江苏佳尔科西亚集团股份有限公司

Jiangsu Jiaerke Pharmaceuticals Group Corp., Ltd.
No.302, Huzhuangtou, Sanhuangmiao, Zhenglu, Tianning, Changzhou, Jiangsu, 213111, China
Tel:0086-519-88930795
Tel:0086-519-88736500

Certificate of Analysis

NO.:C04-2022003

Product Name:	Dehydroepiandro-sterone (DHEA)	Batch No.:		C04-220201(M)	
Quantity:	25kg	Packaging:		25kg/drum	
Manuf. Date:	Dec. 12, 2021	Dec. 12, 2021 Sampling Date		Feb. 17, 2022	
Retest Date:	Dec. 11, 2024	Dec. 11, 2024 Report Date:		Feb. 21, 2022	
Standard:	FP				
Items		Specifications		Results	
1. Appearance:	White or almost wh crystalline powder			ite crystalline vder, Micronized	
2. Identification: IR	corresponds to that	The IR spectrum of sample corresponds to that of working reference standard.		Complies	
3. Melting range:	146℃ to 151℃	146℃ to 151℃		149℃ to 150℃	
4. Specific rotation	: + 11.0° to + 14.0°	+ 11.0° to + 14.0°		+ 12.7°	
5.Sulphated ash:	0.1% Max.	0.1% Max.		0.04%	
6. Hydroxylamine:	5ppm Max.	5ppm Max.		<5ppm	
	Impurity A: 0.1% M	Impurity A: 0.1% Max.		Not detected	
	Impurity B: 0.1% Ma	Impurity B: 0.1% Max.		Not detected	
	Impurity C: 0.02%	Impurity C: 0.02% Max.		Not detected	
	Impurity D: 0.1% M	Impurity D: 0.1% Max.		Not detected	
		Impurity E: 0.1% Max.		Not detected	
7. Related substan	Impurity F: 0.08% N	Impurity F: 0.08% Max.		Not detected	
	Any unspecified imp	Any unspecified impurity:0.1% Max.		RRT 0.53 0.03% RRT 0.62 0.07% RRT 1.47 <0.025% RRT 2.86 0.04%	
	Total impurities: 0.5	Total impurities: 0.5% Max.		0.14%	
8. Assay :	97.5% to 102.0%	97.5% to 102.0%		101.0%	
9. Residual solvents: Methanol: 3000ppm Max Ethanol: 5000ppm Max Toluene: 890ppm Max. Pyridine: 200ppm Max.		Лах. lax.	68ppm <loq(50.0ppm) Not detected Not detected</loq(50.0ppm) 		
*10. Water:	1.0% Max.	1.0% Max.		0.10%	
Conclusions: The product conforms to FP.					
				3. Q	

Prepared by: The

Reviewed by: 体研

Approved by:

