

Lot: 2050718

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

Product : Finasteride Micronized (Form 1)
Quantity : 20kg
Mfg. date : 2017.12.27

Batch No. : FTD171206
Specification : EP9
Expiry date: 2022.12.26

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	$\leq 0.5\%$	0.06%
Specific optical rotation	$+12.0^{\circ} \sim +14.0^{\circ}$	$+13.0^{\circ}$
Related substances	Impurity A $\leq 0.3\%$	0.24%
	Impurity C $\leq 0.3\%$	0.04%
	Any other unknown impurity $\leq 0.10\%$	0.05%
	Total impurities $\leq 0.5\%$	0.33%
Residual Solvents	Methanol $\leq 3000\text{ppm}$	35 ppm
	Ethanol $\leq 5000\text{ppm}$	128 ppm
	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 %	99.2%
Particle Size	100% < 20 μm	Conform

Conclusion: Complies with the requirements of EP9

Q.C. director: 蔡静

QP: 赵静

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