



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 215061

Product:	FINASTERIDE
Lot:	215061
Expiry date:	15/05/2026
Reference:	Cumple PhEur10.5
Synonyms:	Finasteride.
Formula:	C23H36N2O2
Molecular weight:	372,55 g/mol

Assay	Result	Specification	
Identification	Conform	Test PhEur	
Organoleptic properties	Conform	PhEur	
Specific rotation	+13,0	(+12,0) - (+14,0)	
Related substances (HPLC)	Conform		
Loss on drying	0,16 %	<=0,5%	
Assay (HPLC)	98,8 %	98,0 - 102,0 %	
Elemental impurities	Conform	Test PhEur	#
Impurity A	0,27 %	<= 0,3 %	
Impurity C	0,12 %	<= 0,3 %	
Unspecified Impurities	0,05 %	<= 0,10 %	
Total impurities	0,44 %	<= 0,5 %	
Residual solvent: Methanol	<= 3000 ppm	<= 3000 ppm	#
Residual solvent: methylene chloride	<= 600 ppm	<= 600 ppm	#
Residual solvent: Toluene	<= 890 ppm	<= 890 ppm	#
Residual solvent: Isopropyl acetate	<= 5000 ppm	<= 5000 ppm	#
Residual solvent: Ethanol	<= 5000 ppm	<= 5000 ppm	#

Organoleptic characteristics:

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

Date of analysis: 08/10/2021

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00024 HUBEI GEDIAN HUMANWELL PHARMACEUTICAL CO

Manufacturer batch: EU-FTD210502M

Product	Name	Capacity	Batch
1144981	FINASTERIDA	1 g	215061-D-1
1144981	FINASTERIDA	1 g	215061-D-2

1144981	FINASTERIDA	1 g	215061-D-3
1144981	FINASTERIDA	1 g	215061-D-4
1144982	FINASTERIDA	5 g	215061-E-1
1144982	FINASTERIDA	5 g	215061-E-2
1144982	FINASTERIDA	5 g	215061-E-3
1144983	FINASTERIDA	10 g	215061-F-1
1144983	FINASTERIDA	10 g	215061-F-2
1144984	FINASTERIDA	25 g	215061-G-1
1144984	FINASTERIDA	25 g	215061-G-2
1144984	FINASTERIDA	25 g	215061-G-3
1144985	FINASTERIDA	100 g	215061-J-1
1144985	FINASTERIDA	100 g	215061-J-2
1144985	FINASTERIDA	100 g	215061-J-3
1144986	FINASTERIDA	250 g	215061-N-1
1144986	FINASTERIDA	250 g	215061-N-2
1144986	FINASTERIDA	250 g	215061-N-3

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: 04/04/2026

