

江苏佳尔科药业集团股份有限公司

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Certificate of Analysis

No.: C01-2024099

Product name:	Progesterone	Batch No.:	C01-240319
Quantity:	5kg	Packaging:	5kg/carton
Manuf. Date:	Mar. 28, 2024	Sampling date:	Apr. 02, 2024
Retest date:	Mar. 27, 2027	Report date:	Apr. 15, 2024
Standard:	EP11.0		
Items	Specifications	Results	
1. Appearance:	White or almost white, crystalline powder or colorless crystals	White crystalline Powder, Micronized	
2. 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	
3. Loss on drying:	0.5% Max.	0.22%	
4. Specific rotation:	+ 186° to + 194°	+ 188°	
5. Related substances:	Impurity B: 0.2% Max.	0.07%	
	Impurity C: 0.3% Max.	0.19%	
	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.	0.32%	
6. Assay:	97.0% to 102.0%	100.3%	
7. Residual solvents:	Methanol: 3000ppm Max. Ethanol: 5000ppm Max. Toluene: 890ppm Max. Cyclohexanone: 50ppm Max.	Not detected 243ppm Not detected Not detected	
Conclusion: The above product conforms to EP11.0.			

Prepared by:

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Reviewed by:

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Approved by:

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