

Certificate of Analysis Dutasteride

CAS No.	164656-23-9	Code	BIOJDTS001
Batch No	DTS-250402	Manufacture Date	Apr.24, 2025
Expiry Date	Apr.23, 2028	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%	0.04%
Heavy metals	Not more than 20ppm	Complies
Water	Not more than 0.50%	0.14%
Optical rotation	+15.0°~+25.0°	+20.0°
Limit of platinum	Not more than 5 ug/g	Complies
Limit of residual solvents	Acetonitrile≤0.3% Ethyl acetate≤0.2% Dioxane≤0.1% n-Heptane≤0.5%	Not detected Not detected Not detected Not detected
Organic impurities Procedure 1	Dutasteride acid≤0.2% Dutasteride dimethylamide≤0.2% Dutasteride methyl ester≤0.15% Dutasteride ethyl ester≤0.2% Dutasteride 17α-5-ene≤0.2% Dutasteride 17α-epimer≤0.3% Chlorodutasteride≤0.4% Dihydrodutasteride≤0.15% Dutasteride-5-ene≤0.3% Any other individual impurity≤0.1%	Not detected 0.04% Not detected Not detected Not detected 0.07% Not detected 0.01% Not detected 0.03%
Organic impurities Procedure 2	Dutasteride α-dimer≤0.3% Dutasteride β-dimer≤0.5% Any other individual impurity≤0.1% Total impurities≤2.0%	Not detected Not detected 0.06% 0.25%
Assay(HPLC)	97.0%~102.0% (Calculated on the dried basis)	100.1%

Residual solvents	Methanol \leq 3000ppm Dichloromethane \leq 600ppm Toluene \leq 890ppm Chloroform \leq 60ppm Benzene \leq 2ppm Pyridine \leq 200ppm DMF \leq 880ppm	428ppm Not detected Not detected 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.**