 200 mesh 95%min through 300 mesh	Conforms	In-house
Bulk density	-----	0.25g/ml	In-house
Apparent density after	-----	0.50g/ml	In-house

Conclusion: Complies with the requirements of in-house

Report person: 

2021.03.10

质检报告专用章

QP: 

2021.03.10