

Lot: 0091014

Hubei Gedian Humanwell Pharmaceutical Co., Ltd.

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CERTIFICATE OF ANALYSIS

Product (品名): Finasteride

Batch No. (批号): FTD 140606

Quantity (数量): 39.3kg

Specification (规定): EP8.0

Mfg. date (生产日期): 2014.06.29

Expiry date (有效期至): 2019.06.28

Report date (报告日期): 2014.07.11

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°	+12.9°
Loss on drying (干燥失重)	≤ 0.5 %	0.2%
Related substance (相关物质)	Impurity A ≤ 0.3%	0.1%
	Impurity C ≤ 0.3%	0.1%
	Any other unknown impurity ≤ 0.10 %	0.07%
	Total impurities ≤ 0.5 %	0.3%
Residue Solvent (残留溶剂)	Methanol ≤ 3000ppm	Not detected
	Ethanol ≤ 5000 ppm	378ppm
	Methylene chloride ≤ 600ppm	Not detected
	Isopropyl acetate ≤ 5000 ppm	Not detected
	Toluene ≤ 890ppm	Not detected
Assay (含量)	98.0 ~ 102.0 %	100.6%

Conclusion:
(结论)

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

Report person:
(报告人)

徐强

Q.C. director:
(负责人)

蔡咏