



F. & A. PHARMA-Handels-GmbH
Bonhoeffering 41 • D-46236 Dorsten • Germany
Phone: +49(0) 2369-9261947 • Fax: +49(0) 2369-9261950

METAPHARMACEUTICAL

N DE LOTE:

0320322

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, E-mail: gdq@renfu.com.cn

CERTIFICATE OF ANALYSIS



31/03/2022



Product : Finasteride Micronized
Quantity : 10kg
Mfg. date: 2021.10.21
CEP No.: R1-CEP 2013-238-Rev 00

Batch No. : EU-FTD211005M
Specification: EP10
Retest date: 2026.10.20

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)	+12.4°
Loss on drying	≤ 0.5 %	0.06%
Related substances	Impurity A ≤ 0.3%	0.04%
	Impurity C ≤ 0.3%	0.14%
	Any other unknown impurity ≤ 0.10 %	Not detected
	Total impurities ≤ 0.5%	0.18%
Residual Solvents	Methanol ≤ 3000ppm	Not detected
	Ethanol ≤ 5000ppm	337ppm
	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)	99.0%
Particle Size	100% < 20μm	Conform

Conclusion: Complies with the requirements of EP10

Q.C. director: 吴晓斌

QP: 王平

Date: 2022.02.16

Date: 2022.02.16