

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

Batch No. (批号): FTD 141101

Quantity (数量): 39kg

Specification (规定): EP8.0

Mfg. date (生产日期): 2014.11.14

Expiry date (有效期至): 2019.11.13

Report date (报告日期): 2015.03.30

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°	+12.4°
Loss on drying (干燥失重)	≤ 0.5 %	0.07%
Related substance (相关物质)	Impurity A ≤ 0.3% Impurity C ≤ 0.3% Any other unknown impurity ≤ 0.10 % Total impurities ≤ 0.5 %	0.06% 0.20% 0.06% 0.38%
Residue Solvent (残留溶剂)	Methanol ≤ 3000ppm	Not detected
	Ethanol ≤ 5000 ppm	292ppm
	Methylene chloride ≤ 600ppm	Not detected
	Isopropyl acetate ≤ 5000 ppm	Not detected
	Toluene ≤ 890ppm	Not detected
Assay (含量)	98.0 ~ 102.0 %	100.2%

Conclusion:
(结论)

Complies with the requirements of EP8.0
(符合EP8.0版标准)

Report person:
(报告人)

同康梅

Q.C. director:
(负责人)

薛峰