

Lot: 0100319

Hubei Gedian Humanwell Pharmaceutical Co., Ltd.

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CERTIFICATE OF ANALYSIS

Product : Finasteride Micronized (Form D)

Batch No. : FTD190201

Quantity : 10kg

Specification: EP9

Mfg. date : 2019.02.25

Expiry date: 2024.02.24

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	$\leq 0.5\%$	0.10%
Specific optical rotation	$+12.0^{\circ} \sim +14.0^{\circ}$ (on dried substance)	$+12.2^{\circ}$
Related substances	Impurity A $\leq 0.3\%$	0.02%
	Impurity C $\leq 0.3\%$	0.22%
	Any other unknown impurity $\leq 0.10\%$	0.06%
	Total impurities $\leq 0.5\%$	0.34%
Residual Solvents	Methanol ≤ 3000 ppm	Not detected
	Ethanol ≤ 5000 ppm	222ppm
	Methylene chloride ≤ 600 ppm	Not detected
	Isopropyl acetate ≤ 5000 ppm	Not detected
	Toluene ≤ 890 ppm	Not detected
Assay	98.0 ~ 102.0 % (on dried substance)	100.5%
Particle Size	100% < 20 μ m	Conform

Conclusion: Complies with the requirements of EP9

Q.C. director: 薛峰

Date: 2019.04.29

QP: 丁明

Date: 2019.04.29