



FINASTERIDA (EUR. PH.)

PRODUCT CODE: 002493	CAS Nº: 98319-26-7	ANALYSIS Nº: 014/23
MANUFACTURER BATCH: EU-FTD200801M	CERTIFICATE ID: 37.067	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 06/08/2020	
METAPH BATCH: 0011220	RETEST DATE: 05/08/2025	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder	White crystalline powder
Identification	Complies	Complies
Specific optical rotation	+12.0 / +14.0	+12.1
Related substances		
Impurity A	=< 0.3 %	< 0.05 %
Impurity C	=< 0.3 %	0.25 %
Individual impurities	=< 0.10 %	< 0.05 %
Total of impurities	=< 0.5 %	0.25 %
Loss on drying	=< 0.5 %	0.10 %
Assay	98.0 - 102.0 %	100.8 %
Residual solvents		(*) (**)
Ethanol	=< 5000 ppm	515 ppm
Isopropyl acetate	=< 5000 ppm	Not Detected
Methanol	=< 3000 ppm	Not Detected
Toluene	=< 890 ppm	Not Detected
Methylene chloride	=< 600 ppm	Not Detected
Particle size	100 % =< 20 µm	Complies (*)

COMPLIES WITH

European Pharmacopeia 11.0

REMARKS

Finasteride is subjected to the requirements of the ICH Q3D "Elemental Impurities".

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.

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

(**) According to the requirements of guides EMA/CHMP/ICH/82260/2006.

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: 10/02/2023

Signature: Ferran Gonzalez de Rivera Rier

Conclusion: Complies

Original certificate available upon request

Manufacturer: 40000354

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