



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 260564**

Product:	FINASTERIDE
Lot:	260564
Expiry date:	21/12/2029
Reference:	Cumple PhEur12.2
Synonyms:	Finasteride.
Formule:	C23H36N2O2
Poids moléculaire:	372.6 g/mol

Assay	Result	Specification	
Identification	Conform	Test PhEur	
Organoleptic properties	Conform	PhEur	
Specific rotation	+12,8	(+12,0) - (+14,0)	
Related substances (HPLC)	Conform		
Loss on drying	0,01 %	<=0,5%	
Assay (HPLC)	99,8 %	98,0 - 102,0 %	
Nitrosamine impurities	Conform	Test PhEur	#
Elemental impurities	Conform	Test PhEur	#
Impurity A	0,17 %	<= 0,3 %	
Impurity C	< 0,05 %	<= 0,3 %	
Unspecified Impurities	0,06 %	<= 0,10 %	
Total impurities	0,23 %	<= 0,5 %	
Residual solvent: Methanol	< 3000 ppm	<= 3000 ppm	#
Residual solvent: Triethylamine	< 5000 ppm	<= 5000 ppm	#
	< 380 ppm	<= 380 ppm	#
Residual solvent: acetone	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Chloroform	< 60 ppm	<= 60 ppm	#
Residual solvent: Tert-Butylamine	< 200 ppm	<= 200 ppm	#
Residual solvent: Tetrahydrofuran	< 720 ppm	<= 720 ppm	#
Residual solvent: methylene chloride	< 600 ppm	<= 600 ppm	#
Residual solvent: Pyridine	< 200 ppm	<= 200 ppm	#

Organoleptic characteristics: white or almost white, crystalline powder. practically insoluble in water, freely soluble in anhydrous ethanol and in methylene chloride. It shows polymorphism

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

Date of analysis: 16/04/2026

Responsible: B. Chia

Technical director: Montserrat Enrique

Judgement:  
APPROVED

Manufacturer: F01064 HUNAN KEREY PHARMACEUTICAL CO., LTD.

Manufacturer batch: 2194251205

Produit	Nom	Capacité	Lot
1144981	FINASTERIDA	1 g	260564-D-1
1144981	FINASTERIDA	1 g	260564-D-2
1144981	FINASTERIDA	1 g	260564-D-3
1144982	FINASTERIDA	5 g	260564-E-1
1144983	FINASTERIDA	10 g	260564-F-1
1144984	FINASTERIDA	25 g	260564-G-1
1144985	FINASTERIDA	100 g	260564-J-1
1144985	FINASTERIDA	100 g	260564-J-2
1144986	FINASTERIDA	250 g	260564-N-1
1144986	FINASTERIDA	250 g	260564-N-2
1144987	FINASTERIDA	500 g	260564-O-1
1144987	FINASTERIDA	500 g	260564-O-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

ACOFARMA DISTRIBUCIÓN, S.A.

C/ Llobregat, 20 - 08223 Terrassa (Barcelona)

Tel./ 93-736.00.88

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