



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 240801

Product:	DUTASTERIDE
Lot:	240801
Expiry date:	18/01/2029
Reference:	Cumple PhEur11.4
Synonyms:	
Formula:	C ₂₇ H ₃₀ F ₆ N ₂ O ₂
Molecular weight:	528,5 g/mol

Assay	Result	Specification	#
Residual solvent: methylene chloride	< 600 ppm	<= 600 ppm	#
Residual solvent: Ethanol	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Methanol	< 3000 ppm	<= 3000 ppm	#
Residual solvent: Acetonitrile	< 410 ppm	<= 410 ppm	#
	< 380 ppm	<= 380 ppm	#
Residual solvent: Pyridine	< 200 ppm	<= 200 ppm	#
Residual solvent: Toluene	< 890 ppm	<= 890 ppm	#
Impurity B	< 0,05 %	<= 0,15 %	
Impurity C	< 0,05 %	<= 0,2 %	
Impurity A	< 0,05 %	<= 0,2 %	
Impurity G	< 0,05 %	<= 0,3 %	
Impurity H	ND	<= 0,3 %	
Impurity E	< 0,05 %	<= 0,3 %	
Impurity F	< 0,05 %	<= 0,4 %	
Not specif. impurities with retention time > dutasteride	< 0,05 %	<= 0,10 %	
Total impurities (sum test A + B)	0,06 %	<= 1,5 %	
Impurity I	< 0,05 %	<= 0,5 %	
Unspecified Impurities	0,06 %	<= 0,10 %	
Identification	Conform (A,B)	Test PhEur (A,B)	
Related substances (HPLC)	Conform	Test PhEur	
Water	0,01 %	<= 0,2 %	
Organoleptic properties	Conform	PhEur	
Specific rotation	+35,8	(+33,0) - (+39,0)	
Elemental impurities	Conform	Test PhEur	#
Sulphated ashes	0,02 %	<= 0,1 %	
Assay	99,8 %	97,0 - 102,0 %	

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: 22/05/2024

Judgement:
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00024 HUBEI GEDIAN HUMANWELL PHARMACEUTICAL CO

Manufacturer batch: DT240103

Product	Name	Capacity	Batch
1111038	DUTASTERIDA	1 g	240801-D-1
1111038	DUTASTERIDA	1 g	240801-D-2
1111038	DUTASTERIDA	1 g	240801-D-3
1111040	DUTASTERIDA	10 g	240801-F-1
1111040	DUTASTERIDA	10 g	240801-F-2
1111040	DUTASTERIDA	10 g	240801-F-3
1111041	DUTASTERIDA	50 g	240801-I-1
1111041	DUTASTERIDA	50 g	240801-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

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