

METAPHARMACEUTICAL

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江苏佳尔科药业集团股份有限公司

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08 MAY 2023

Certificate of Analysis

Product Name:	Dehydroepiandrosteron (DHEA)	Batch No.:	C04-230301 (M)
Quantity:	70kg	Packaging:	
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 impurities: 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:

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