



**HUNAN YUXIN PHARMACEUTICAL CO., LTD.**  
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## CERTIFICATE OF ANALYSIS

Product name	Finasteride		
Batch No.	FSD-200103	Quantity	20.0kg
Mfg. Date	Jan.,03, 2020	Expiry date	Jan.,02, 2025
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°	+13.8°
Loss on drying	max.0.5%	0.07%
Particle size	100%≤20um ,90%≤10um	complies
Related substances (HPLC)		
Impurity A	max.0.3%	0.15%
Impurity C	max.0.3%	0.02%
unspecified impurities	max.0.10%	0.08%
Total impurities	Max.0.5%	0.24%
Assay (HPLC, based on drying)	98.0%~102.0%	99.1%
Residual solvents		
Acetone	Max.5000ppm	23ppm
Chloroform	Max.60ppm	n.d
THF	Max.720ppm	n.d
Toluene	Max.890ppm	n.d
Methanol	Max.3000ppm	38ppm
tert-Butanol	Max.5000ppm	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	panyong	Checker
	panwang	Approved by
		yangmingcheng

Fecha Entrada: 16-03-2020  
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Lote: 0092556

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