

## Certificate of Analysis Dutasteride

CAS No.	164656-23-9	Code	BIOJDTS001
Batch No	DTS-240801	Manufacture Date	Aug.31, 2024
Expiry Date	Aug.30, 2027	Quantity	100G

Testing Items	Specifications	Results
Character	White or off-white powder	Off-white powder
Identification	A: Infrared absorption	Complies
	B: The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the assay.	Complies
Solubility	Soluble in ethanol and methanol, slightly soluble in polyethylene glycol 400, and insoluble in water.	Complies
Residue on ignition	Not more than 0.1%	0.06%
Heavy metals	Not more than 20ppm	Complies
Water	Not more than 0.50%	0.20%
Optical rotation	+15.0 ° ~ +25.0 °	+20.9 °
Limit of platinum	Not more than 5 ug/g	Complies
Limit of residual solvents	Acetonitrile ≤ 0.3%	Not detected
	Ethyl acetate ≤ 0.2%	0.0525%
	Dioxane ≤ 0.1%	Not detected
	n-Heptane ≤ 0.5%	Not detected
Organic impurities Procedure 1	Dutasteride acid ≤ 0.2%	Not detected
	Dutasteride dimethylamide ≤ 0.2%	0.03%
	Dutasteride methyl ester ≤ 0.15%	Not detected
	Dutasteride ethyl ester ≤ 0.2%	0.03%
	Dutasteride 17α-5-ene ≤ 0.2%	0.02%
	Dutasteride 17α-epimer ≤ 0.3%	Not detected
	Chlorodutasteride ≤ 0.4%	Not detected
	Dihydrodutasteride ≤ 0.15%	0.05%
Dutasteride-5-ene ≤ 0.3%	0.33%	
Any other individual impurity ≤ 0.1%	Not detected	
Organic impurities Procedure 2	Dutasteride α-dimer ≤ 0.3%	0.04%
	Dutasteride β-dimer ≤ 0.5%	Not detected
	Any other individual impurity ≤ 0.1%	Not detected
	Total impurities ≤ 2.0%	Not detected
Assay(HPLC)	97.0%~102.0% (Calculated on the dried basis)	100.4%

Residual solvents	Methanol $\leq$ 3000ppm Dichloromethane $\leq$ 600ppm Toluene $\leq$ 890ppm Chloroform $\leq$ 60ppm Benzene $\leq$ 2ppm Pyridine $\leq$ 200ppm DMF $\leq$ 880ppm	170ppm 190ppm 169ppm Not detected Not detected Not detected Not detected
Conclusion	This product conforms to USP42 standard	

**\*Storage condition: Store below 25°C, Protect from moisture and light.**