



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 233134

Product:	FINASTERIDE
Lot:	233134
Expiry date:	20/03/2028
Reference:	Cumple PhEur11.2
Synonyms:	Finasteride.
Formula:	C23H36N2O2
Molecular weight:	372.6 g/mol

Assay	Result	Specification	
Identification	Conform	Test PhEur	
Organoleptic properties	Conform	PhEur	
Specific rotation	(+13,2)	(+12,0) - (+14,0)	
Related substances (HPLC)	Conform		
Loss on drying	0,07 %	<=0,5%	
Assay (HPLC)	100,2 %	98,0 - 102,0 %	
Nitrosamine impurities	Conform	Test PhEur	#
Elemental impurities	Conform	Test PhEur	#
Impurity A	0,1 %	<= 0,3 %	
Impurity C	< 0,05 %	<= 0,3 %	
Unspecified Impurities	0,06 %	<= 0,10 %	
Total impurities	0,16 %	<= 0,5 %	
Residual solvent: Methanol	< 3000 ppm	<= 3000 ppm	#
Residual solvent: Ethyl acetate	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Toluene	< 890 ppm	<= 890 ppm	#
Residual solvent: acetone	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Chloroform	< 60 ppm	<= 60 ppm	#
Residual solvent: Tert-Butanol	< 3500 ppm	<= 3500 ppm	#
Residual solvent: Tetrahydrofuran	<720 ppm	<= 720 ppm	#

Organoleptic characteristics:

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

Date of analysis: 25/07/2023

Judgement:
APPROVED

Responsible: B.Chia

Technical director: Montserrat Enrique

Manufacturer: F00440 HUNAN YUXIN PHARMACEUTICAL CO., LTD.

Manufacturer batch: FSD-230305

Product	Name	Capacity	Batch
1144981	FINASTERIDA	1 g	233134-D-1
1144981	FINASTERIDA	1 g	233134-D-2
1144981	FINASTERIDA	1 g	233134-D-3
1144981	FINASTERIDA	1 g	233134-D-4
1144982	FINASTERIDA	5 g	233134-E-1
1144982	FINASTERIDA	5 g	233134-E-2
1144982	FINASTERIDA	5 g	233134-E-3
1144982	FINASTERIDA	5 g	233134-E-4
1144983	FINASTERIDA	10 g	233134-F-1
1144983	FINASTERIDA	10 g	233134-F-2
1144983	FINASTERIDA	10 g	233134-F-3
1144984	FINASTERIDA	25 g	233134-G-1
1144984	FINASTERIDA	25 g	233134-G-2
1144984	FINASTERIDA	25 g	233134-G-3
1144984	FINASTERIDA	25 g	233134-G-4
1144985	FINASTERIDA	100 g	233134-J-1
1144985	FINASTERIDA	100 g	233134-J-2
1144986	FINASTERIDA	250 g	233134-N-1
1144986	FINASTERIDA	250 g	233134-N-2
1144986	FINASTERIDA	250 g	233134-N-3
1144986	FINASTERIDA	250 g	233134-N-4
1144987	FINASTERIDA	500 g	233134-O-1
1144987	FINASTERIDA	500 g	233134-O-2
1144987	FINASTERIDA	500 g	233134-O-3
1144987	FINASTERIDA	500 g	233134-O-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

ACOFARMA DISTRIBUCIÓN, S.A.
C/ Llobregat, 20 - 08223 Terrassa (Barcelona)
Tel./ 93-736.00.88

www.acofarma.com

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