

Lot: 0061016

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CERTIFICATE OF ANALYSIS

Product (品名): Cyproterone Acetate micronized

Batch No. (批号): CPA150301

Quantity (数量): 51kg

Specification (规定): EP8.0

Mfg. date (生产日期): 2015.03.08

Expiry date (有效期至): 2020.03.07

Report date(报告日期): 2015.05.21

Item	Specifications	Results
Description	White or almost white crystalline powder	Almost white crystalline powder
Identification	IR	Conform
Melting Point	About 210 °C	208.5~210.5°C
Loss on drying	≤ 0.5 %	0.08%
Specific optical rotation	+152° ~ +157°	+156°
Sulphated ash	≤ 0.1 %	0.01%
Related substances	Total impurities ≤ 0.5%	0.03%
	Impurity E: 3,6,20-trioxo-1β,2β-dihydro-3'H- cyclopropa[1,2]-pregna-1,4-dien-17-yl acetate ≤ 0.2 %	Not detected
	Impurity F: 6-chloro-17-hydroxy-1β,2β-dihydro-3'H- cyclopropa[1,2]-pregna-1,4,6-trien-3,20-dione ≤ 0.4 %	Not detected
	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 %	Not detected
Residual solvents	Ethanol ≤ 5000ppm	474 ppm
	Chloroform ≤ 60ppm	Conform
	Dichloromethane ≤ 600ppm	Conform
	Ethyl acetate ≤ 5000ppm	Conform
Assay	97.0 ~ 103.0 %	101.3%
Microbial control	Total Aerobic Count ≤ 1,000cfu/g	Conform
	Yeasts & Molds ≤ 100cfu/g	
Particle Size	99% ≤ 20um	Conform

Conclusion:

(结论)

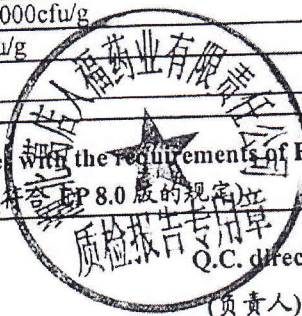
Complies with the requirements of EP 8.0

(符合 EP 8.0 规定的标准)

Report person:

(报告人)

同康梅



Q.C. director: 薛峰

(负责人)