

4180

FINASTERIDA GRANEL

8 432780 041805

Lote: 0081628

QC-00203871

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GUINAMA
ANALYTICAL

00818-20-71
372,80
023H38N202



ChongQing Waycome Pharmaceutical Co., Ltd.

CERTIFICATE OF ANALYSIS

Analytical Report No. WLK-20181101

Product	Finasteride	Batch No.	20181101
Quantity	40kg	Manuf. Date	Nov.29, 2018
Test Standard	EP9.0	Retest Date	Nov.28, 2020
Storage	Protected from light		

TEST	SPECIFICATIONS	RESULTS
Description	White or almost white crystalline powder	White crystalline powder
Solubility	Practically insoluble in water, freely soluble in ethanol and in methylene chloride	Complies
Assay (HPLC, based on drying)	98.0% ~ 102.0%	99.0%
Identification (IR)	Complies with the standard	Complies
Loss on drying	≤0.5%	0.48%
Related substances (HPLC)	Impurity A: ≤0.3% Impurity C: ≤0.3% Other single impurity: ≤0.10% Total impurities: ≤0.5%	0.20% 0.15% 0.07% 0.48%
Specific rotation	+12.0° ~ +14.0°	+13.5°

Conclusion: The test product complies with the requirements of EP9.0

Quality Manager:

朱永平

Rechecker:

易洪斌

Analyst:

刘媛

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