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CERTIFICATE OF ANALYSIS



Product : Dutasteride

Batch No. : DT240103

Quantity : 2kg

Specification : EP11

Mfg. date: 2024.01.19

Retest date: 2029.01.18

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

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	B: Comparison: Dutasteride CRS.	Sample spectrum is similar to that of reference standard.
Specific optical rotation	+33.0° ~ +39.0°	+35.0°
Water	≤0.2 %	0.02%
Related substances	Impurity A ≤0.2%	Not detected
	Impurity B ≤0.15%	Not detected
	Impurity E ≤0.3%	0.05%
	Impurity C ≤0.2%	Not detected
	Impurity F ≤0.4%	Not detected
	Impurity G ≤0.3%	0.03%
	Unspecified impurities ≤0.10%	0.01%
	Impurity H ≤0.3%	0.01%
	Impurity I ≤0.5%	0.01%
	Unspecified impurities eluting after dutasteride ≤0.10%	Not detected
Residual Solvents	Total impurities ≤1.5%	0.14%
	Methanol ≤3000ppm	Not detected
	Ethanol ≤5000ppm	2023ppm
	Acetonitrile ≤410 ppm	57ppm
	Dichloromethane ≤600 ppm	Not detected
	Dioxane ≤380 ppm	Not detected
	Pyridine ≤200 ppm	Not detected
Sulphated ash	Toluene ≤890 ppm	Not detected
	≤0.1 %	0.01%
Assay	97.0~102.0%(anhydrous substance)	100.1%

Conclusion: Complies with the requirements of EP11

Q.C. director: 吴晓微

QP: 江华

Date: 2024.01.30

METAPHARMACEUTICAL Date: 2024.01.30

N DE LOTE:

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21/02/2024

