

江苏佳尔科药业集团股份有限公司

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Certificate of Analysis

No.:C04-2020010

Product Name:	Dehydroepiandrosterone (DHEA)	Batch No.:	C04-200302(M)
Quantity:	400kg	Packaging:	25kg/drum
Manuf. Date:	Feb. 20, 2020	Sampling Date:	Mar. 16, 2020
Retest Date:	Feb. 19, 2023	Report Date:	Mar. 26, 2020
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 should be 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°	+13.1°	
5. Loss on drying:	0.5% Max.	0.14%	
6. Sulphated ash:	0.1% Max.	0.04%	
7. Hydroxylamine:	5ppm Max.	<5ppm	
8. 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.	Not detected	
	Impurity F: 0.08% Max.	Not detected	
	Any unspecified impurity:0.1% Max.	RRT0.52 < 0.025%	RRT0.60 0.05%
Total impurity: 0.5% Max.	0.08%		
9. Assay	97.5% to 102.0%	99.4%	
10. Residual solvents	Methanol: 3000ppm Max. Ethanol: 5000ppm Max. Toluene: 890ppm Max. Pyridine: 200ppm Max.	Not detected Not detected Not detected Not detected	
*11.Total aerobic microbial count:	10 ³ cfu/g Max.	< 10 ¹ cfu/g	
*12. Mold &Yeast:	10 ² cfu/g Max.	< 10 ¹ cfu/g	
*13. BTAG bacteria:	Negative(N<10)	N<10	
*14. a). Bulk density: b). Tapped density:	—	a). 0.2886g/ml b). 0.6326g/ml	
*15.Particle size:	90% min. through 300mesh(48 μ m)	Complies	
*16. Lead:	0.5ppm Max.	Complies	
*17.Arsenic (As):	1ppm Max.	Complies	
*18.Mercury:	0.3ppm Max.	Complies	
*19.Cadmium:	1ppm Max.	Complies	
*Product code:	C04	*Country of origin:	China
		*Source:	Wild Yam
*We guarantee that we haven't used irradiation & ETO treatment of DHEA.			
Conclusions:	The product conforms to BZC04-02.		

Prepared by:

Reviewed by:

Approved by:

*16/*17/*18/*19: One randomly selected batch is tested annually.