

lot: 0040214

常州佳尔科药业集团有限公司
Changzhou Jiaerke Pharmaceuticals Group Corp., Ltd.

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Certificate of Analysis

Product Name:	Dehydroepiandro-sterone (DHEA)	Batch No.:	C04-130312(M)
Quantity:	100kg	Packaging:	25kg/drum
Manuf. Date:	Mar. 12, 2013	Test Date:	Mar. 30, 2013
Re-test Date:	Mar. 11, 2016	Report Date:	May 06, 2013
Standard:	JEKBZ-C04-01		
Items	Specifications	Results	
1. Appearance:	White or almost white crystalline powder	White crystalline powder, Micronized	
2. Assay (HPLC):	98.5% to 102.0%	99.3%	
3. Melting range:	149°C to 151°C	149°C to 151°C	
4. Specific rotation:	+ 12° to +15°	+13°	
5. Loss on drying:	0.50% Max.	0.33%	
6. Sulphated ash:	0.1% Max.	0.04%	
7. Related substances:	Any impurity: 0.10% max. Total impurities: 0.50% max.	0.06% 0.06%	
8. Residual solvents:	Methanol: 1500ppm Max. Ethanol: 2000ppm Max. Toluene: 890ppm Max. Pyridine: 50ppm Max.	22ppm Not detected Not detected Not detected	
9. Particle size:	100% pass 30 μm; 90% pass 10 μm	Complies	
Conclusions:	The product conforms to JEKBZ-C04-01.		

QA Manager: 张永平
2013.5.6

Reported by: 王凤娟
2013.5.6