

Hubei Gedian Humanwell Pharmaceutical Co., Ltd.

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[Http://www.steroid-chem.com](http://www.steroid-chem.com), E-mail: rfzthx@steroid-chem.com**CERTIFICATE OF ANALYSIS**

Product: Dutasteride

Batch No.: DT191201 M

Quantity: 100g

Specification : EP10

Mfg. date: 2019.12.30

Retest date: 2022.12.29

Item	Specifications	Results
Description	White or pale yellow powder	Pale yellow powder
Identification	A:Comparison:Dutasteride CRS.	Sample spectrum is similar to that of reference standard.
Specific optical rotation	+33.0° ~ +39.0°	+37.1°
Residue on ignition	≤0.1 %	0.08%
Water	≤0.2 %	0.04%
Related substances	Impurity A ≤0.2%	0.08%
	Impurity B ≤0.15%	0.01%
	Impurity E ≤0.3%	0.06%
	Impurity C ≤0.2%	Not detected
	Impurity F ≤0.4%	0.04%
	Impurity G ≤0.3%	0.01%
	Unspecified impurities ≤0.10%	0.05%
	Impurity H ≤0.3%	Not detected
	Impurity I ≤0.5%	0.01%
	Unspecified impurities eluting after dutasteride ≤0.10%	Not detected
	Total impurities ≤1.5%	0.28%
Residual Solvents	Methanol ≤3000ppm	Not detected
	Ethanol ≤5000ppm	3196ppm
	Acetonitrile ≤410 ppm	47ppm
	Dichloromethane ≤600 ppm	Not detected
	Dioxane ≤380 ppm	Not detected
	Pyridine ≤200 ppm	Not detected
	Toluene ≤890 ppm	Not detected
Assay	97.0~102.0%	100.5%

Conclusion: Complies with the requirements of EP10

Q.C. director:

QP:

Date:

2020.01.20

Date:

2020.01.20