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

DUTASTERIDA (EUR. PH.)

PRODUCT CODE: 009709	CAS Nº: 164656-23-9	ANALYSIS Nº: 208/25	
MANUFACTURER BATCH:	HG-DT250501	CERTIFICATE ID:	47.312
SUPPLIER BATCH:	----	MANUFACTURING DATE:	26/05/2025
METAPH BATCH:	0040725	RETEST DATE:	25/05/2030

ATTRIBUTES	SHOULD BE	IS
Appearance	White or pale yellow powder	White powder
Solubility	Practically insoluble in water, freely soluble in methylene chloride, soluble or sparingly soluble in anhydrous ethanol	Complies (*)
Identification A	Complies	Complies
Identification B	Complies	Complies
Specific optical rotation	+33.0 / +39.0	+35.1
Related substances		
Method A		
Impurity F	=< 0.4 %	Not Detected
Impurity E	=< 0.3 %	< 0.05 %
Impurity G	=< 0.3 %	< 0.05 %
Impurity A	=< 0.2 %	< 0.05 %
Impurity C	=< 0.2 %	Not Detected
Impurity B	=< 0.15 %	Not Detected
Unspecified impurities	=< 0.10 %	< 0.05 %
Method B		
Impurity I	=< 0.5 %	Not Detected
Impurity H	=< 0.3 %	Not Detected
Unspecified impurities after Dutasteride	=< 0.10 %	Not Detected
Total impurities	=< 1.5 %	< 0.05 %
Water	=< 0.2 %	0.08 %
Sulfated ash	=< 0.1 %	< 0.01 %
Assay	97.0 - 102.0 %	99.1 %

COMPLIES WITH

European Pharmacopeia 11.0

REMARKS

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

Dutasteride 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.

Analysis date: 20/10/2025
Signature: Albert Sánchez López (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000354
HUBEI GEDIAN HUMANWELL PHARMACEUTICAL Co., Ltd.
Nº 1 Zhiqing Road, Railway Station Economic Development Zone, Huangzhou District

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STORAGE

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

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