

Lot: 0061115

Hubel Gedian Humanwell Pharmaceutical Co., Ltd.

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CERTIFICATE OF ANALYSIS

Product (品名): Finasteride Micronized (FORM 1)

Batch No. (批号): FTD 150803

Quantity (数量): 3 kg

Specification (规定): EP8.0

Mfg. date (生产日期): 2015.08.03

Expiry date (有效期至): 2020.08.02

Report date (报告日期): 2015.08.15

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 %	0.18%
Related substance (相关物质)	Impurity A ≤ 0.3% Impurity C ≤ 0.3% Any other unknown impurity ≤ 0.10 % Total impurities ≤ 0.5 %	0.10% 0.18% Not detected 0.48%
Residue Solvent (残留溶剂)	Methanol ≤ 3000ppm	143 ppm
	Ethanol ≤ 5000 ppm	284ppm
	Methylene chloride ≤ 600ppm	64 ppm
	Isopropyl acetate ≤ 5000 ppm	Not detected
	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标准)

Report person:
(报告人)

周康报

