



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 216608**

Product:	DUTASTERIDE
Lot:	216608
Expiry date:	12/07/2026
Reference:	Cumple PhEur10.5
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	#
Elemental impurities	Conform	Test PhEur	#
Assay	98,9 %	97,0 - 102,0 %	
Sulphated ashes	0,00 %	<= 0,1 %	
Impurity H	<= 0,05 %	<= 0,3 %	
Impurity G	<= 0,05 %	<= 0,3 %	
Impurity F	<= 0,05 %	<= 0,4 %	
Impurity E	<= 0,05 %	<= 0,3 %	
Impurity C	NDT	<= 0,2 %	
Impurity B	<= 0,05 %	<= 0,15 %	
Impurity A	<= 0,05 %	<= 0,2 %	
Residual solvent: Ethyl acetate	<= 5000 ppm	<= 5000 ppm	#
Residual solvent: methylene chloride	<= 600 ppm	<= 600 ppm	#
Residual solvent: Acetonitrile	<= 410 ppm	<= 410 ppm	#
Residual solvent: Methanol	<= 3000 ppm	<= 3000 ppm	#
Total impurities (sum test A + B)	<= 1,5 %	<= 1,5 %	
Not specif. impurities with retention time > dutasteride	<= 0,05 %	<= 0,10 %	
Unspecified Impurities	<= 0,05 %	<= 0,10 %	
Impurity I	<= 0,05 %	<= 0,5 %	
Residual solvent: Diisopropyl ether	<= 880 ppm	<= 100 ppm	#
Residual solvent: Heptane	<= 380 ppm	<= 5000 ppm	#
Residual solvent: Dimethylformamide	<= 5000 ppm	<= 880 ppm	#
	<= 380 ppm	<= 380 ppm	#
Residual solvent: acetone	<= 5000 ppm	<= 5000 ppm	#
Residual solvent: Toluene	<= 890 ppm	<= 890 ppm	#
Residual solvent: Cyclohexane	<= 3880 ppm	<= 3880 ppm	#
Water	0,03 %	<= 0,2 %	
Related substances (HPLC)	Conform	Test PhEur	
Specific rotation	+38 °	(+33°) - (+39°)	
Organoleptic properties	Conform	PhEur	
Identification	Conform (A,B)	Test PhEur (A,B)	

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: 24/01/2022

Judgement:  
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00024 HUBEI GEDIAN HUMANWELL PHARMACEUTICAL CO

Manufacturer batch: DT21072

Product	Name	Capacity	Batch
1111038	DUTASTERIDA	1 g	216608-D-1
1111040	DUTASTERIDA	10 g	216608-F-1

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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