


CERTIFICATE OF ANALYSIS

N DE LOTE:

0090623

Product : Finasteride Micronized
Quantity : 10kg
Mfg. date: 2023.05.07
CEP No.: RI-CEP 2013-238-Rev 00

Batch No. : EU-FTD230505M
Specification: EP10
Retest date: 2028.05.06

12/06/2023



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)	+12.9°
Loss on drying	≤ 0.5 %	0.13%
Related substances	Impurity A ≤ 0.3%	0.12%
	Impurity C ≤ 0.3%	0.14%
	Any other unknown impurity ≤ 0.10 %	0.04%
	Total impurities ≤ 0.5%	0.31%
Residual Solvents	Methanol ≤ 3000ppm	Not detected
	Ethanol ≤ 5000ppm	384ppm
	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)	100.0%
Particle Size	100% < 20μm	Conform

Conclusion: Complies with the requirements of EP10

Q.C. director: 吴海微

QP: 王强

Date: 2023.05.23

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