

METAPHARMACEUTICAL

N DE LOTE:

04/11/2024

F&A PHARMA

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CERTIFICATE OF ANALYSIS



Product : Finasteride Micronized

Batch No. : EU-FTD240802M1

Quantity : 10kg

Specification: EP11

Mfg. date: 2024.08.24

Retest date: 2029.08.23

CEP No.: R1-CEP 2013-238-Rev 00

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)	+12.8°
Loss on drying	≤ 0.5 %	0.22%
Related substances	Impurity A ≤ 0.3%	0.14%
	Impurity C ≤ 0.3%	0.12%
	Any other unknown impurity ≤ 0.10 %	Not detected
	Total impurities ≤ 0.5%	0.26%
Residual Solvents	Methanol ≤ 3000ppm	Not detected
	Ethanol ≤ 5000ppm	732ppm
	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)	100.6%
Particle Size	100% < 20μm	17.4μm

Conclusion: Complies with the requirements of EP11

Q.C. director: 吴秀微

QP: 江峰

Date: 2024.10.10

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