

FINASTERIDA (EUR. PH.)

PRODUCT CODE: 002493	CAS Nº: 98319-26-7	ANALYSIS Nº: 206/25
MANUFACTURER BATCH: FSD-250404	CERTIFICATE ID: 47.308	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 08/04/2025	
METAPH BATCH: 0020725	EXPIRY DATE: 07/04/2030	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder	White crystalline powder
Solubility	Practically insoluble in water, freely soluble in ethanol and in methylene chloride	Complies (*)
Identification	Complies	Complies
Specific optical rotation	+12.0 / +14.0	+12.7
Related substances		
Impurity A	=< 0.3 %	< 0.05 %
Impurity C	=< 0.3 %	< 0.05 %
Individual impurities	=< 0.10 %	< 0.05 %
Total of impurities	=< 0.5 %	< 0.05 %
Loss on drying	=< 0.5 %	0.04 %
Assay	98.0 - 102.0 %	99.3 %

COMPLIES WITH

European Pharmacopeia 11.0

REMARKS

It shows polymorphism.

Product fully analyzed within the EU, in compliance with the currents regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

Finasteride is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

All data controlled by Metapharmaceutical Industrial SL.

(*) Data adapted from the manufacturer's certificate of analysis.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

STORAGE

Store in a cool place. Keep the container tightly closed in a dry and well-ventilated place.

Analysis date: 25/07/2025
 Signature: Albert Sánchez López (QP)
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40001070
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