



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 201097

Product:	FINASTERIDE
Lot:	201097
Expiry date:	03/06/2025
Reference:	Cumple PhEur10.2
Synonyms:	Finasteride.
Formula:	C23H36N2O2
Molecular weight:	372,55 g/mol

Assay	Result	Specification	
Specific rotation	12,8 °	(+12,0) - (+14,0)	
Residual solvent: methylene chloride	<= 600 ppm	<= 600 ppm	#
Organoleptic properties	Conform	PhEur	
Residual solvent: Methanol	<= 3000 ppm	<= 3000 ppm	#
Loss on drying (1 g, 105°C)	0,02 %	<= 0,5%	
Residual solvent: Isopropyl acetate	<= 5000 ppm	<= 5000 ppm	#
Related substances (HPLC)	Conform		
Residual solvent: Toluene	<= 890 ppm	<= 890 ppm	#
Assay (HPLC)	98,4 %	98,0 - 102,0 %	
Residual solvent: Ethanol	<= 5000 ppm	<= 5000 ppm	#
Impurity C	0,07 %	<= 0,3 %	
Impurity A	<= 0,05 %	<= 0,3 %	
Identification	Conform	Test PhEur	
Total impurities	0,07 %	<= 0,5 %	
Unspecified Impurities	<= 0,05 %	<= 0,10 %	

Organoleptic characteristics:

Conservation: In tightly closed containers. Protect from light and moisture.

Date of analysis: 22/09/2020

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00024 HUBEI GEDIAN HUMANWELL PHARMACEUTICAL CO

Manufacturer batch: FTD200601M

Product	Name	Capacity	Batch
1144981	FINASTERIDA	1 g	201097-D-1
1144981	FINASTERIDA	1 g	201097-D-2
1144981	FINASTERIDA	1 g	201097-D-3

1144981	FINASTERIDA	1 g	201097-D-4
1144982	FINASTERIDA	5 g	201097-E-1
1144982	FINASTERIDA	5 g	201097-E-2
1144983	FINASTERIDA	10 g	201097-F-1
1144984	FINASTERIDA	25 g	201097-G-1
1144985	FINASTERIDA	100 g	201097-J-1
1144986	FINASTERIDA	250 g	201097-N-1
M0014560	FINASTERIDA		201097

This certificate is not initialled as it is computer processed, it is validated with the originals available at Acofarma.

Original manufacturer's certificate available on request.

(#) Parameter controlled by the manufacturer

(=) UE certificate

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