



METAPHARMACEUTICAL

CERTIFICATE OF ANALYSIS

N DE LOTE:

0011220

Product : Finasteride Micronized
Quantity : 10kg
Mfg. date: 2020.08.06
CEP No.: R1-CEP 2013-238-Rev 00

Batch No.: EU-FTD200801M
Specification: EP10
Retest date: 2025.08.05

23/11/2023

Item	Specifications	Results
Description	White or almost white crystalline powder	Almost white crystalline powder
Identification	IR: Comparison: Finasteride CRS.	Sample spectrum is similar to that of reference standard.
Specific optical rotation	+12.0° ~ +14.0° (On dried substance)	+12.5°
Loss on drying	≤ 0.5 %	0.10%
Related substances	Impurity A ≤ 0.3%	0.02%
	Impurity C ≤ 0.3%	0.13%
	Any other unknown impurity ≤ 0.10 %	0.04%
	Total impurities ≤ 0.5%	0.23%
Residual Solvents	Methanol ≤ 3000ppm	Not detected
	Ethanol ≤ 5000ppm	515ppm
	Methylene chloride ≤ 600ppm	Not detected
	Isopropyl acetate ≤ 5000 ppm	Not detected
	Toluene ≤ 890ppm	Not detected
Pd	≤ 10ppm	Not detected
Assay	98.0 ~ 102.0 % (On dried substance)	101.3%
Particle Size	100% < 20μm	Conform

Conclusion: Complies with the requirements of EP10

Q.C. director:

QP:

Date:

2020.11.13

Date:

2020.11.13