



CERTIFICATE OF ANALYSIS



Product : Finasteride Micronized
 Quantity : 15kg
 Mfg. date: 2023.05.15
 CEP No.: R1-CEP 2013-238-Rev 00

Batch No. : EU-FTD230509M
 Specification: EP11
 Retest date: 2028.05.14

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)	+13.3°
Loss on drying	≤ 0.5 %	0.04%
Related substances	Impurity A ≤ 0.3%	0.12%
	Impurity C ≤ 0.3%	0.12%
	Any other unknown impurity ≤ 0.10 %	Not detected
	Total impurities ≤ 0.5%	0.24%
Residual Solvents	Methanol ≤ 3000ppm	Not detected
	Ethanol ≤ 5000ppm	414ppm
	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)	99.8%
Particle Size	100% < 20μm	Conform

Conclusion: Complies with the requirements of EP11

Q.C. director: 吴雪微

QP: 丁华

Date: 2023.09.22

Date: 2023.09.22