

**Hubei Gedian Humanwell Pharmaceutical Co., Ltd.**  
Address: Gedian Economic Development District, E-zhou 436070, Hubei, P. R. China



### CERTIFICATE OF ANALYSIS

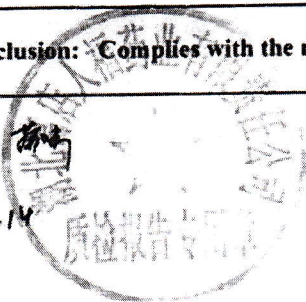
Product : Finasteride Micronized (Form 1)  
Quantity : 3kg  
Mfg. date : 2016.10.16

Batch No. : FTD 161001-1  
Specification : EP8.0  
Expiry date: 2021.06.30

| Item                      | Specifications                           | Results                                                   |
|---------------------------|------------------------------------------|-----------------------------------------------------------|
| Description               | White or almost white crystalline powder | Almost white crystalline powder                           |
| Identification            | IR:Comparison:finasteride CRS.           | Sample spectrum is similar to that of reference standard. |
| Loss on drying            | $\leq 0.5\%$                             | 0.07%                                                     |
| Specific optical rotation | $+12.0^{\circ} \sim +14.0^{\circ}$       | $+12.5^{\circ}$                                           |
| Related substances        | Impurity A $\leq 0.3\%$                  | 0.06%                                                     |
|                           | Impurity C $\leq 0.3\%$                  | 0.16%                                                     |
|                           | Any other unknown impurity $\leq 0.10\%$ | 0.06%                                                     |
|                           | Total impurities $\leq 0.5\%$            | 0.31%                                                     |
| Residual Solvents         | Methanol $\leq 3000\text{ppm}$           | Not detected                                              |
|                           | Ethanol $\leq 5000\text{ppm}$            | 400ppm                                                    |
|                           | Methylene chloride $\leq 600\text{ppm}$  | Not detected                                              |
|                           | Isopropyl acetate $\leq 5000\text{ppm}$  | Not detected                                              |
|                           | Toluene $\leq 890\text{ppm}$             | Not detected                                              |
| Assay                     | 98.0 ~ 102.0 %                           | 99.1%                                                     |
| Particle Size             | 100% $\leq 20\mu\text{m}$                | Conform                                                   |

Conclusion: Complies with the requirements of EP8.0

Q.C. director:



QP: 赵静

Date: 2016.11.14

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