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CERTIFICATE OF ANALYSIS



Product(品名): Testosterone

Batch No.(批号): GT220807W

Quantity(数量): 5kg

Specification(规定): EP10.1

Mfg. date(生产日期): 2022.08.23

Retest date(复验日期): 2025.08.22

Item (项目)	Specifications (标准)	Results (结果)
Description (性状)	White or almost white crystalline powder, or colourless or yellowish-white crystals	Almost white crystalline powder
Identification (鉴别)	IR: Comply with the reference spectrum	Conform
Melting point (熔点)	153°C ~ 157°C	154.5°C ~ 155.0°C
Loss on drying (干燥失重)	≤1.0%	0.02%
Specific optical rotation (比旋度)	+106° ~ +114°	+109.3°
Related substances (有关物质)	Impurity K ≤ 0.15% Impurity C ≤ 0.3% Impurity I ≤ 0.2% Any other impurity ≤ 0.10% Total impurities ≤ 0.6%	0.03% 0.14% 0.02% 0.06% 0.32%
Residual solvent (残留溶剂)	Methanol ≤ 3000ppm Ethanol ≤ 5000ppm Ethyl formate ≤ 5000ppm Ethyl acetate ≤ 5000ppm pyridine ≤ 200ppm	Not detected Not detected Not detected 1584ppm Not detected
Assay (含量)	98.0% ~ 102.0%	101.0%
Particle Size (粒径)	90% ≤ 20μm 99% ≤ 30μm	Conform

Conclusion: Complies with the requirements of EP10.1

Report person:

QP:

METAPHARMACEUTICAL

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24/02/2023