

# Hubei Gedian Humanwell Pharmaceutical Co., Ltd.

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## CERTIFICATE OF ANALYSIS

Product : Finasteride

Batch No. : FTD210303M

Quantity : 650g

Specification: USP43

Mfg. date: 2021.03.13

Expiry date: 2026.03.12

Item	Specifications	Results
Description	White to off-white, crystalline solid	Off-white crystalline solid
Identification	A: Infrared Absorption.	Sample spectrum is similar to that of reference standard.
	B: The retention time of the major peak in the chromatogram of the Assay preparation corresponds to that in the chromatogram of the Standard preparation, as obtained in the Assay.	The retention time of the major peak in the chromatogram of the Assay preparation corresponds to that in the chromatogram of the Standard preparation, as obtained in the Assay.
Specific optical rotation	-56.0° ~ -60.0° (On anhydrous basis)	-58.7°
Water	≤ 0.3 %	0.08%
Related substances	Individual impurity ≤ 0.5 %	0.16%
	Total impurities ≤ 1.0%	0.26%
Residual Solvents	Methanol ≤ 3000ppm	Not detected
	Ethanol ≤ 5000ppm	254ppm
	Methylene chloride ≤ 600ppm	Not detected
	Isopropyl acetate ≤ 5000 ppm	Not detected
	Toluene ≤ 890ppm	Not detected
Residue on ignition	≤ 0.1 %	0.05%
Heavy metal	≤ 10ppm	Conform
Assay	98.5 ~ 101.0 % (On anhydrous basis)	100.1%
Particle Size	90% ≤ 10μm	Conform

Conclusion: Complies with the requirements of USP43

Q.C. director:

QP:

Date: 2021.03.12

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