



## DUTASTERIDA (EUR. PH.)

PRODUCT CODE: 009709	CAS Nº: 164656-23-9	ANALYSIS Nº: 230/23
MANUFACTURER BATCH: DT220301M	CERTIFICATE ID: 39.469	
SUPPLIER BATCH: 0120934	MANUFACTURING DATE: 18/03/2022	
METAPH BATCH: 0130923	RETEST DATE: 17/03/2026	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or pale yellow powder	Polvo blanco
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	+36.9
Related substances		
Method A		(*)
Impurity F	=< 0.4 %	< 0.05 %
Impurity E	=< 0.3 %	< 0.05 %
Impurity G	=< 0.3 %	< 0.05 %
Impurity A	=< 0.2 %	< 0.05 %
Impurity C	=< 0.2 %	< 0.05 %
Impurity B	=< 0.15 %	< 0.05 %
Unspecified impurities	=< 0.10 %	< 0.05 %
Method B		(*)
Impurity I	=< 0.5 %	Not Detected
Impurity H	=< 0.3 %	Not Detected
Unspecified impurities after	=< 0.10 %	< 0.05 %
Dutasteride		
Total impurities	=< 1.5 %	< 0.05 %
Water	=< 0.2 %	0.19 %
Sulfated ash	=< 0.1 %	0.05 %
Assay	97.0 - 102.0 %	100.3 %

### COMPLIES WITH

European Pharmacopeia 11.0

### REMARKS

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 supplier'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: 22/09/2023  
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



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MANUFACTURER BATCH:	DT220301M	CERTIFICATE ID:	39.469
SUPPLIER BATCH:	0120934	MANUFACTURING DATE:	18/03/2022
METAPH BATCH:	0130923	RETEST DATE:	17/03/2026

### STORAGE

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

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