

Certificate of analysis Dutasteride

CAS No.	164656-23-9	Code	BIOJDTS001
Batch No	DTS-240701	Manufacture Date	Aug.19, 2024
Expiry Date	Aug.18, 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%	Complies
Heavy metals	Not more than 20ppm	Complies
Water	Not more than 0.50%	0.14%
Optical rotation	+15.0 ° ~ +25.0 °	+21.3 °
Limit of platinum	Not more than 5 ug/g	Complies
Limit of residual solvents	Acetonitrile ≤ 0.3%	Not detected
	Ethyl acetate ≤ 0.2%	0.04141%
	Dioxane ≤ 0.1%	Not detected
	n-Heptane ≤ 0.5%	Not detected
	Pyridine ≤ 0.2%	Not detected
	Toluene ≤ 0.2%	Not detected
Organic impurities Procedure 1	Dutasteride acid ≤ 0.2%	0.01%
	Dutasteride dimethylamide ≤ 0.2%	Not detected
	Dutasteride methyl ester ≤ 0.15%	Not detected
	Dutasteride ethyl ester ≤ 0.2%	Not detected
	Dutasteride 17α-5-ene ≤ 0.2%	Not detected
	Dutasteride 17α-epimer ≤ 0.3%	Not detected
	Chlorodutasteride ≤ 0.4%	Not detected
	Dutasteride-5-ene ≤ 0.3%	Not detected
Any other individual impurity ≤ 0.1%	0.05%	
Organic impurities Procedure 2	Dihydrodutasteride ≤ 0.15%	Not detected
	Dutasteride α-dimer ≤ 0.3%	Not detected
	Dutasteride β-dimer ≤ 0.5%	Not detected
	Any other individual impurity ≤ 0.1%	0.08%
	Total impurities ≤ 2.0%	0.22%

Assay(HPLC)	97.0%~102.0% (Calculated on the dried basis)	100.2%
Residual solvents	Methanol \leq 3000ppm Chloroform \leq 60ppm	Not detected Not detected
Conclusion	This product conforms to USP2024 standard	

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