

Hubei Gedian Humanwell Pharmaceutical Co., Ltd.

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METAPHARMACEUTICAL

N DE LOTE:

0140122

CERTIFICATE OF ANALYSIS

Product : Dutasteride

Batch No. : DT210704

Quantity : 1kg

Specification : EP10

Mfg. date: 2021.07.26

Retest date: 2026.07.25

Item	Specifications	Results
Appearance	White or pale yellow powder	White powder
Solubility	Practically insoluble in water, freely soluble in methylene chloride, soluble or sparingly soluble in anhydrous ethanol	Conform
Identification	IR: Comparison: Dutasteride CRS.	Sample spectrum is similar to that of reference standard.
Specific optical rotation	+33.0° ~ +39.0°	+37.6°
Water	≤ 0.2 %	0.04%
Related substances	Impurity A ≤ 0.2%	0.08%
	Impurity B ≤ 0.15%	0.02%
	Impurity E ≤ 0.3%	0.04%
	Impurity C ≤ 0.2%	0.00%
	Impurity F ≤ 0.4%	0.14%
	Impurity G ≤ 0.3%	0.04%
	Unspecified impurities ≤ 0.10%	0.05%
	Impurity H ≤ 0.3%	Not detected
	Impurity I ≤ 0.5%	0.02%
	Unspecified impurities eluting after dutasteride ≤ 0.10%	0.01%
Residual Solvents	Total impurities ≤ 1.5%	0.43%
	Methanol ≤ 3000 ppm	Not detected
	Ethanol ≤ 5000 ppm	2363 ppm
	Acetonitrile ≤ 410 ppm	271 ppm
	Dichloromethane ≤ 600 ppm	Not detected
	Dioxane ≤ 380 ppm	Not detected
	Pyridine ≤ 200 ppm	Not detected
Sulphated ash	Toluene ≤ 890 ppm	Not detected
	≤ 0.1 %	0.01%
Assay	97.0 ~ 102.0% (anhydrous substance)	99.8%

Conclusion: Complies with the requirements of EP10

Q.C. director: 吴雪梅

Date: 2021.12.17

QP: 1213

Date: 2021.12.17