

**F&A PHARMA**

F. & A. PHARMA-Handels-GmbH

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人福医药

CERTIFICATE OF ANALYSIS

Product(品名): Testosterone

Batch No.(批号): GT220804

Quantity(数量): 164.02kg

Specification(规定): EP10.1

Mfg. date(生产日期): 2022.08.20

Retest date(复验日期): 2025.08.19

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℃ ~ 157℃	154.5℃ ~ 155.0℃
Loss on drying (干燥失重)	≤1.0%	0.16%
Specific optical rotation (比旋度)	+ 106°~ + 114°	+111.1°
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%	0.04% 0.04% 0.01% 0.05% 0.14%
Residual solvent (残留溶剂)	Methanol ≤3000ppm Ethanol≤5000ppm Ethyl formate≤5000ppm Ethyl acetate≤5000ppm pyridine≤200ppm	Not detected Not detected Not detected 397ppm Not detected
Assay (含量)	98.0%~102.0%	100.6%

Conclusion: Complies with the requirements of EP10.1

Report person: QP: 

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