

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

Product Name:	Dehydroepiandrosteron (DHEA)	Batch No.:	C04-230301 (M)
Quantity:	70kg	Packaging:	5kg/carton*6 10kg/carton*1 15kg/drum*2
Manuf. Date:	Mar. 06, 2023	Sampling Date:	Apr. 4, 2023
Retest Date:	Mar. 05, 2026	Report Date:	Apr.10, 2023
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 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°	+ 12.9°
5.Sulphated ash:		0.1% Max.	0.05%
6.Hydroxylamine:		5ppm Max.	<5ppm
7. 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.	<0.025%
		Impurity F: 0.08% Max.	Not detected
		Any unspecified impurity:0.1% Max.	RRT 0.54 <0.025% RRT 0.63 0.03% RRT 1.45 <0.025% RRT 2.69 0.05% RRT 3.25 <0.025&
		Total impurites: 0.5% Max.	0.08%
8. Assay:		97.5% to 102.0%	99.5%
9. Residual solvents:		Methanol: 3000ppm Max. Ethanol: 5000ppm Max. Toluene: 890ppm Max. Pyridine: 200ppm Max.	39ppm <LOQ(50.0pm) Not detected Not detected
*10.Water:		1.0%Max	0.14%
Conclusions:		The product conforms to FP	

Prepared by: 任远

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Approved by: 王璋明