

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.:C01-2021089

Product Name:	Progesterone	Batch No.:	C01-210606(M)
Quantity:	100kg	Packaging:	20kg/drum
Manuf. Date:	May 21, 2021	Sampling Date:	June 12, 2021
Retest Date:	May 20, 2024	Report Date:	June 25, 2021
Standard:	USP43		
Items	Specifications	Results	
1.Characters	White or creamy white crystalline powder	White crystalline powder, Micronized	
2.Identification: A: Infrared absorption B: Ultraviolet absorption	The IR spectrum of sample, exhibits maxima only at the same wavelength as that a similar preparation of USP Progesterone RS. The UV absorption spectra of the test solution and the standard solution exhibit maxima at the same wavelengths.	Complies	
3.Melting range :	126°C to 131°C	128.5~130°C	
4.Specific rotation :	+175° to +183°	+182°	
5.Loss on drying:	0.5% Max.	0.10%	
6.Related Substances:	Impurity B: 0.2% Max.	0.06%	
	Impurity C: 0.3% Max.	0.21%	
	Impurity D+E: 0.15% Max.	Not detected	
	Impurity G: 0.15% Max.	0.06%	
	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.	Not detected	
	Any unspecified impurity: 0.10% Max.	Not detected	
	Sum of impurities other than H: 1.0% Max.	0.33%	
7.Residual solvents :	Methanol: 3000ppm Max. Ethanol: 5000ppm Max. Toluene: 890ppm Max. Cyclohexanone: 50ppm Max.	Not detected 157ppm Not detected Not detected	
8.Assay :	97.0%~103.0%	100.3%	
*9.Particle size:	100% through 10um; 90% through 5um.	Complies	
*Source:	Yam source		
Conclusions:	The product conforms to USP43 requirements.		

Prepared by: [Signature]

Reviewed by: [Signature]

Approved by: [Signature]