

Lot: 9010813

Hubei Gedian Humanwell Pharmaceutical Co., Ltd.

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CERTIFICATE OF ANALYSIS

Product (品名): Finasteride Micronized

Batch No. (批号): FTD 130611

Quantity (数量): 40.19 kg

Specification (规定): EP7.0

Mfg. date (生产日期): 2013.06.25

Expiry date (有效期至): 2018.06.24

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)	Meet the requirements	Meet the requirements
Specific optical rotation (比旋度)	+12.0~+14.0°	+12.9°
Loss on drying (干燥失重)	≤0.5 %	0.10%
Related substance (相关物质)	Impurity A ≤0.3% Impurity B ≤0.3% Impurity C ≤0.3% Any other unknown impurity ≤0.10 % Total impurities ≤0.6 %	0.12% No detected 0.07% 0.07% 0.26%
Residue Solvent (残留溶剂)	Methanol ≤3000ppm Ethanol ≤5000 ppm Methylene chloride ≤600ppm Isopropyl acetate ≤5000 ppm Toluene ≤800ppm	Conform
Assay (含量)	98.0 ~ 102.0	99.4%

Conclusion:
(结论)

Complies with the requirements of EP7.0
(符合 EP7.0 版标准)

Analyst:
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