

Lot: 081213

Hubei Gedian Humanwell Pharmaceutical Co., Ltd.

Address: Gedian Economic Development District, E-zhou, 436070, Hubei, P. R. China

**CERTIFICATE OF ANALYSIS**

Product (品名): Cyproterone Acetate

Batch No. (批号): CPA 130913

Quantity (数量): 60.2kg

Specification (规定): EP7.4

Mfg. date (生产日期): 2013.09.25

Expiry date (有效期至): 2018.09.24

Item	Specifications	Results
Appearance	White or almost white crystalline powder	Almost White crystalline powder
Solubility	Practically insoluble in water, very soluble in methylene chloride, freely soluble in acetone, soluble in methanol, sparingly soluble in ethanol	Conform
Identification	IR	Conform
Melting Point	About 210 °C	209.0°C ~211.5°C
Loss on drying	≤ 0.5 %	0.13%
Specific optical rotation	+152° ~ +157°	+157°
Sulphated ash	≤ 0.1 %	0.06%
Related substances	Total impurities ≤ 0.5 %	0.17%
	Impurity E ≤ 0.2 %	0.06%
	Impurity F ≤ 0.4 %	0.04%
	Impurities B ≤ 0.15%	Not detected
	Impurities C ≤ 0.15%	Not detected
	Impurities G ≤ 0.15%	Not detected
	Unspecified impurities ≤ 0.10%	Conform
Residual solvents	Ethanol ≤ 5000ppm	316ppm
	Chloroform ≤ 60ppm	Not detected
	Dichloromethane ≤ 600ppm	Not detected
	Ethyl acetate ≤ 5000ppm	Not detected
Assay	97.0 ~ 103.0 %	102.5%
Particle Size	99% ≤ 10µm, 90% ≤ 5µm	Conform

Conclusion:

Complies with the requirements of EP7.4

(结论)

(符合 EP7.4 版的规定)

Analyst: 唐伟运

(检验员)

Checker: 何冬梅

(复核员)

Q.C. director: 蔡咏

(负责人)

