

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.:C01-2023160

Product Name:		Progesterone	Batch No.:	C01-230619
Quantity:		100kg	Packaging:	10kg/drum
Manuf. Date:		June 30, 2023	Sampling Date:	July 07, 2023
Retest Date:		June 29, 2026	Report Date:	July 19, 2023
Standard:		USP-NF 2023		
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°		+181°
5.Loss on drying:		0.5% Max.		0.10%
6.Related Substances:	Impurity B: 0.2% Max.		0.05%	
	Impurity C: 0.3% Max.		0.20%	
	Impurity D+E: 0.15% Max.		Not detected	
	Impurity G: 0.15% Max.		0.05%	
	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.		0.31%	
7.Residual solvents :		Methanol: 3000ppm Max. Ethanol: 5000ppm Max. Toluene: 890ppm Max. Cyclohexanone: 50ppm Max.		Not detected 230ppm Not detected Not detected
8.Assay :		97.0%~103.0%		99.3%
*9.Particle size:		100% pass 20µm 90% pass 10µm		Complies
Conclusions:		The product conforms to USP-NF 2023 requirements.		

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