Lot: 0020618

江苏佳尔科药业集团有限公司
Jiangsu Jiaerke Pharmaceuticals Group Corp., Ltd.
Sanhuangmiao, Zhenglu, Wujin, Changzhou, Jiangsu 213111, China
Tel:0086-519-88930795 Fax:0086-519-88736500

Certificate of Analysis

Product Name:	Dehydroepiandro-sterone (DHEA)	**Batch No.:**	C04-180412
Quantity:	10kg	**Packaging:**	10kg/drum
Manuf. Date:	Apr. 10, 2018	**Test Date:**	May 06, 2018
Re-test Date:	Apr. 09, 2021	**Report Date:**	May 14, 2018
Standard:	FP		

Items	Specifications	Results
1. Appearance:	White or almost white crystalline powder	White crystalline powder, Micronized
2. Assay (HPLC):	98.0% to 102.0%	99.3%
3. Identification: IR	The IR spectrum of sample should be corresponds to that of working reference standard.	Complies
4. Melting range:	148℃ to 151℃	149℃ to 150℃
5. Specific rotation:	+ 11.0° to +14.0°	+12.9°
6. Water:	1.0% Max.	0.20%
7.Sulphated ash:	0.1% Max.	0.04%
8. Heavy metals(Pb):	10ppm Max.	<10ppm
9. Hydroxylamine:	5ppm Max.	<5ppm
10. Related substances:	Impurity A: 0.10% Max.	Not detected
	Impurity B: 0.10% Max.	Not detected
	Impurity C: 0.02% Max.	Not detected
	Impurity D: 0.10% Max.	Not detected
	Impurity E: 0.10% Max.	<0.025%
	Impurity F: 0.08% Max.	Not detected
	Any unspecified impurity:0.10% Max.	RRT0.52 <0.025% RRT0.60 0.05% RRT0.88 <0.025% RRT3.11 0.03%
	Total impurity: 0.50% Max.	0.08%
11.Residualsolvents :	Methanol: 1500ppm Max. Ethanol: 2000ppm Max. Toluene: 890ppm Max. Pyridine: 50ppm Max.	169ppm <LOQ(32.1ppm) Not detected Not detected
12.Particle size:	90% pass 50 μm; 50% pass 15 μm	Complies
Conclusions:	The product conforms to FP.	

QA Manager:

Reported by:

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TRANSO-PHARM HANDELS-GMBH