

江苏佳尔科药业集团股份有限公司  
Jiangsu Jiaerke Pharmaceuticals Group Corp., Ltd.

No.302, Huzhuangtou, Sanhuangmiao, Zhengguo Tianjing, Changzhou, Jiangsu, 213111, China

Tel:0086-519-88960735 Fax:0086-519-88736500



Certificate of Analysis

No.: C16-2025013

No.: C16-2025013			
Product Name:	Testosterone	Batch No.:	C16-250303(M)
Quantity:	400kg	Packaging:	20kg/drum
Manuf. Date:	Jan. 02, 2025	Sampling Date:	Mar. 15, 2025
Retest Date:	Jan. 01, 2028	Report Date:	Mar. 21, 2025
Standard:	USP Testosterone Monograph		
Items		Specifications	Results
1.Appearance:		White or almost white crystalline powder	White crystalline Powder, Micronized
2.Identification:		IR spectrum of sample should correspond to that of working standard. UV spectrum of sample should correspond to that of working standard.	Complies  Complies
3.Loss on drying :		1.0% Max.	0.70%
4.Melting range :		153°C~ 157°C	153.5~154.5°C
4.Specific optical rotation (on dried basis):		+101° to +105°	+102°
6.Related substances:		Impurity A: 0.1% Max.	Not detected
		Impurity B: 0.1% Max.	Not detected
		Impurity C: 0.5% Max.	Not detected
		Impurity E: 0.1% Max.	Not detected
		Impurity G: 0.1% Max.	Not detected
		Impurity H: 0.1% Max.	Not detected
		Impurity I: 0.2% Max.	0.13%
		Impurity K: 0.1% Max.	Not detected
		Any unspecified impurity: 0.1% Max.	Not detected
		Total impurities: 0.6% Max.	0.13%
7.Assay (on dried basis):		97.0% ~103.0%	100.4%
8.Residual solvents:		Methanol: 3000ppm Max. Ethanol: 5000ppm Max. Acetone: 5000ppm Max.	Not detected 10ppm Not detected
*9.Particle size:		90% pass 30 μ m	Complies
Conclusions:		The product conforms to USP Testosterone Monograph.	

Prepared by: 陈峰

Reviewed by: 陈峰

Approved by: 魏志峰

Letco QA REVIEWED

Initial/Date: 40 4-15-25

Date Format: M-D-Y

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