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CERTIFICATE OF ANALYSIS

Product: Dutasteride

Batch No.: DT180501

Quantity: 350g

Specification: EP9

Mfg. date: 2018.05.11

Retest date: 2021.05.10

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°	+37.5°
Residue on ignition	≤0.1 %	0.08%
Water	≤0.2 %	0.08%
Related substances	Impurity A ≤0.2%	0.02%
	Impurity B ≤0.15%	0.01%
	Impurity E ≤0.3%	0.06%
	Impurity C ≤0.2%	Not detected
	Impurity F ≤0.4%	0.24%
	Impurity G ≤0.3%	Not detected
	Unspecified impurities ≤0.10%	Not detected
	Impurity H ≤0.3%	0.01%
	Impurity I ≤0.5%	0.05%
	Unspecified impurities eluting after dutasteride ≤0.10%	Not detected
Residual Solvents	Total impurities ≤1.5%	0.38%
	Methanol ≤3000ppm	Not detected
	Ethanol ≤5000ppm	572ppm
	Acetonitrile ≤410 ppm	Not detected
	Dichloromethane ≤600 ppm	Not detected
	Dioxane ≤380 ppm	Not detected
	Pyridine ≤200 ppm	Not detected
Assay	Toluene ≤890 ppm	Not detected
	97.0~102.0%	99.5%

Conclusion: Complies with the requirements of EP9

Q.C. director: 蔡明

QP: 赵静

Date: 2018.12.04

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