



江苏佳尔科药业集团股份有限公司

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Certificate of Analysis

Product name:	Dehydroepiandrosterone (DHEA)	Batch No.:	C04-250601(M)
Quantity:	15kg	Packaging:	5kg/carton*3
Manuf. Date:	June. 29, 2024	Sampling Date:	June. 4, 2025
Retest Date:	June. 28, 2027	Report Date:	June. 12, 2025
Standard:	BZC04-02		
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 150.5°C	
4.Loss on drying:	0.5% Max	0.10%	
5.Specific rotation:	+ 11.0° to + 14.0°	+ 13.3°	
6.Sulphated ash:	0.1% Max.	0.05%	
7.Hydroxylamine:	5ppm Max.	<5ppm	
8.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	Not detected	
	Any unspecified impurity:0.10% Max.	RRT 0.55 <0.025% RRT 0.63 0.03% RRT 0.68 0.004%	
	Total Impurities: 0.5% Max	0.06%	
10. Assay:	98.0% to 102.0%	100.0%	
10.Residual solvents:	Methanol:3000ppm Max. Ethanol:5000ppm Max. Toluene:890ppm Max. Pyridine:200ppm Max. Benzene:2ppm Max	5ppm <LQD(50.0pm) Not detected Not detected Not detected	
*11.Particle size:	90% pass 30µm	Complies	
Conclusion:	The product conforms to BZC04-02.		

Prepared by: 陈研

Reviewed by: 陈研

Approved by: 胡安峰

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