



Hubei Zhuxi Humanwell Pharmaceutical Co., Ltd.

Address: Industrial park, Zhuxi County, Shiyan, Hubei 442300, China

TEL: +86-719-2738828 FAX: +86-719-2738828

Http://:www.zxhumanwell.com, E-mail: market@renfu.com.cn

CERTIFICATE OF ANALYSIS

Product(品名): Testosterone micronized Batch No.(批号): GT250902W1

Quantity(数量): 25kg Specification(规定): EP11

Mfg. date(生产日期): 2025.09.14 Retest date(复验日期): 2028.09.13

CEP number (CEP 2022-181 - Rev 01)

Item (项目)	Specifications (标准)	Results (结果)
Description (性状)	White or almost white crystalline powder, or colourless or yellowish-white crystals	White crystalline powder
Identification (鉴别)	IR: Comply with the reference spectrum	Conform
Melting point (熔点)	153°C ~ 157°C	154.0°C ~ 155.5°C
Loss on drying (干燥失重)	≤1.0%	0.24%
Specific optical rotation (比旋度)	+106° ~ +114°	+112.1°
Related substances (有关物质)	Impurity K ≤ 0.15% Impurity C ≤ 0.3% Impurity I ≤ 0.2% Unspecified impurities ≤ 0.10% Total impurities ≤ 0.6%	0.04% 0.11% 0.01% 0.05% 0.21%
Residual solvent (残留溶剂)	Methanol ≤ 3000ppm Ethanol ≤ 5000ppm Ethyl formate ≤ 5000ppm Ethyl acetate ≤ 5000ppm pyridine ≤ 200ppm	Not detected Not detected Not detected 821ppm Not detected
Assay (dried substance) (含量)	98.0% ~ 102.0%	100.5%
Particle Size (粒径)	90% ≤ 20μm 99% ≤ 30μm	Conform

Conclusion: Complies with the requirements of EP11

Report person: 柳婷婷

Date: 2025.10.30

QP: 张海波

Date: 2025.10.30

METAPHARMACEUTICAL

N DE LOTE:

0421125

26/11/25