



FINASTERIDE (FORM-I) (EUR. PH.)

PRODUCT CODE: 002493	CAS Nº: 98319-26-7	ANALYSIS Nº: 280/24
MANUFACTURER BATCH: EU-FTD240802M1	CERTIFICATE ID: 44.043	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 24/08/2024	
METAPH BATCH: 0051124	RETEST DATE: 23/08/2029	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder	White crystalline powder
Identification	Complies	Complies
Specific optical rotation	+12.0 / +14.0	+12.5
Related substances		
Impurity A	=< 0.3 %	0.1 %
Impurity C	=< 0.3 %	0.1 %
Individual impurities	=< 0.10 %	Not Detected
Total of impurities	=< 0.5 %	0.2 %
Loss on drying	=< 0.5 %	0.2 %
Assay	98.0 - 102.0 %	99.5 %

COMPLIES WITH

European Pharmacopeia 11.0

REMARKS

It shows polymorphism.

Product fully analyzed within the EU, in compliance with the current 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: 05/12/2024
Signature: Albert Sanchez Lopez (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000354
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