

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 I)

Quantity : 10kg

Mfg. date : 2019.03.16

Batch No. : FTD190306

Specification: EP9

Expiry date: 2024.03.15

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	$\leq 0.5\%$	0.00%
Specific optical rotation	$+12.0^{\circ} \sim +14.0^{\circ}$ (on dried substance)	$+12.7^{\circ}$
Related substances	Impurity A $\leq 0.3\%$	0.02%
	Impurity C $\leq 0.3\%$	0.17%
	Any other unknown impurity $\leq 0.10\%$	0.04%
	Total impurities $\leq 0.5\%$	0.22%
Residual Solvents	Methanol ≤ 3000 ppm	98ppm
	Ethanol ≤ 5000 ppm	434ppm
	Methylene chloride ≤ 600 ppm	Not detected
	Isopropyl acetate ≤ 5000 ppm	Not detected
	Toluene ≤ 890 ppm	Not detected
Assay	98.0 ~ 102.0 % (on dried substance)	100.1%
Particle Size	100% < 20 μ m	Conform

Conclusion: Complies with the requirements of EP9

Q.C. director:

QP:

Date:

2019.06.06

Date:

2019.06.06