

Hubei Gedian Humanwell Pharmaceutical Co., Ltd.

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METAPHARMACEUTICAL

N DE LOTE:

0181022

CERTIFICATE OF ANALYSIS

Product : Dutasteride

Batch No. : DT220302

Quantity : 1kg

Specification : EP10

Mfg. date: 2022.03.19

Retest date: 2027.03.18

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°	+37.2°
Water	≤ 0.2 %	0.02%
Related substances	Impurity A ≤ 0.2%	Not detected
	Impurity B ≤ 0.15%	
	Impurity E ≤ 0.3%	0.04%
	Impurity C ≤ 0.2%	0
	Impurity F ≤ 0.4%	Not detected
	Impurity G ≤ 0.3%	Not detected
	Unspecified impurities ≤ 0.10%	Not detected
	Impurity H ≤ 0.3%	Not detected
	Impurity I ≤ 0.5%	0.01%
	Unspecified impurities eluting after dutasteride ≤ 0.10%	0.01%
	Total impurities ≤ 1.5%	0.06%
Residual Solvents	Methanol ≤ 3000ppm	Not detected
	Ethanol ≤ 5000ppm	1435ppm
	Acetonitrile ≤ 410 ppm	75ppm
	Dichloromethane ≤ 600 ppm	Not detected
	Dioxane ≤ 380 ppm	Not detected
	Pyridine ≤ 200 ppm	Not detected
	Toluene ≤ 890 ppm	Not detected
Sulphated ash	≤ 0.1 %	0
Assay	97.0 ~ 102.0% (anhydrous substance)	100.2%

Conclusion: Complies with the requirements of EP10

Q.C. director: 吴雪薇

QP: 王华

Date: 2022.06.13

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