



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 227033

Product:	FLUTAMIDE
Lot:	227033
Expiry date:	30/11/2027
Reference:	Cumple PhEur11.0
Synonyms:	
Formula:	C ₁₁ H ₁₁ F ₃ N ₂ O ₃
Molecular weight:	276,22 g/mol

Assay	Result	Specification	
Identification	Conform		
Organoleptic properties	Conform		
Melting point	113 °C	Approx. 112 °C	
Elemental impurities	Conform	Test PhEur	#
Related substances (HPLC)	Conform		=
Loss on drying	0,03 %	<= 0,5%	
Sulphated ashes	0,06 %	<= 0,1%	=
Assay (HPLC)	99,3 %	97,5- 102,0 %	
Impurity A	0,03 %	<= 0,2 %	=
Impurity B	ND	<= 0,2 %	=
Impurity C	0,01 %	<= 0,2 %	=
Unspecified Impurities	ND	<= 0,10 %	=
Total impurities	0,04 %	<= 0,5 %	=
Residual solvent: Ethanol	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Toluene	< 890 ppm	<= 890 ppm	#

Organoleptic characteristics: Light yellow, crystalline powder. Practic. insoluble in water, freely soluble in acetone and in ethanol 96%, practic. insoluble in heptane.

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 03/02/2023

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00394 DERIVADOS QUÍMICOS, S.A.U.

Manufacturer batch: 670002R03N

Product	Name	Capacity	Batch
1145226	FLUTAMIDA	5 g	227033-E-2
1145226	FLUTAMIDA	5 g	227033-E-4

1145226	FLUTAMIDA	5 g	227033-E-5
1145226	FLUTAMIDA	5 g	227033-E-7
1145227	FLUTAMIDA	25 g	227033-G-1
1145228	FLUTAMIDA	100 g	227033-J-1
1145228	FLUTAMIDA	100 g	227033-J-2
1145228	FLUTAMIDA	100 g	227033-J-3
1145228	FLUTAMIDA	100 g	227033-J-4
1145228	FLUTAMIDA	100 g	227033-J-5
1145231	FLUTAMIDA	1 kg	227033-P-1
1145231	FLUTAMIDA	1 kg	227033-P-2
1145231	FLUTAMIDA	1 kg	227033-P-3
1145231	FLUTAMIDA	1 kg	227033-P-4
1370215	FLUTAMIDA (FLB)	5 g	227033-E-1
1370215	FLUTAMIDA (FLB)	5 g	227033-E-3
1370215	FLUTAMIDA (FLB)	5 g	227033-E-6

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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