

late: 2020616

Hubei Gedian Humanwell Pharmaceutical Co., Ltd.

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



CERTIFICATE OF ANALYSIS

Product (品名): Finasteride Micronized (Form 1)

Batch No. (批号): FTD 160106

Quantity (数量): 40kg

Specification (规定): EP8.0

Mfg. date (生产日期): 2016.01.06

Expiry date (有效期至): 2021.01.05

Report date (报告日期): 2016.01.20

Item (项目)	Specifications (标准)	Results (结果)
Description (性状)	White or almost white crystalline powder	Almost white crystalline powder
Identification (鉴别)	IR	Meet the requirements
Specific optical rotation (比旋度)	+12.0~+14.0°	+13.1°
Loss on drying (干燥失重)	≤ 0.5 %	0.21%
Related substance (相关物质)	Impurity A ≤ 0.3% Impurity C ≤ 0.3% Any other unknown impurity ≤ 0.10 % Total impurities ≤ 0.5 %	0.16% 0.2% 0.03% 0.3%
Residue Solvent (残留溶剂)	Methanol ≤ 3000ppm	81 ppm
	Ethanol ≤ 5000 ppm	221 ppm
	Methylene chloride ≤ 600ppm	9ppm
	Isopropyl acetate ≤ 5000 ppm	12ppm
	Toluene ≤ 890ppm	Not detected
Assay (含量)	98.0 ~ 102.0 %	99.9%
Particle Size (粒度)	100% ≤ 20 μm	Conform

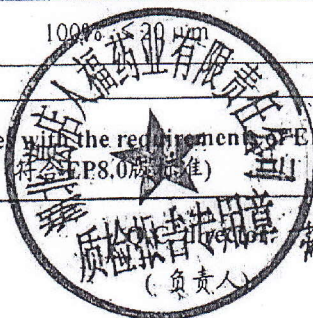
Conclusion:
(结论)

Complies with the requirements of EP8.0
(符合 EP8.0 规定)

Report person:

(报告人)

杨进



(负责人)