

**F&A PHARMA**

F. & A. PHARMA-Handels-GmbH

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CERTIFICATE OF ANALYSIS

Product name	Finasteride		
Batch No.	FSD-200801	Quantity	25kg
Mfg. Date	Aug.,07, 2020	Expiry date	Aug.,06, 2025
Specification	EP10		

Items	Standard	Results			
Description	white or almost white crystalline powder	almost white crystalline powder			
Identification(IR)	complies with the standard	complies			
Solubility	Practically insoluble in water, freely soluble in ethanol and in methylene chloride.	complies			
Specific optical rotation	+12.0° ~+14.0°	+12.2°			
Loss on drying	max.0.5%	0.07%			
Particle size	100%≤30um	complies			
Related substances (HPLC)					
Impurity A	max.0.3%	0.28%			
Impurity C	max.0.3%	0.08%			
unspecified impurities	max.0.10%	0.03%			
Total impurities	Max.0.5%	0.29%			
Assay (HPLC, based on drying)	98.0%~102.0%	99.8%			
Residual solvents					
Acetone	Max.5000ppm	23ppm			
Chloroform	Max.60ppm	n.d			
THF	Max.720ppm	n.d			
Dichloromethane	Max.600ppm	n.d			
Toluene	Max.890ppm	n.d			
Methanol	Max3000ppm	n.d			
Benzene	Max.2ppm	n.d			
Storage	Preserve in tight containers, and store at controlled room temperature.				
Conclusion: The product complies with the requirements of EP10.					
Analyst	panyong	Checker	panwang	Approved by	yangmingcheng