

Lot: 0111114

Hubei Gedian Humanwell Pharmaceutical Co., Ltd.

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CERTIFICATE OF ANALYSIS

Product (品名): Cyproterone Acetate micronized

Batch No. (批号): CPA140701

Quantity (数量): 38kg

Specification (规定): EP8.0

Mfg. date (生产日期): 2014.07.14

Expiry date (有效期至): 2019.07.13

Report date(报告日期): 2014.09.02

Item	Specifications	Results
Description	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	209.5~210.0°C
Loss on drying	≤ 0.5 %	0.05%
Specific optical rotation	+152° ~ +157°	+155°
Sulphated ash	≤ 0.1 %	0.01%
Related substances	Total impurities ≤ 0.5%	0.2%
	Impurity E: 3,6,20-trioxo-1β,2β-dihydro-3'H- cyclopropa[1,2]-pregna-1,4-dien-17-yl acetate ≤ 0.2 %	0.1%
	Impurity F: 6-chloro-17-hydroxy-1β,2β-dihydro-3'H- cyclopropa[1,2]-pregna-1,4,6-trien-3,20-dione ≤ 0.4 %	0.02%
	Impurities B: 6-methoxy-3,20-dioxo-1β,2β-dihydro-3'H - cyclopropa[1,2]-pregna-1,4,6-trien-17-yl acetate ≤ 0.15 %	Not detected
	Impurities C: 6-chloro-1α-chloromethyl -3,20-dioxopregna-4,6-dien-17-yl acetate ≤ 0.15 %	Not detected
	Impurities G: 6β-chloro-7α-hydroxy-3,20-dioxo-1β,2β-dihydro -3'H- cyclopropa[1,2]-pregna-1,4-dien-17-yl acetate ≤ 0.15 %	Not detected
	Unspecified impurities ≤ 0.10 %	0.06%
Residual solvents	Ethanol ≤ 5000ppm	34 ppm
	Chloroform ≤ 60ppm	Not detected
	Dichloromethane ≤ 600ppm	11ppm
	Ethyl acetate ≤ 5000ppm	Not detected
Assay	97.0 ~ 103.0 %	101.8%
Particle Size	100% ≤ 20 μm	Conform

Conclusion:

(结论)

Complies with the requirements of EP 8.0

(符合EP 8.0版的规定)

Report person:

(报告人)

Q.C. director:

(负责人)

