

江苏佳尔科药业集团股份有限公司

Jiangsu Jiaerke Pharmaceuticals Group Corp., Ltd.

No.302, Huzhuangtou, Sanhuanghiao, Zhenglu, Tianning Changzhou, Jiangsu, 213111, China

Tel:0086-519-88930795 Fax:0086-519-88736500

Certificate of Analysis

26/08/2025

Product name:	Progesterone	Batch No.:	C60-250702 (M)
Quantity:	100kg	Packaging:	25kg/drum
Manuf. Date:	July 14, 2025	Sampling date:	July 23, 2025
Retest date:	July 13, 2028	Report date:	July 28, 2025
Standard:	EP11.0		
Items	Specifications	Results	
1. Appearance:	White or almost white, crystalline powder or colorless crystals	White crystalline Powder, Micronized	
2. Assay:	97.0% to 102.0%	99.9%	
3. Identification:			
A. Infrared absorption spectrophotometry:	A:IR spectrum of sample should correspond to that of working standard.	Complies	
B. Thin-layer chromatography	B:Conforms to Results (254nm)	Complies	
4. Specific rotation:	+ 186° to + 194°	+ 190°	
5. Related substances:	Impurity B: 0.2% Max.	Not detected	
	Impurity C: 0.3% Max.	Not detected	
	Impurity D+E: 0.15% Max.	Not detected	
	Impurity G: 0.15% Max.	Not detected	
	Impurity H: 0.15% Max.	Not detected	
	Impurity I: 0.6% Max.	0.09%	
	Impurity J: 0.15% Max.	<0.05%	
	Impurity K: 0.15% Max.	0.05%	
	Impurity L: 0.15% Max.	Not detected	
	Impurity M: 0.15% Max.	<0.05%	
	Any unspecified impurity: 0.10% Max.	<0.05%	
	Sum of impurities other than H: 1.0% Max.	0.2%	
6. Loss on drying:	0.5% Max.	0.13%	
7. Residual solvents:	Methanol: 3000ppm Max. Ethanol: 5000ppm Max. Acetonitrile:410ppm Max. Benzene:2ppm Max. Dichloromethane:600ppm Max. Toluene: 890ppm Max. N,N-Dimethylformamide: 880ppm Max.	Not detected 397ppm Not detected Not detected Not detected Not detected Not detected	
Conclusion: The above product conforms to EP11.0.			

Prepared by:

吴同海

Reviewed by:

陈妍

Approved by:

胡安峰