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METAPHARMACEUTICAL

N DE LOTE:

0240921

CERTIFICATE OF ANALYSIS

Product : Dutasteride

Batch No. : DT210702

Quantity : 700g

Specification : EP10

Mfg. date: 2021.07.13

Retest date: 2026.07.12

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 %	0.00%
Related substances	Impurity A ≤0.2%	0.10%
	Impurity B ≤0.15%	0.03%
	Impurity E ≤0.3%	0.03%
	Impurity C ≤0.2%	Not detected
	Impurity F ≤0.4%	0.13%
	Impurity G ≤0.3%	Not detected
	Unspecified impurities ≤0.10%	Not detected
	Impurity H ≤0.3%	0.00%
	Impurity I ≤0.5%	0.02%
	Unspecified impurities eluting after dutasteride ≤0.10%	0.01%
Residual Solvents	Total impurities ≤1.5%	0.32%
	Methanol ≤3000ppm	Not detected
	Ethanol ≤5000ppm	2758ppm
	Acetonitrile ≤410 ppm	78ppm
	Dichloromethane ≤600 ppm	Not detected
	Dioxane ≤380 ppm	Not detected
	Pyridine ≤200 ppm	Not detected
Sulphated ash	Toluene ≤890 ppm	Not detected
	≤0.1 %	0.05%
Assay	97.0~102.0%(anhydrous substance)	100.2%

Conclusion: Complies with the requirements of EP10

Q.C. director: 王立新

QP: 王立新

Date: 2021.10.21

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