

METAPHARMACEUTICAL

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0520525

30/05/2025

江苏佳尔科药业集团股份有限公司

Jiangsu Jiaerke Pharmaceuticals Group Corp., Ltd.

No.302, Huzhuangtou, Sanhuangmiao, Zhenglu, Tianning, Changzhou, Jiangsu, 213111, China

Tel:0086-519-88930795 Fax:0086-519-88736500

Certificate of Analysis

No.:C01-2025120

Product name:	Progesterone	Batch No.:	C01-250409
Quantity:	30kg	Packaging:	10kg/carton
Manuf. date:	Apr. 16, 2025	Sampling Date:	Apr. 21, 2025
Re-test date:	Apr. 15, 2028	Report date:	May 06, 2025
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:	Comparison: Progesterone CRS.	Complies	
B. Thin-layer chromatography	Conforms to Results (254nm)	Complies	
3. Loss on drying:	0.5% Max.	0.13%	
4. Specific optical rotation:	+ 186° to + 194°	+ 190°	
5. Related substances:	Impurity B: 0.2% Max.	0.05%	
	Impurity C: 0.3% Max.	0.11%	
	Impurity D+E: 0.15% Max.	Not detected	
	Impurity G: 0.15% Max.	Not detected	
	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.	0.06%	
	Any unspecified impurity: 0.10% Max.	Not detected	
	Sum of impurities other than H: 1.0% Max.	0.22%	
6. Assay:	97.0% to 102.0%	99.3%	
7. Residual solvents:	Ethanol: 5000ppm Max. Methanol: 3000ppm Max. Toluene: 890ppm Max. Cyclohexanone: 50ppm Max.	196ppm Not detected Not detected Not detected	
*8. Particle size:	99% pass 20µm	Complies	
Conclusion: The above product conforms to EP11.0.			

Prepared by:

王强

Reviewed by:

陈妍

Approved by:

胡志峰



MASTERSIZER



Result Analysis Report

Sample Name:
Progesterone - Average
Sample Source & type:
Progesterone
Sample bulk lot ref:
C01-250409

SOP Name:
Progesterone
Measured by:
yuanmengting
Result Source:
Averaged

Measured:
29 April 2025 13:39:15
Analysed:
29 April 2025 13:39:16

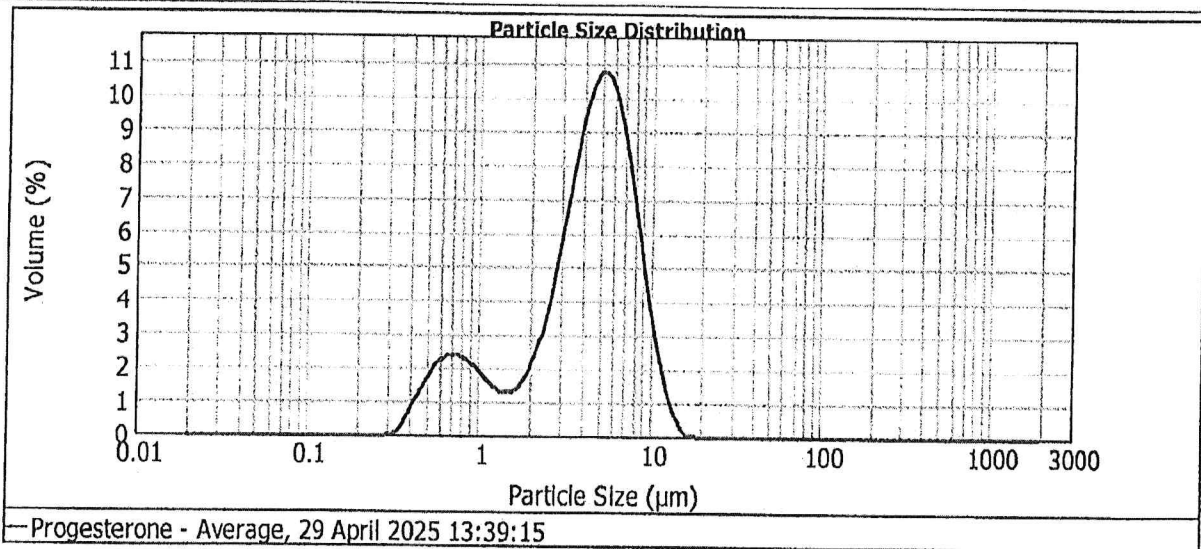
Particle Name: Default	Accessory Name: Hydro 2000MU (A)	Analysis model: General purpose	Sensitivity: Normal
Particle RI: 1.520	Absorption: 0.1	Size range: 0.020 to 2000.000 μm	Obscuration: 15.28 %
Dispersant Name: Water	Dispersant RI: 1.330	Weighted Residual: 2.307 %	Result Emulation: Off

Concentration: 0.0065 %Vol	Span : 1.716	Uniformity: 0.506	Result units: Volume
Specific Surface Area: 2.52 m^2/g	Surface Weighted Mean D[3,2]: 2.378 μm	Vol. Weighted Mean D[4,3]: 4.690 μm	

d(0.1): 0.845 μm

d(0.5): 4.451 μm

d(0.9): 8.484 μm



Size (μm)	Vol Under %	Size (μm)	Vol Under %	Size (μm)	Vol Under %	Size (μm)	Vol Under %	Size (μm)	Vol Under %	Size (μm)	Vol Under %
0.174	0.00	0.906	12.14	6.057	58.82	21.140	100.00	65.043	100.00	301.152	100.00
0.192	0.00	1.092	13.35	5.901	68.00	23.414	100.00	72.040	100.00	333.548	100.00
0.213	0.00	1.210	14.42	6.203	72.85	25.000	100.00	75.000	100.00	369.429	100.00
0.236	0.00	1.340	15.36	6.871	79.38	26.933	100.00	79.789	100.00	400.160	100.00
0.261	0.00	1.484	16.23	7.610	85.03	28.722	100.00	80.000	100.00	453.185	100.00
0.289	0.00	1.644	17.11	8.429	89.74	30.000	100.00	80.000	100.00	501.803	100.00
0.321	0.02	1.820	18.10	9.335	93.43	31.812	100.00	100.000	100.00	555.930	100.00
0.355	0.10	2.016	19.31	10.000	95.37	35.000	100.00	108.406	100.00	615.734	100.00
0.393	0.41	2.233	20.89	10.339	96.15	35.234	100.00	120.070	100.00	681.970	100.00
0.435	1.04	2.473	22.97	11.452	97.99	38.000	100.00	132.996	100.00	755.332	100.00
0.482	1.84	2.739	25.72	12.684	98.11	39.025	100.00	147.292	100.00	838.885	100.00
0.534	3.11	3.034	29.26	14.048	99.71	43.223	100.00	163.137	100.00	926.679	100.00
0.592	4.62	3.360	33.69	15.000	99.91	47.872	100.00	180.686	100.00	1026.254	100.00
0.655	6.04	3.722	38.94	16.559	99.96	48.000	100.00	200.123	100.00	1138.652	100.00
0.726	7.66	4.122	45.01	17.233	100.00	50.000	100.00	221.650	100.00	1258.925	100.00
0.804	9.25	4.566	51.73	19.087	100.00	53.022	100.00	245.494	100.00		
0.890	10.76	5.000	58.02	20.000	100.00	60.000	100.00	271.903	100.00		

Operator notes: *Handwritten notes*