



HUNAN YUXIN PHARMACEUTICAL CO., LTD.

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CERTIFICATE OF ANALYSIS

Product name	Finasteride		
Batch No.	FSD-250302	Quantity	25.0kg
Mfg. Date	Mar.,06, 2025	Expiry date	Mar.,05, 2030
Specification	EP9		

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°	+13.5°
Loss on drying	max.0.5%	0.06%
Particle size	100%≤30um	complies
Related substances (HPLC)		
Impurity A	max.0.3%	0.03%
Impurity C	max.0.3%	0.01%
unspecified impurities	max.0.10%	0.02%
Total impurities	Max.0.5%	0.06%
Assay (HPLC, based on drying)	98.0%~102.0%	99.8%
Residual solvents		
Acetone	Max.5000ppm	n.d
Chloroform	Max.60ppm	n.d
Dichloromethane	Max.600ppm	n.d
THF	Max.720ppm	n.d
Toluene	Max.890ppm	n.d
Methanol	Max.3000ppm	n.d
tert-Butanol	Max.1000ppm	n.d
Ethyl acetate	Max.5000ppm	n.d
Acetic Acid	Max.5000ppm	n.d
Storage	Preserve in tight containers, and store at controlled room temperature.	
Conclusion: The product complies with the requirements of EP9.		
Analyst	huyejiao	Checker
	panwang	Approved by
	yangmingcheng	