METAPHARMACEUTICAL IND SL
Josep Plà, 163, 2n 5a / Tel. 933 089 976 / info@metapharmaceutical.com

FINASTERIDA (EUR. PH.)

PRODUCT CODE: 002493	CAS Nº: 98319-26-7	ANALYSIS Nº: 025/25	
MANUFACTURER BATCH:	EU-FTD240806M1	CERTIFICATE ID:	44.921
SUPPLIER BATCH:	----	MANUFACTURING DATE:	28/08/2024
METAPH BATCH:	0230125	RETEST DATE:	27/08/2029

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder	White crystalline powder
Identification	Complies	Complies
Specific optical rotation	+12.0 / +14.0	+13,3
Related substances		
Impurity A	=< 0.3 %	< 0.05 %
Impurity C	=< 0.3 %	0.10 %
Individual impurities	=< 0.10 %	< 0.05 %
Total of impurities	=< 0.5 %	0.10 %
Loss on drying	=< 0.5 %	0,1 %
Assay	98.0 - 102.0 %	99,2 %

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.

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: 28/02/2025
Signature: Albert Sánchez López (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000354
HUBEI GEDIAN HUMANWELL PHARMACEUTICAL Co., Ltd.
Gedian Economic Development District,
E-zhou