

Lot. 9081219


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Certificate of Analysis

Product Name:	Dehydroepiandro-sterone (DHEA)	Batch No.:	C04-190803(M)
Quantity:	100kg	Packaging:	10kg/carton
Manuf. Date:	June 26, 2019	Sampling Date:	Aug. 10, 2019
Retest Date:	June 25, 2022	Report date:	Aug. 19, 2019
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 should be corresponds to that of working reference standard.	Complies	
3. Melting range:	148°C to 151°C	149°C to 150.5°C	
4. Specific rotation:	+ 11.0° to + 14.0°	+ 13.2°	
5. Water:	0.5% Max.	0.06%	
6.Sulphated ash:	0.1% Max.	0.04%	
7. Heavy metals :	10ppm Max.	<10ppm	
8. Hydroxylamine:	5ppm Max.	Complies	
9.Lead (Pb):	3ppm Max.	Complies	
10.Arsenic(As) :	1ppm Max.	Complies	
11.Mercury(Hg):	0.1ppm Max.	Complies	
12.Cadmium (Cd):	1ppm Max.	Complies	
13. 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.	0.04%	
	Impurity F: 0.08% Max.	Not detected	
	Any unspecified impurity:0.10% Max.	RRT 0.51	< 0.025%
		RRT 0.60	<0.025%
		RRT 1.50	<0.025%
RRT 3.00		0.05%	
RRT 3.67		<0.025%	
Total impurity: 0.50% Max.	0.08%		
14. Assay (HPLC, on dried basis)	98.0% to 102.0%	99.8%	
15. Residual solvents	Methanol: 1500ppm Max. Ethanol: 2000ppm Max. Toluene: 890ppm Max. Pyridine: 50ppm Max.	42ppm Not detected Not detected Not detected	
16.Total plate count:	1000cfu/g Max.	< 10cfu/g	
17.Yeast & Mold:	100cfu/g Max.	< 10cfu/g	
18.E.coli:	Negative	Negative	
19. Particle size:	100% through 40mesh; 40%~60% through 80mesh; ≤20% through 200mesh	100% through 40mesh 54% through 80mesh 6% through 200mesh	
Conclusions:	The product conforms to FP.		

QA Manager: 张亚红

Reported by: 吴凤明