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CERTIFICATE OF ANALYSIS



29/11/2021



Product : Finasteride Micronized

Batch No. : EU-FTD211002M

Quantity : 5kg

Specification: EP10

Mfg. date: 2021.10.04

Retest date: 2026.10.03

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)	+12.5°
Loss on drying	≤ 0.5 %	0.03%
Related substances	Impurity A ≤ 0.3%	0.03%
	Impurity C ≤ 0.3%	0.10%
	Any other unknown impurity ≤ 0.10 %	0.06%
	Total impurities ≤ 0.5%	0.24%
Residual Solvents	Methanol ≤ 3000ppm	Not detected
	Ethanol ≤ 5000ppm	435ppm
	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)	99.9%
Particle Size	100% < 20μm	Conform

Conclusion: Complies with the requirements of EP10

Q.C. director: [Signature]

QP: [Signature]

Date: 2021.11.09

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