

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 1)
Quantity : 4kg
Mfg. date : 2017.02.13

Batch No. : EU-FTD 170202
Specification : EP9
Expiry date: 2022.02.12

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	$\leq 0.5\%$	0.14%
Specific optical rotation	$+12.0^{\circ} \sim +14.0^{\circ}$	$+12.6^{\circ}$
Related substances	Impurity A $\leq 0.3\%$	0.04%
	Impurity C $\leq 0.3\%$	0.18%
	Any other unknown impurity $\leq 0.10\%$	0.03%
	Total impurities $\leq 0.5\%$	0.30%
Residual Solvents	Methanol $\leq 3000\text{ppm}$	124ppm
	Ethanol $\leq 5000\text{ppm}$	224ppm
	Methylene chloride $\leq 600\text{ppm}$	Not detected
	Isopropyl acetate $\leq 5000\text{ppm}$	Not detected
	Toluene $\leq 890\text{ppm}$	Not detected
Assay	98.0 ~ 102.0 %	99.6%
Particle Size	$100\% \leq 20\mu\text{m}$	Conform

Conclusion: Complies with the requirements of EP9

Q.C. director: 蔡静

QP: 赵静

Date: 2017.02.21

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