



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 224077**

Product:	DUTASTERIDE
Lot:	224077
Expiry date:	18/03/2027
Reference:	Cumple PhEur10.8
Synonyms:	
Formula:	C <sub>27</sub> H <sub>30</sub> F <sub>6</sub> N <sub>2</sub> O <sub>2</sub>
Molecular weight:	528,5 g/mol

Assay	Result	Specification	
Not specif. impurities with retention time > dutasteride	< 0,05 %	<= 0,10 %	
Unspecified Impurities	< 0,05 %	<= 0,10 %	
Residual solvent: Methanol	< 3000 ppm	<= 3000 ppm	#
Total impurities (sum test A + B)	< 0,005 %	<= 1,5 %	
Impurity G	< 0,05 %	<= 0,3 %	
Impurity F	< 0,05 %	<= 0,4 %	
Impurity I	NDT	<= 0,5 %	
Impurity H	NDT	<= 0,3 %	
Impurity B	NDT	<= 0,15 %	
Impurity A	< 0,05 %	<= 0,2 %	
Impurity E	< 0,05 %	<= 0,3 %	
Impurity C	NDT	<= 0,2 %	
Elemental impurities	Conform	Test PhEur	#
Assay	100,3 %	97,0 - 102,0 %	
Related substances (HPLC)	Conform	Test PhEur	
Specific rotation	+37,9	(+33,0) - (+39,0)	
Sulphated ashes	0,0 %	<= 0,1 %	
Water	0,02 %	<= 0,2 %	
Organoleptic properties	Conform	PhEur	
Identification	Conform (A,B)	Test PhEur (A,B)	
Residual solvent: Toluene	< 890 ppm	<= 890 ppm	#
	< 380 ppm	<= 380 ppm	#
Residual solvent: methylene chloride	< 600 ppm	<= 600 ppm	#
Residual solvent: Acetonitrile	< 410 ppm	<= 410 ppm	#
Residual solvent: Pyridine	< 200 ppm	<= 200 ppm	#
Residual solvent: Ethanol	< 5000 ppm	<= 5000 ppm	#

Organoleptic characteristics: White or pale yellow powder. Practically insoluble in water, freely soluble in methylene chloride, soluble or sparingly soluble in anhydrous ethanol.

Conservation:

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Date of analysis: 22/09/2022

Judgement:  
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00024 HUBEI GEDIAN HUMANWELL PHARMACEUTICAL CO

Manufacturer batch: DT220302

Product	Name	Capacity	Batch
1111038	DUTASTERIDA	1 g	224077-D-1
1111038	DUTASTERIDA	1 g	224077-D-2
1111040	DUTASTERIDA	10 g	224077-F-1
1111040	DUTASTERIDA	10 g	224077-F-2
1111041	DUTASTERIDA	50 g	224077-I-1
1111041	DUTASTERIDA	50 g	224077-I-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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