

Hubei Zhuxi Humanwell Pharmaceutical Co., Ltd.

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CERTIFICATE OF ANALYSIS

Product (品名): DHEA Batch No. (批号): DHEA190503
Quantity (数量): 50 KG Specification (规定): In house
Mfg. date (生产日期): 2019.05.25 Expiry date (有效期至): 2021.05.24

Item	Specifications	Results
Description	White or almost white crystalline powder	White crystalline powder
Identification	IR	Conform
Melting point	147~152°C	149.0~150.5°C
Loss on drying	≤0.5%	0.12%
Specific optical rotation	+12° ~+15°	+12.5°
Sulfated ash	≤0.1 %	0.05%
Particle size	90% through 80 mesh	90% through 80 mesh
Heavy metals	≤10ppm	<10ppm
Lead	≤0.5ppm	<0.5ppm
Arsenic	≤1.5ppm	<1.5ppm
Cadmium	≤0.5ppm	<0.5ppm
Mercury	≤0.1ppm	<0.1ppm
Related substances	Single impurity ≤0.2% Total impurities ≤1.0%	0.15% 0.21%
Residual solvent	Methanol ≤1500ppm Ethanol ≤2500ppm Acetone ≤2500ppm Dichloromethane ≤300ppm Ethyl acetate ≤2500ppm	93ppm Not detected Not detected Not detected Not detected
Assay	99.0%Min	100.7%
Microbial control	Total Plate Count ≤1,000cfu/g Yeasts & Molds ≤100cfu/g E.coli Negative Salmonella Negative Staphylococcus aureus Negative	<1,000cfu/g <100cfu/g Negative Negative Negative

Conclusion: Complies with the requirements of In house

Report person:

质量管理部

Q.C. director: