



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 231604

Product:	DUTASTERIDE
Lot:	231604
Expiry date:	17/03/2027
Reference:	Cumple PhEur11.0
Synonyms:	
Formule:	C ₂₇ H ₃₀ F ₆ N ₂ O ₂
Poids moléculaire:	528,5 g/mol

Assay	Result	Specification	
Specific rotation	+36,0	(+33,0) - (+39,0)	
Related substances (HPLC)	Conform	Test PhEur	
Identification	Conform(A,B)	Test PhEur (A,B)	
Organoleptic properties	Conform	PhEur	
Assay	98,8 %	97,0 - 102,0 %	
Elemental impurities	Conform	Test PhEur	#
Water	0,03 %	<= 0,2 %	
Sulphated ashes	0,00 %	<= 0,1 %	
Impurity F	ND	<= 0,4 %	
Impurity G	ND	<= 0,3 %	
Impurity C	ND	<= 0,2 %	
Impurity E	< 0,05 %	<= 0,3 %	
Unspecified Impurities	< 0,05 %	<= 0,10 %	
Not specif. impurities with retention time > dutasteride	< 0,05 %	<= 0,10 %	
Impurity H	< 0,05 %	<= 0,3 %	
Impurity I	< 0,05 %	<= 0,5 %	
Impurity A	0,07 %	<= 0,2 %	
Impurity B	< 0,05 %	<= 0,15 %	
	< 380 ppm	<= 380 ppm	#
Residual solvent: Acetonitrile	<410 ppm	<= 410 ppm	#
Residual solvent: methylene chloride	< 600 ppm	<= 600 ppm	#
Total impurities (sum test A + B)	0,07 %	<= 1,5 %	
Residual solvent: Methanol	< 3000ppm	<= 3000 ppm	#
Residual solvent: Toluene	< 890 ppm	<= 890 ppm	#
Residual solvent: Ethanol	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Pyridine	< 200 ppm	<= 200 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:

Date of analysis: 19/04/2023

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00024 HUBEI GEDIAN HUMANWELL PHARMACEUTICAL CO

Manufacturer batch: DT220301

Produit	Nom	Capacité	Lot
1111038	DUTASTERIDA	1 g	231604-D-1
1111038	DUTASTERIDA	1 g	231604-D-2
1111040	DUTASTERIDA	10 g	231604-F-1
1111040	DUTASTERIDA	10 g	231604-F-2
1111040	DUTASTERIDA	10 g	231604-F-3
1111041	DUTASTERIDA	50 g	231604-I-1
1111041	DUTASTERIDA	50 g	231604-I-2
1111041	DUTASTERIDA	50 g	231604-I-3
1111041	DUTASTERIDA	50 g	231604-I-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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