

**DUTASTERIDE (EUR. PH.)**

PRODUCT CODE: 009709	CAS Nº: 164656-23-9	ANALYSIS Nº: 197/24
MANUFACTURER BATCH: DT240503	CERTIFICATE ID: 43.072	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 04/05/2024	
METAPH BATCH: 0190724	RETEST DATE: 03/05/2029	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or pale yellow powder	Pale yellow 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	+35.0
Related substances		
Method A		
Impurity F	=< 0.4 %	Not Detected
Impurity E	=< 0.3 %	Not Detected
Impurity G	=< 0.3 %	Not Detected
Impurity A	=< 0.2 %	< 0.05 %
Impurity C	=< 0.2 %	Not Detected
Impurity B	=< 0.15 %	< 0.05 %
Unspecified impurities	=< 0.10 %	0.07 %
Method B		
Impurity I	=< 0.5 %	Not Detected
Impurity H	=< 0.3 %	Not Detected
Unspecified impurities after	=< 0.10 %	Not Detected
Dutasteride		
Total impurities	=< 1.5 %	0.07 %
Water	=< 0.2 %	0.1 %
Sulfated ash	=< 0.1 %	< 0.1 %
Assay	97.0 - 102.0 %	99.4 %

**COMPLIES WITH**

European Pharmacopeia 11.0

**REMARKS**

Product fully analyzed within the EU, in compliances 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.

(\*) 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: 30/08/2024  
Signature: Albert Sanchez Lopez (QP)  
Conclusion: Complies  
Original certificate available upon request

Manufacturer: 40000354



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METAPH BATCH:	0190724	RETEST DATE:	03/05/2029

### STORAGE

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

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