

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


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Certificate of Analysis

No.: C16-2026013

Product Name:	Testosterone	Batch No.:	C16-251222
Quantity:	40kg	Packaging:	20kg/drum
Manuf. Date:	Dec. 23, 2025	Sampling Date:	Mar. 05, 2026
Retest Date:	Dec. 22, 2028	Report Date:	Mar. 11, 2026
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	
3.Loss on drying :	1.0% Max.	0.29%	
4.Melting range :	153°C~ 157°C	153.5~154.5°C	
5.Specific optical rotation (on dried basis):	+101° to +105°	+102°	
6.Related substances:	Impurity A: 0.1% Max.	<0.05%	
	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.	<0.05%	
	Impurity H: 0.1% Max.	Not detected	
	Impurity I: 0.2% Max.	0.10%	
	Impurity K: 0.1% Max.	Not detected	
	Any unspecified impurity: 0.1% Max.	RRT0.18 <0.05%	
	Total impurities: 0.6% Max.	0.10%	
7.Assay (on dried basis):	97.0% ~103.0%	99.8%	
8.Residual solvents:	Methanol: 3000ppm Max.	Not detected	
	Ethanol: 5000ppm Max.	15ppm	
	Acetone: 5000ppm Max.	Not detected	
*9.Particle size:	90% pass 30 μ m	Complies	
Conclusions:	The product conforms to USP Testosterone Monograph.		

Prepared by: 

Reviewed by: 

Approved by: 