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CERTIFICATE OF ANALYSIS



F&A PHARMA

27/02/2023



Product : Finasteride Micronized

Batch No. : EU-FTD221208M

Quantity : 10kg

Specification: EP10 METAPHARMACEUTICA

Mfg. date: 2022.12.18

Retest date: 2027.12.17

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

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0220223

Item	Specifications	Results
Description	White or almost white crystalline powder	Almost white crystalline powder
Identification	IR: Comparison: finasteride-ERS.	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 %	0.06%
Related substances	Impurity A ≤ 0.3%	0.05%
	Impurity C ≤ 0.3%	0.13%
	Any other unknown impurity ≤ 0.10 %	0.04%
	Total impurities ≤ 0.5%	0.22%
Residual Solvents	Methanol ≤ 3000ppm	Not detected
	Ethanol ≤ 5000ppm	378ppm
	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)	100.5%
Particle Size	100% < 20μm	Conform

Conclusion: Complies with the requirements of EP10

Q.C. director: 吴秀微

QP: 王强

Date: 2023.02.07

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