



# Hubei Gedian Humanwell Pharmaceutical Co., Ltd.

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## CERTIFICATE OF ANALYSIS

Product : Finasteride Micronized  
Quantity : 15kg  
Mfg. date: 2022.03.28  
CEP No.: R1-CEP 2013-238-Rev 00

Batch No. : EU-FTD220308M  
Specification: EP10  
Retest date: 2027.03.27



| 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. |
| Specific optical rotation | +12.0° ~ +14.0° (On dried substance)     | +13.2°                                                    |
| Loss on drying            | ≤ 0.5 %                                  | 0.07%                                                     |
| Related substances        | Impurity A ≤ 0.3%                        | 0.06%                                                     |
|                           | Impurity C ≤ 0.3%                        | 0.08%                                                     |
|                           | Any other unknown impurity ≤ 0.10 %      | 0.05%                                                     |
|                           | Total impurities ≤ 0.5%                  | 0.19%                                                     |
| Residual Solvents         | Methanol ≤ 3000ppm                       | Not detected                                              |
|                           | Ethanol ≤ 5000ppm                        | 620ppm                                                    |
|                           | Methylene chloride ≤ 600ppm              | Not detected                                              |
|                           | Isopropyl acetate ≤ 5000 ppm             | Not detected                                              |
|                           | Toluene ≤ 890ppm                         | Not detected                                              |
| Pd                        | ≤ 10ppm                                  | Not detected                                              |
| Assay                     | 98.0 ~ 102.0 % (On dried substance)      | 100.2%                                                    |
| Particle Size             | 100% < 20μm                              | Conform                                                   |

Conclusion: Complies with the requirements of EP10

Q.C. director: 吴秀微

Date: 2022.05.06

QP: 1213

Date: 2022.05.06