

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.:C01-2021173

Product Name:	Progesterone	Batch No.:	C01-211201(M)
Quantity:	440kg	Packaging:	20kg/drum
Manuf. Date:	Nov. 10, 2021	Sampling Date:	Dec. 02, 2021
Retest Date:	Nov. 09, 2024	Report Date:	Dec. 07, 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°	+180°	
5.Loss on drying:	0.5% Max.	0.10%	
6.Related Substances:	Impurity B: 0.2% Max.	0.06%	
	Impurity C: 0.3% Max.	0.19%	
	Impurity D+E: 0.15% Max.	Not detected	
	Impurity G: 0.15% Max.	0.05%	
	Impurity H: 0.15% Max.	0.07%	
	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.	0.30%	
7.Residual solvents :	Methanol: 3000ppm Max. Ethanol: 5000ppm Max. Toluene: 890ppm Max. Cyclohexanone: 50ppm Max.	Not detected 163ppm Not detected Not detected	
8.Assay :	97.0%~103.0%	100.7%	
Conclusions:	The product conforms to USP43 requirements.		

Prepared by: 陈杰

Reviewed by: 陈妍

Approved by: 魏其峰



Result Analysis Report

Sample Name:
progesterone - Average

SOP Name:
Wet-number

Measured:
03 December 2021 13:35:39

Sample Source & type:
progesterone

Measured by:
zhangyu

Analysed:
03 December 2021 13:35:40

Sample bulk lot ref:
C01-211201(M)

Result Source:
Averaged

Particle Name:
Default

Accessory Name:
Hydro 2000MU (A)

Analysis model:
General purpose

Sensitivity:
Enhanced

Particle RI:
1.520

Absorption:
0.1

Size range:
0.020 to 2000.000 um

Obscuration:
15.15 %

Dispersant Name:
Water

Dispersant RI:
1.330

Weighted Residual:
2.360 %

Result Emulation:
Off

Concentration:
0.0061 %Vol

Span :
0.959

Uniformity:
0.384

Result units:
Number

Specific Surface Area:
2.73 m²/g

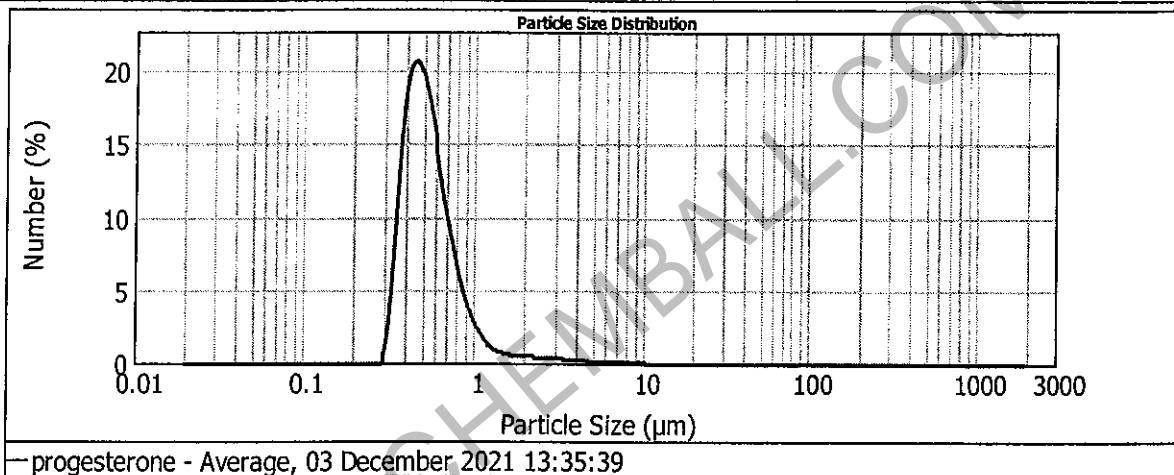
Surface Weighted Mean D[3,2]:
2.198 um

Vol. Weighted Mean D[4,3]:
4.223 um

d(0.1): 0.380 um

d(0.5): 0.517 um

d(0.9): 0.876 um



Size (um)	Number Under %	Size (um)	Number Under %	Size (um)	Number Under %	Size (um)	Number Under %	Size (um)	Number Under %
0.174	0.00	1.340	96.43	9.335	99.99	38.000	100.00	180.686	100.00
0.192	0.00	1.484	96.97	10.000	100.00	39.025	100.00	200.123	100.00
0.213	0.00	1.644	97.39	10.339	100.00	43.223	100.00	221.650	100.00
0.236	0.00	1.820	97.75	11.452	100.00	47.872	100.00	245.494	100.00
0.261	0.00	2.016	98.07	12.684	100.00	48.000	100.00	271.903	100.00
0.289	0.00	2.233	98.36	14.048	100.00	50.000	100.00	301.152	100.00
0.321	0.35	2.473	98.64	15.000	100.00	53.022	100.00	333.548	100.00
0.355	4.18	2.739	98.89	15.559	100.00	60.000	100.00	369.429	100.00
0.393	13.77	3.034	99.12	17.233	100.00	65.043	100.00	409.169	100.00
0.435	26.82	3.360	99.33	19.087	100.00	72.040	100.00	453.185	100.00
0.482	40.76	3.722	99.50	20.000	100.00	75.000	100.00	501.936	100.00
0.534	53.90	4.122	99.64	21.140	100.00	79.789	100.00	555.930	100.00
0.592	65.49	4.566	99.74	23.414	100.00	80.000	100.00	615.734	100.00
0.655	74.57	5.000	99.82	25.000	100.00	90.000	100.00	681.970	100.00
0.726	81.62	5.057	99.83	25.933	100.00	100.000	100.00	755.332	100.00
0.804	86.90	5.601	99.89	28.722	100.00	108.408	100.00	836.585	100.00
0.890	90.48	6.203	99.93	30.000	100.00	120.070	100.00	926.579	100.00
0.986	92.95	6.871	99.95	31.812	100.00	132.986	100.00	1026.254	100.00
1.092	94.60	7.610	99.98	35.000	100.00	147.292	100.00	1136.652	100.00
1.210	95.69	8.429	99.99	35.234	100.00	163.137	100.00	1258.925	100.00

Operator notes: 张 2021.12.03

张 2021.12.03