

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 : 8kg
Mfg. date : 2016.10.31

Batch No. : FTD 161003
Specification : EP8.0
Expiry date: 2021.10.30

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	$\leq 0.5\%$	0.03%
Specific optical rotation	$+12.0^{\circ} \sim +14.0^{\circ}$	$+12.9^{\circ}$
Related substances	Impurity A $\leq 0.3\%$	0.13%
	Impurity C $\leq 0.3\%$	0.22%
	Any other unknown impurity $\leq 0.10\%$	0.03%
	Total impurities $\leq 0.5\%$	0.38%
Residual Solvents	Methanol $\leq 3000\text{ppm}$	218ppm
	Ethanol $\leq 5000\text{ppm}$	278ppm
	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 %	98.9%
Particle Size	100% $\leq 20\mu\text{m}$	Conform

Conclusion: Complies with the requirements of EP8.0

Q.C. director:

QP:

Date: 2016.12.02

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