

**CERTIFICATE OF ANALYSIS**

Product : Dutasteride

Batch No. : DT240503

Quantity : 5kg

Specification : EP11

Mfg. date: 2024.05.04

Retest date: 2029.05.03

Certificate of suitability No. R0-CEP 2020-298-Rev 01

Item	Specifications	Results
Appearance	White to pale yellow powder	White powder
Solubility	Practically insoluble in water, freely soluble in methylene chloride, soluble or sparingly soluble in anhydrous ethanol	Conform
Identification	B: Comparison: Dutasteride CRS.	Sample spectrum is similar to that of reference standard.
Specific optical rotation	+33.0° ~ +39.0°	+35.7°
Water	≤ 0.2 %	0.02%
Related substances	Impurity A ≤ 0.2%	0.04%
	Impurity B ≤ 0.15%	0
	Impurity E ≤ 0.3%	0.04%
	Impurity C ≤ 0.2%	0
	Impurity F ≤ 0.4%	Not detected
	Impurity G ≤ 0.3%	0.02%
	Unspecified impurities ≤ 0.10%	Not detected
	Impurity H ≤ 0.3%	Not detected
	Impurity I ≤ 0.5%	0
	Unspecified impurities eluting after dutasteride ≤ 0.10%	Not detected
	Total impurities ≤ 1.5%	0.10%
Residual Solvents	Methanol ≤ 3000ppm	Not detected
	Ethanol ≤ 5000ppm	1969ppm
	Acetonitrile ≤ 410 ppm	Not detected
	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)	99.8%

Conclusion: Complies with the requirements of EP11

Q.C. director: 吴海微

QP: 江峰

Date: 2024.07.04

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METAPHARMACEUTICAL

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