



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 212403

Product:	FINASTERIDE
Lot:	212403
Expiry date:	07/08/2025
Reference:	Cumple PhEur10.4
Synonyms:	Finasteride.
Formula:	C23H36N2O2
Molecular weight:	372,55 g/mol

Assay	Result	Specification	
Loss on drying	0,06 %	<=0,5%	
Residual solvent: Isopropyl acetate	<= 5000 ppm	<= 5000 ppm	#
Assay (HPLC)	99,7 %	98,0 - 102,0 %	
Residual solvent: Ethanol	<= 5000 ppm	<= 5000 ppm	#
Specific rotation	+13,1	(+12,0) - (+14,0)	
Residual solvent: methylene chloride	<= 600 ppm	<= 600 ppm	#
Related substances (HPLC)	Conform		
Residual solvent: Toluene	<= 890 ppm	<= 890 ppm	#
Identification	Conform	Test PhEur	
Total impurities	0,13 %	<= 0,5 %	
Organoleptic properties	Conform	PhEur	
Residual solvent: Methanol	<= 3000 ppm	<= 3000 ppm	#
Impurity C	0,13 %	<= 0,3 %	
Unspecified Impurities	<= 0,05 %	<= 0,10 %	
Elemental impurities	Conform	Test PhEur	#
Impurity A	<= 0,05 %	<= 0,3 %	

Organoleptic characteristics:

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

Date of analysis: 18/05/2021

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00024 HUBEI GEDIAN HUMANWELL PHARMACEUTICAL CO

Manufacturer batch: EU-FTD200802M

Product	Name	Capacity	Batch
1144981	FINASTERIDA	1 g	212403-D-1
1144981	FINASTERIDA	1 g	212403-D-2

1144982	FINASTERIDA	5 g	212403-E-1
1144982	FINASTERIDA	5 g	212403-E-2
1144982	FINASTERIDA	5 g	212403-E-3
1144983	FINASTERIDA	10 g	212403-F-1
1144983	FINASTERIDA	10 g	212403-F-2
1144983	FINASTERIDA	10 g	212403-F-3
1144984	FINASTERIDA	25 g	212403-G-1
1144985	FINASTERIDA	100 g	212403-J-1
1144985	FINASTERIDA	100 g	212403-J-2
1144986	FINASTERIDA	250 g	212403-N-1
1144986	FINASTERIDA	250 g	212403-N-2

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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Date of edition: 22/06/2025