

CERTIFICATE OF ANALYSIS

Product name	Dutasteride		
Batch No.	200301	Quantity	22.0kg
Mfg. Date	Mar 28, 2020	Expiry date	Mar 27, 2023
Specification	EP8		
Items	Specification	Results	
Appearance	white or pale yellow powder	pale yellow powder	
Solubility	practically insoluble in water, freely soluble in methylene chloride, soluble or sparingly soluble in anhydrous ethanol.	complies	
Identification (A and B)	A: Specific optical rotation B: IR	complies	
Specific optical rotation	+ 33.0° to + 39.0° (anhydrous substance)	+ 36.1°	
Related substances (HPLC)			
Test A: ---impurity A	Not more than 0.2%	<0.05%	
---impurity B	Not more than 0.15%	<0.05%	
---impurity C	Not more than 0.2%	<0.05%	
---impurity E	Not more than 0.3%	<0.05%	
---impurity F	Not more than 0.4%	<0.05%	
---impurity G	Not more than 0.3%	<0.05%	
---unspecified impurities	Not more than 0.10%	0.10%	
Test B: ---impurity I	Not more than 0.5%	<0.05%	
---impurity H	Not more than 0.3%	<0.05%	
---unspecified impurities	Not more than 0.10%	0.10%	
total for tests A and B	Not more than 1.5%	0.33%	
Water	Not more than 0.2%	0.15%	
Sulfated ash	Not more than 0.1%	0.06%	
Assay (by HPLC)	97.0% to 102.0%(anhydrous substance)	99.9%	
Residual solvents			
Methanol	Not more than 3000ppm	169ppm	
Dichloromethane	Not more than 600ppm	450ppm	
Toluene	Not more than 890ppm	154ppm	
Chloroform	Not more than 60ppm	n.d	
Benzene	Not more than 2ppm	n.d	
Pyridine	Not more than 200ppm	n.d	
DMF	Not more than 880ppm	n.d	
Conclusion: The test product complies with of EP8.			