

Lote: 0050918

Hubei Gedian Humanwell Pharmaceutical Co., Ltd.

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CERTIFICATE OF ANALYSIS

Product : Finasteride Micronized (Form1)

Quantity : 10kg

Mfg. date : 2018.06.07

Batch No. : FTD180601

Specification : EP9

Expiry date: 2023.06.06

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	$\leq 0.5\%$	0.00%
Specific optical rotation	$+12.0^{\circ} \sim +14.0^{\circ}$	$+12.8^{\circ}$
Related substances	Impurity A $\leq 0.3\%$	0.01%
	Impurity C $\leq 0.3\%$	0.19%
	Any other unknown impurity $\leq 0.10\%$	0.07%
	Total impurities $\leq 0.5\%$	0.32%
Residual Solvents	Methanol $\leq 3000\text{ppm}$	Not detected
	Ethanol $\leq 5000\text{ppm}$	928ppm
	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 %	99.7%
Particle Size	100% < 20 μm	Conform

Conclusion: Complies with the requirements of EP9

Q.C. director:

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QP:

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Date: 2018.07.10

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