

江苏佳尔科药业集团股份有限公司
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Certificate of Analysis

No.:C01-2026117

Product Name:	Progesterone	Batch No.:	C01-260415
Quantity:	50kg	Packaging:	25kg/drum
Manuf. Date:	Apr. 22, 2026	Sampling Date:	Apr. 27, 2026
Retest Date:	Apr. 21, 2029	Report Date:	May. 07, 2026
Standard:	USP Progesterone Monograph		*YAM SOURCED
Items		Specifications	Results
1.Characters		White or creamy white crystalline powder	White crystalline powder, Micronized
2.Identification: A: Infrared 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
B: Ultraviolet absorption			Complies
3.Melting range :		126°C to 131°C	128~129°C
4.Specific rotation :		+175° to +183°	+180°
5.Loss on drying:		0.5% Max.	0.12%
6.Related Substances:	Impurity B: 0.2% Max.		0.05%
	Impurity C: 0.3% Max.		0.13%
	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.		<0.05%
	Any unspecified impurity: 0.10% Max.		Not detected
	Sum of impurities other than H: 1.0% Max.		0.2%
7.Assay :		97.0%~103.0%	99.8%
8.Residual solvents :		Ethanol: 5000ppm Max. Methanol: 3000ppm Max. Toluene: 890ppm Max. Cyclohexanone: 50ppm Max.	100ppm Not detected Not detected Not detected
*9.Particle size:		100% pass 20µm 90% pass 10µm	Complies
Conclusions:		The product conforms to USP Progesterone Monograph requirements.	

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