

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.:C04-2021072

Product Name:	Dehydroepiandrosterone (DHEA)	Batch No.:	C04-210901 (M)
Quantity:	10kg	Packaging:	10kg/drum
Manuf. Date:	Aug. 13, 2021	Sampling Date:	Sep. 03, 2021
Retest Date:	Aug. 12, 2024	Report Date:	Dec. 23, 2021
Standard:	FP		
Items	Specifications	Results	
1. Appearance:	White or almost white crystalline powder	White crystalline powder, Micronized	
2. Identification: IR	The IR spectrum of sample should be corresponds to that of working reference standard.	Complies	
3. Melting range:	146°C to 151°C	149°C to 150°C	
4. Specific rotation:	+ 11.0° to + 14.0°	+ 13.3°	
5. Water:	1.0% Max.	0.10%	
6. Sulphated ash:	0.1% Max.	0.05%	
7. Hydroxylamine:	5ppm Max.	<5ppm	
8. Related substances:	Impurity A: 0.1% Max.	Not detected	
	Impurity B: 0.1% Max.	Not detected	
	Impurity C: 0.02% Max.	Not detected	
	Impurity D: 0.1% Max.	Not detected	
	Impurity E: 0.1% Max.	Not detected	
	Impurity F: 0.08% Max.	Not detected	
	Any unspecified impurity:0.1% Max.	RRT 0.58 <0.025% RRT 0.61 0.03% RRT 2.94 <0.025%	
	Total impurity: 0.5% Max.	0.03%	
9. Assay :	97.5% to 102.0%	100.0%	
10. Residual solvents:	Methanol: 3000ppm Max. Ethanol: 5000ppm Max. Toluene: 890ppm Max. Pyridine: 200ppm Max.	35ppm <LOQ(50.0ppm) Not detected Not detected	
*11. Particle size:	90% pass 50 μ m; 50% pass 15 μ m	Complies	
Conclusions:	The product conforms to FP.		

Prepared by: 陈杰

Reviewed by: 陈杰

Approved by: 胡其峰



MASTERSIZER



Result Analysis Report

Sample Name:
DHEA - Average

SOP Name:
DHEA

Measured:
22 December 2021 13:29:56

Sample Source & type:
DHEA

Measured by:
zhangyu

Analysed:
22 December 2021 13:29:57

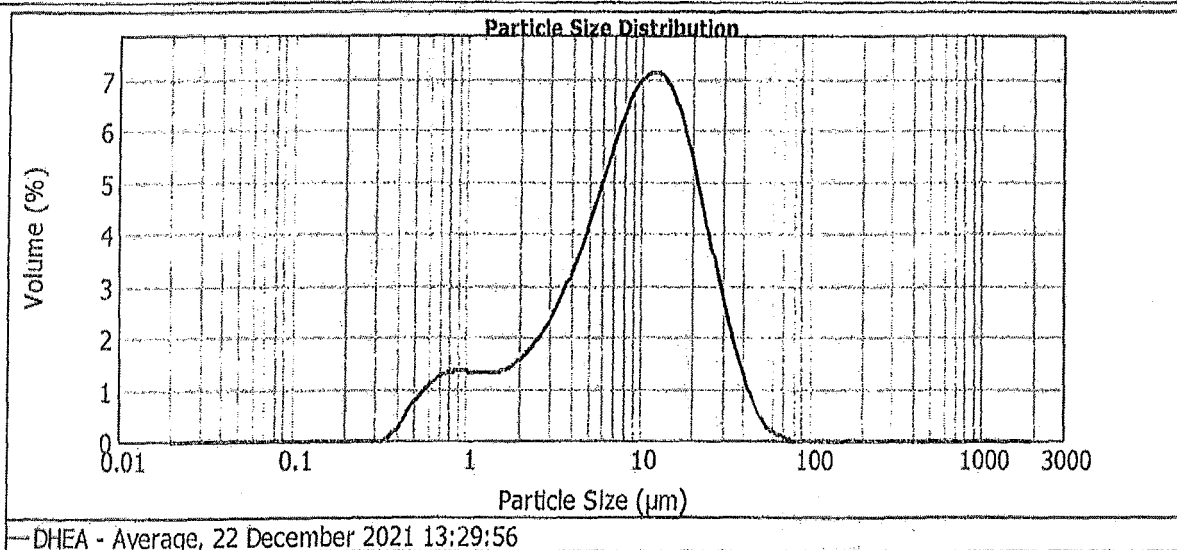
Sample bulk lot ref:
C04-210901(M)

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: 13.76 %
Dispersant Name: Water	Dispersant RI: 1.330	Weighted Residual: 1.437 %	Result Emulation: Off

Concentration: 0.0093 %Vol	Span : 2.467	Uniformity: 0.764	Result units: Volume
Specific Surface Area: 1.48 m ² /g	Surface Weighted Mean D[3,2]: 4.062 um	Vol. Weighted Mean D[4,3]: 11.675 um	

d(0.1): 1.582 um d(0.5): 9.319 um d(0.9): 24.572 um



Size (um)	Vol Under %	Size (um)	Vol Under %	Size (um)	Vol Under %	Size (um)	Vol Under %	Size (um)	Vol Under %	Size (um)	Vol Under %
0.174	0.00	0.988	5.95	5.057	27.83	21.140	85.45	65.043	99.93	301.152	100.00
0.192	0.00	1.092	6.84	5.601	30.77	23.414	88.65	72.040	100.00	333.548	100.00
0.213	0.00	1.210	7.71	6.203	34.02	25.000	90.46	76.000	100.00	369.429	100.00
0.236	0.00	1.340	8.58	6.871	37.60	25.933	91.39	79.789	100.00	409.169	100.00
0.261	0.00	1.484	9.45	7.610	41.48	28.722	93.67	80.000	100.00	453.185	100.00
0.289	0.00	1.644	10.34	8.429	45.66	30.000	94.60	90.000	100.00	501.936	100.00
0.321	0.00	1.820	11.27	9.335	50.08	31.812	95.60	100.000	100.00	555.930	100.00
0.355	0.00	2.018	12.27	10.000	53.17	35.000	98.85	108.408	100.00	615.734	100.00
0.393	0.08	2.233	13.35	10.339	54.69	35.234	98.83	120.070	100.00	681.970	100.00
0.435	0.25	2.473	14.53	11.452	59.42	38.000	97.78	132.988	100.00	755.332	100.00
0.482	0.62	2.739	15.84	12.684	64.19	39.025	98.00	147.292	100.00	839.535	100.00
0.534	1.12	3.034	17.30	14.048	68.90	43.223	98.77	163.137	100.00	928.579	100.00
0.592	1.75	3.380	18.94	15.000	71.88	47.872	99.30	180.686	100.00	1028.254	100.00
0.655	2.48	3.722	20.79	15.559	73.47	48.000	99.31	200.123	100.00	1136.652	100.00
0.726	3.30	4.122	22.88	17.233	77.80	50.000	99.46	221.650	100.00	1258.925	100.00
0.804	4.16	4.588	25.21	19.087	81.82	53.022	99.84	245.494	100.00		
0.890	5.05	5.000	27.53	20.000	83.63	60.000	99.88	271.903	100.00		

Operator notes: 张子 2021.12.22

7/10/2021.12.22