

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
Quantity : 500kg
Mfg. date: 2025.10.15

Batch No. : HG-HTTII251005M3
Specification: USP2025
Retest date: 2030.10.14

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	129.0~130.0°C
Specific optical rotation	+175°~+183° (On the dried basis)	+180.1°
Loss on drying	≤0.5 %	0.02%
Related substances	Impurity B ≤0.2%	0.06%
	Impurity J ≤0.15%	Not detected
	Impurity K ≤0.15%	Not detected
	Impurity C ≤0.3%	0.14%
	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%	0.01%
	Unspecified impurity ≤0.10%	Not detected
	Total impurities (without impurity H) ≤1.0%	0.20%
Residual Solvents	Methanol ≤3000ppm	Not detected
	Ethanol ≤5000ppm	261ppm
Residue on ignition	≤0.1%	0.07%
Assay	97.0 ~ 102.0% (On the dried basis)	99.4%
Particle Size	90% pass 5μm	4.7μm

Conclusion: Complies with the requirements of USP2025

Q.C. director:

QP:

Date: 2025.12.10

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Lotco QA REVIEWED
Initial/Date: SB 12/20/25
Date Format: Y-M-D
Tracking #: 25L23-B01