

lot: 0100419

Hubel Gedian Humanwell Pharmaceutical Co., Ltd.

Address: Gedian Economic Development District, E-zhou 436070, Hubei, P. R. China



CERTIFICATE OF ANALYSIS

Product : Finasteride Micronized (Form I)

Batch No. : FTD190108

Quantity : 10kg

Specification: EP9

Mfg. date : 2019.01.27

Expiry date: 2024.01.26

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	$\leq 0.5\%$	0.05%
Specific optical rotation	$+12.0^{\circ} \sim +14.0^{\circ}$ (on dried substance)	$+12.9^{\circ}$
Related substances	Impurity A $\leq 0.3\%$	0.01%
	Impurity C $\leq 0.3\%$	0.16%
	Any other unknown impurity $\leq 0.10\%$	0.08%
	Total impurities $\leq 0.5\%$	0.32%
Residual Solvents	Methanol $\leq 3000\text{ppm}$	Not detected
	Ethanol $\leq 5000\text{ppm}$	284ppm
	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 % (on dried substance)	100.3%
Particle Size	100% $\leq 20\mu\text{m}$	Conform

Conclusion: Complies with the requirements of EP9

Q.C. director: 薛峰

QP: 赵静

Date: 2019.02.15

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