

Finasteride EP11

Batch no Mf date

FTD240315 Mar 23 2024

Expiry

Mar 22 2029

Molecular Structure

Molecular Formula

 $C_{23}H_{36}N_2O_2$

Molecular Weight

372.55

CAS Registry Number

98319-26-7

Jun 03 2023

Tests	<u>Specifications</u>	Results
Appearance	White or almost white crystalline powder	Almost white crystalline powder
Solubility	Freely soluble in methylene chloride and in ethanol, practically insoluble in water	Conforms
Identification	IR	Positive
Optical rotation	+12 ~ +14°	+12. 6°
Loss on drying	≤ 0.5%	0. 05%
Pd	≤ 10 ppm	Conforms
Related substances	Impurity A ≤ 0.3%	0. 12%
	Impurity C ≤ 0.3%	0. 14%
	Any other impurity ≤ 0.1%	ND
	Total impurities ≤ 0.5%	0. 23%
Residual solvents	Methanol ≤ 3000 ppm	ND
	Ethanol ≤ 5000 ppm	283 ppm
	Dichloromethane ≤ 600 ppm	ND
	Isopropyl acetate ≤ 5000 ppm	ND
	Toluene ≤ 890 ppm	ND
Assay (odb)	98.0 \sim 102.0% of $C_{23}H_{36}N_2O_2$	100. 3%

Packaging & storage	Protect from light
Conclusion	Material complies with EP11

