

CAS No.	164656-23-9	Code	BIOJDTS001
Batch No	2195240201	Manufacture Date	Feb.28, 2024
Retest Date	Feb.27, 2027	Quantity	100G

<b>Testing Items</b>	Specifications	Results	
Character	White or off-white powder	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	Complies	
	obtained in the assay.		
Solubility	Practically insoluble in water, freely soluble in methylene chloride, soluble or sparingly soluble in anhydrous ethanol	Complies	
Residue on ignition	Not more than 0.1%	Complies	
Heavy metals	Not more than 20ppm	Complies	
Water	Not more than 0.50%	0.36%	
Optical rotation	+15.0 °~ +25.0 °	+20.8 °	
Residual solvents(GC)	Acetonitrile≤3000ppm	6.1ppm	
	Ethyl acetate≤2000ppm	346.0ppm	
	Dioxane≤1000ppm	Not detected	
	n-Heptane≤5000ppm	Not detected	
	Pyridine≤2000ppm	Not detected	
	Toluene≤2000ppm	Not detected	
	Methanol≤3000ppm	Not detected	
	Chloroform≤60ppm	Not detected	
Organic impurities Procedure 1	Dutasteride acid≤0.2%	0.02%	
	Dutasteride dimethylamide≤0.2%	0.01%	
	Dutasteride methyl ester≤0.15%	0.02%	
	Dutasteride ethyl ester≤0.2%	Not detected	
	Dutasteride 17α-5-ene≤0.2%	Not detected	
	Dutasteride 17α-epimer≤0.3%	0.02%	
	Chlorodutasteride≤0.4%	Not detected	
	Dutasteride-5-ene≤0.3%	Not detected	
	Any other individual impurity≤0.1%	0.01%	
Organic impurities Procedure 2	Dihydrodutasteride≤0.15%	0.02%	
	Dutasteride α-dimer≤0.3%	Not detected	
	Dutasteride β-dimer≤0.5%	Not detected	
	Any other individual impurity≤0.1%	0.03%	
	Total impurities≤2.0%	0.22%	
Assay(HPLC)	97.0%~102.0%(Calculated on the dried basis)	99.8%	
Conclusion This product conforms to USP43 standard			

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

