



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 225386**

Product:	FINASTERIDE
Lot:	225386
Expiry date:	15/06/2027
Reference:	Cumple PhEur10.8
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	0,11 %	<=0,5%	
Assay (HPLC)	99,4 %	98,0 - 102,0 %	
Elemental impurities	Conform	Test PhEur	#
Impurity A	< 0,05 %	<= 0,3 %	
Impurity C	0,15 %	<= 0,3 %	
Unspecified Impurities	0,05 %	<= 0,10 %	
Total impurities	0,30 %	<= 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: 25/11/2022

Judgement:  
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00024 HUBEI GEDIAN HUMANWELL PHARMACEUTICAL CO

Manufacturer batch: EU-FTD220603M

Product	Name	Capacity	Batch
1144981	FINASTERIDA	1 g	225386-D-1
1144981	FINASTERIDA	1 g	225386-D-2

1144981	FINASTERIDA	1 g	225386-D-3
1144981	FINASTERIDA	1 g	225386-D-4
1144981	FINASTERIDA	1 g	225386-D-5
1144982	FINASTERIDA	5 g	225386-E-1
1144982	FINASTERIDA	5 g	225386-E-2
1144982	FINASTERIDA	5 g	225386-E-3
1144982	FINASTERIDA	5 g	225386-E-4
1144983	FINASTERIDA	10 g	225386-F-1
1144983	FINASTERIDA	10 g	225386-F-2
1144983	FINASTERIDA	10 g	225386-F-3
1144983	FINASTERIDA	10 g	225386-F-4
1144983	FINASTERIDA	10 g	225386-F-5
1144984	FINASTERIDA	25 g	225386-G-1
1144984	FINASTERIDA	25 g	225386-G-2
1144984	FINASTERIDA	25 g	225386-G-3
1144984	FINASTERIDA	25 g	225386-G-4
1144984	FINASTERIDA	25 g	225386-G-5
1144985	FINASTERIDA	100 g	225386-J-1
1144985	FINASTERIDA	100 g	225386-J-2
1144985	FINASTERIDA	100 g	225386-J-3
1144985	FINASTERIDA	100 g	225386-J-4
1144986	FINASTERIDA	250 g	225386-N-1
1144986	FINASTERIDA	250 g	225386-N-2
1144986	FINASTERIDA	250 g	225386-N-3
1144986	FINASTERIDA	250 g	225386-N-4

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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