

Hubei Gedian Humanwell Pharmaceutical Co., Ltd.

Address: No.25 Juxian Road, Gedian Economic Development District, E-zhou 436070, Hubei Province, China

TEL: +86-711-3811610 FAX: +86-711-3811590

[Http://www.steroid-chem.com](http://www.steroid-chem.com), E-mail: gdq@renfu.com.cn



CERTIFICATE OF ANALYSIS

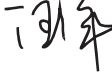
Product : Finasteride Micronized
Quantity : 7kg
Mfg. date: 2020.04.12
CEP No.: R1-CEP 2013-238-Rev 00

Batch No. : EU-FTD200405
Specification: EP10
Retest date: 2025.04.11

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)	+12.7°
Loss on drying	≤ 0.5 %	0.03%
Related substances	Impurity A ≤ 0.3%	Not detected
	Impurity C ≤ 0.3%	0.09%
	Any other unknown impurity ≤ 0.10 %	0.04%
	Total impurities ≤ 0.5%	0.16%
Residual Solvents	Methanol ≤ 3000ppm	Not detected
	Ethanol ≤ 5000ppm	242ppm
	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)	99.4%
Particle Size	100% < 20μm	Conform

Conclusion: Complies with the requirements of EP10

Q.C. director: 

QP: 

Date: 2020.11.17

Date: 2020.11.19