

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 : 2018.09.19

Batch No. : FTD180901

Specification : EP9

Expiry date: 2023.09.18

Item	Specifications	Results
Description	White or almost white crystalline powder	Almost white crystalline powder
Solubility	practically insoluble in water, freely soluble in ethanol and in methylene chloride.	Conform
Identification	IR:Comparison:finasteride CRS.	Sample spectrum is similar to that of reference standard.
Loss on drying	$\leq 0.5\%$	0.10%
Specific optical rotation	$+12.0^{\circ} \sim +14.0^{\circ}$	$+12.5^{\circ}$
Related substances	Impurity A $\leq 0.3\%$	0.02%
	Impurity C $\leq 0.3\%$	0.18%
	Any other unknown impurity $\leq 0.10\%$	0.06%
	Total impurities $\leq 0.5\%$	0.26%
Residual Solvents	Methanol $\leq 3000\text{ppm}$	108ppm
	Ethanol $\leq 5000\text{ppm}$	498ppm
	Methylene chloride $\leq 600\text{ppm}$	Not detected
	Isopropyl acetate $\leq 5000\text{ppm}$	20ppm
	Toluene $\leq 890\text{ppm}$	Not detected
Assay	98.0 ~ 102.0 %	100.6%
Particle Size	100% < 20 μm	Conform

Conclusion: Complies with the requirements of EP9

Q.C. director:

QP: 赵静

Date: 2018.11.15

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