

**Hubei Gedian Humanwell Pharmaceutical Co., Ltd.**

Address: No.1 Zhiqing Road, Railway Station Economic Development Zone

Huangzhou District China-438011 Huanggang, Hubei province



**CERTIFICATE OF ANALYSIS**

Product : Progesterone

Batch No. : HG-IHTTH250702M3

Quantity : 500kg

Specification: USP2025

Mfg. date: 2025.07.25

Retest date: 2030.07.24

Item	Specifications	Results
Appearance	White or almost white crystalline powder.	Almost white crystalline powder
Identification	IR:Comparison: progesterone CRS.	Sample spectrum is similar to that of reference standard.
	UV:Comparison: progesterone CRS.	Sample spectrum is similar to that of reference standard.
Melting range	126~131°C	129.5~130.0°C
Specific optical rotation	+175°~+183° (On the dried basis)	+180.6°
Loss on drying	≤0.5 %	0.07%
Related substances	Impurity B ≤0.2%	0.06%
	Impurity J ≤0.15%	Not detected
	Impurity K ≤0.15%	Not detected
	Impurity C ≤0.3%	0.17%
	Impurity M ≤0.15%	Not detected
	Impurity L ≤0.15%	Not detected
	Impurity I ≤0.6%	Not detected
	Impurity D+E ≤0.15%	Not detected
	Impurity G ≤0.15%	Not detected
	Impurity H ≤0.15%	0
	Unspecified impurity ≤0.10%	Not detected
	Total impurities (without impurity H) ≤1.0%	0.22%
Residual Solvents	Methanol ≤3000ppm	Not detected
	Ethanol ≤5000ppm	259ppm
Residue on ignition	≤0.1%	0.04%
Assay	97.0 ~ 102.0% (On the dried basis)	99.2%
Particle Size	90% pass 6µm	Conform

Conclusion: Complies with the requirements of USP2025

Q.C. director:

QP:

Date: 2025.10.13

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Letco QA REVIEWED  
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