

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 : 2019.05.18

Batch No. : FTD190504

Specification: EP9

Expiry date: 2024.05.17

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	$\leq 0.5\%$	0.15%
Specific optical rotation	$+12.0^{\circ} \sim +14.0^{\circ}$ (on dried substance)	$+12.8^{\circ}$
Related substances	Impurity A $\leq 0.3\%$	0.03%
	Impurity C $\leq 0.3\%$	0.14%
	Any other unknown impurity $\leq 0.10\%$	0.08%
	Total impurities $\leq 0.5\%$	0.31%
Residual Solvents	Methanol $\leq 3000\text{ppm}$	94ppm
	Ethanol $\leq 5000\text{ppm}$	665ppm
	Methylene chloride $\leq 600\text{ppm}$	Not detected
	Isopropyl acetate $\leq 5000\text{ppm}$	6ppm
	Toluene $\leq 890\text{ppm}$	10ppm
Assay	98.0 ~ 102.0 % (on dried substance)	99.9%
Particle Size	100% $< 20\mu\text{m}$	Conform

Conclusion: Complies with the requirements of EP9

Q.C. director: 蒋瑞

Date: 2019.11.21

QP: 蒋瑞

Date: 2019.11.21