

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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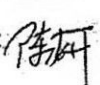
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Certificate of Analysis

No.: C16-2025026

Product Name:	Testosterone	Batch No.:	C16-250401(M)
Quantity:	100kg	Packaging:	20kg/drum
Manuf. Date:	Feb. 22, 2025	Sampling Date:	Apr. 19, 2025
Retest Date:	Feb. 21, 2028	Report Date:	July 14, 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	
3.Loss on drying :	1.0% Max.	0.43%	
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.	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%	100.6%	
8.Residual solvents:	Methanol: 3000ppm Max.	Not detected	
	Ethanol: 5000ppm Max.	15ppm	
	Acetone: 5000ppm Max.	Not detected	
*9.Particle size:	90% pass 30 μm	Complies	
Conclusions:	The product conforms to USP Testosterone Monograph.		

Prepared by: 

Reviewed by: 

Approved by: 

KalChem 
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Letco QA REVIEWED
Initial/Date: SB 8/6/25
Date Format: m-D-Y
Tracking #: 25H05-B11