

Lote: 905/217

Hubei Gedian Humanwell Pharmaceutical Co., Ltd.
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CERTIFICATE OF ANALYSIS

Product : Finasteride Micronized (Form1)
Quantity : 10kg
Mfg. date : 2017.11.06

Batch No. : FTD171102
Specification : EP9
Expiry date: 2022.11.05

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	$\leq 0.5\%$	0.08%
Specific optical rotation	$+12.0^{\circ} \sim +14.0^{\circ}$	$+12.9^{\circ}$
Related substances	Impurity A $\leq 0.3\%$	0.02%
	Impurity C $\leq 0.3\%$	0.19%
	Any other unknown impurity $\leq 0.10\%$	0.08%
	Total impurities $\leq 0.5\%$	0.41%
Residual Solvents	Methanol $\leq 3000\text{ppm}$	100ppm
	Ethanol $\leq 5000\text{ppm}$	512ppm
	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 %	100.7%
Particle Size	100% < 20 μm	Conform

Conclusion: Complies with the requirements of EP9

Q.C. director: 蔡伟

QP: 赵静

Date: 2017.11.16

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