

Lot: 9080216

**Hubel Gedian Humanwell Pharmaceutical Co., Ltd.**

Address: Gedian Economic Development District, E-zhou 436070, Hubei, P. R. China



## CERTIFICATE OF ANALYSIS

Product (品名): Finasteride Micronized (FORM 1)

Batch No. (批号): FTD 151005

Quantity (数量): 3 kg

Specification (规定): EP8.0

Mfg. date (生产日期): 2015.10.05

Expiry date (有效期至): 2020.10.04

Report date (报告日期): 2015.10.10

| 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°                                                                                              | +13.0°                                  |
| Loss on drying (干燥失重)           | ≤ 0.5 %                                                                                                   | 0.12%                                   |
| Related substance (相关物质)        | Impurity A ≤ 0.3%<br>Impurity C ≤ 0.3%<br>Any other unknown impurity ≤ 0.10 %<br>Total impurities ≤ 0.5 % | 0.10%<br>0.12%<br>Not detected<br>0.40% |
| Residue Solvent (残留溶剂)          | Methanol ≤ 3000ppm                                                                                        | 140 ppm                                 |
|                                 | Ethanol ≤ 5000 ppm                                                                                        | 224ppm                                  |
|                                 | Methylene chloride ≤ 600ppm                                                                               | 62 ppm                                  |
|                                 | Isopropyl acetate ≤ 5000 ppm                                                                              | Not detected                            |
|                                 | Toluene ≤ 890ppm                                                                                          | Not detected                            |
| Assay (含量)                      | 98.0 ~ 102.0 %                                                                                            | 99.8%                                   |
| Particle Size (粒度)              | 100% ≤ 20 μ m                                                                                             | Conform                                 |

Conclusion:  
(结论)

Complies with the requirements of EP8.0

Report person:  
(报告人)

周康梅

