

江苏佳尔科药业集团有限公司

Jiangsu Jiaerke Pharmaceuticals Group Corp., Ltd.

Sanhuangmiao, Zhenglu, Wujin, Changzhou, Jiangsu 213111, China

Tel: 0086-519-88930795

Fax: 0086-519-88736500

Certificate of Analysis

Product name:	Progesterone	Batch No.:	C01-170106(M)
Quantity:	25kg	Packaging:	25kg/drum
Manuf. Date:	Dec. 17, 2016	Test date:	Jan. 11, 2017
Re-test date:	Dec. 16, 2019	Report date:	Feb. 07, 2017
Standard:	EP9		
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%	99.6%	
3. Identification: A. Infrared absorption spectrophotometry: B. Thin-layer chromatography	Comparison: Progesterone CRS. Conforms to Results (254nm)	Complies	
4. Specific rotation:	+ 186° to + 194°	+ 190°	
5. Related substances:	Impurity B: 0.2% Max.	0.06%	
	Impurity C: 0.3% Max.	0.23%	
	Impurity D+E: 0.15% Max.	Not detected	
	Impurity G: 0.15% Max.	0.09%	
	Impurity H: 0.15% Max.	<0.05%	
	Impurity I: 0.6% Max.	Not detected	
	Impurity J: 0.15% Max.	Not detected	
	Impurity K: 0.15% Max.	Not detected	
	Impurity L: 0.15% Max.	Not detected	
	Impurity M: 0.15% Max.	<0.05%	
	Any unspecified impurity: 0.10% Max.	Not detected	
	Sum of impurities other than H: 1.0% Max.	0.38%	
6. Loss on drying:	0.5% Max.	0.21%	
7. Residual solvents:	Methanol: 3000ppm Max. Ethanol: 5000ppm Max. Toluene: 890ppm Max. Cyclohexanone: 50ppm Max.	Not detected 266ppm Not detected Not detected	
8. Particle size:	95% pass 20 μ m	Complies	
Conclusion: The above product conforms to EP9.			

QA Manager:

周亚红

Reported by:

吴凤娟