

Lot: 0030214

Hubei Gedian Humanwell Pharmaceutical Co., Ltd.

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CERTIFICATE OF ANALYSIS

Product (品名): **Finasteride Form I**
(非那雄胺)

Batch No. (批号): **FTD130922**

Quantity (数量): **46.88kg**

Specification (规定): **EP8.0**

Mfg. date (生产日期): **2013. 09. 26**

Expiry date (有效期至): **2018. 09. 25**

Item (项目)	Specifications (规定)	Results (结果)
Description (性状)	White or almost white crystalline powder	White crystalline powder
Identification (鉴别)	Meet the requirements	Meet the requirements
Specific optical rotation (比旋度)	+12° ~ +14°	+12.9°
Loss on drying (干燥失重)	≤ 0.5%	0.20%
Related substances (有关物质)	Impurity A ≤ 0.3%	0.08%
	Impurity C ≤ 0.3%	0.10%
	Any other unknown impurity ≤ 0.1%	0.06%
	Total impurities ≤ 0.5%	0.22%
Residue solvent (残留溶剂)	Methanol ≤ 3000ppm	Conform
	Ethanol ≤ 5000ppm	
	Methylene chloride ≤ 600ppm	
	Isopropyl acetate ≤ 5000ppm	
	Toluene ≤ 890ppm	
Assay (含量)	98.0 ~ 102.0 %	100.6%

Conclusion:
(结论)

Complies with the requirements of EP8.0

(符合 EP8.0 版的规定)

Analyst:
(检验员)

李名远

Checker:
(复核员)

质检报告专用章

Q.C. director:
(负责人)

薛洪