

## Finasteride EP11

Batch no Mf date Expiry

EU-FTD240803 Aug 25 2024 Aug 24 2029

Molecular Structure

Molecular Formula

 $C_{23}H_{36}N_2O_2$ 

Molecular Weight

372.55

CAS Registry Number

98319-26-7

Nov 07 2024

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. 7°
Loss on drying	≤ 0.5%	0. 18%
Pd	≤ 10 ppm	Conforms
Related substances	Impurity A ≤ 0.3%	0. 13%
	Impurity C ≤ 0.3%	0. 12%
	Any other impurity ≤ 0.1%	ND
	Total impurities ≤ 0.5%	0. 24%
Residual solvents	Methanol ≤ 3000 ppm	ND
	Ethanol ≤ 5000 ppm	730 ppm
	Dichloromethane ≤ 600 ppm	ND
	Isopropy∣ acetate ≤ 5000 ppm	ND
	Toluene ≤ 890 ppm	ND
Assay (odb)	98.0 $^{\sim}$ 102.0% of $C_{23}H_{36}N_2O_2$	100. 4%

Packaging & storage	Protect from light	
Conclusion	Material complies with EP11	*

