

Batch No. : FTD190306

Specification: EP9

Expiry date: 2024.03.15

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.
Loss on drying	≤0.5 %	0.00%
Specific optical rotation	+12.0°~ +14.0°(on dried substance)	+12.7°
Related substances	Impurity A≤0.3%	0.02%
	Impurity C≤0.3%	0.17%
	Any other unknown impurity ≤0.10 %	0.04%
	Total impurities≤0.5%	0.22%
Residual Solvents	Methanol ≤3000ppm	98ppm
	Ethanol ≤5000ppm	434ppm
	Methylene chloride≤600ppm	Not detected
	Isopropyl acetate≤5000 ppm	Not detected
	Toluene≤890ppm	Not detected
Assay	98.0 ~ 102.0 %(on dried substance)	100.1%
Particle Size	100%<20μm	Conform

Conclusion: Complies with the requirements of EP9

岸上

12/12

2019.06.06

2019.06.06