

Hubei Gedian Humanwell Pharmaceutical Co., Ltd.

Address: No.25 Juxian Road, Gedian Economic Development District, E-zhou 436070, Hubei Province, China



METAPHARMACEUTICAL

N DE LOTE:

0010622

CERTIFICATE OF ANALYSIS

Product : Dutasteride

Quantity : 1kg

Mfg. date: 2022.03.20

Batch No. : DT220303

Specification : EP10

Retest date: 2027.03.19

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	$+33.0^{\circ} \sim +39.0^{\circ}$	$+37.3^{\circ}$
Water	$\leq 0.2\%$	0.05%
Related substances	Impurity A $\leq 0.2\%$	Not detected
	Impurity B $\leq 0.15\%$	0
	Impurity E $\leq 0.3\%$	0.04%
	Impurity C $\leq 0.2\%$	0
	Impurity F $\leq 0.4\%$	Not detected
	Impurity G $\leq 0.3\%$	Not detected
	Unspecified impurities $\leq 0.10\%$	Not detected
	Impurity H $\leq 0.3\%$	Not detected
	Impurity I $\leq 0.5\%$	0
	Unspecified impurities eluting after dutasteride $\leq 0.10\%$	0.01%
	Total impurities $\leq 1.5\%$	0.05%
Residual Solvents	Methanol $\leq 3000\text{ppm}$	Not detected
	Ethanol $\leq 5000\text{ppm}$	1421ppm
	Acetonitrile $\leq 410\text{ppm}$	73ppm
	Dichloromethane $\leq 600\text{ppm}$	Not detected
	Dioxane $\leq 380\text{ppm}$	Not detected
	Pyridine $\leq 200\text{ppm}$	Not detected
	Toluene $\leq 890\text{ppm}$	Not detected
Sulphated ash	$\leq 0.1\%$	0
Assay	97.0~102.0%(anhydrous substance)	100.5%

Conclusion: Complies with the requirements of EP10

Q.C. director: 吴磊

Date: 2022.05.07

QP: 王

Date: 2022.05.07