



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 250046

Product:	FLUTAMIDE
Lot:	250046
Expiry date:	30/09/2027
Reference:	Cumple PhEur11.6
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	0,08 %	<= 0,5%	
Sulphated ashes	0,00 %	<= 0,1%	
Assay (HPLC)	100,1 %	97,5- 102,0 %	
Impurity A	< 0,05 %	<= 0,2 %	
Impurity B	< 0,05 %	<= 0,2 %	
Impurity C	< 0,05 %	<= 0,2 %	
Unspecified Impurities	< 0,05 %	<= 0,10 %	
Total impurities	< 0,05 %	<= 0,5 %	
Residual solvent: Methanol	<= 5000 ppm	<= 5000 ppm	#
Residual solvent: Toluene	<= 890 ppm	<= 890 ppm	#
Nitrosamine impurities	Conform		#
Residual solvent: Benzene	<= 2 ppm	<= 2 ppm	#
Residual solvent: Pyridine	<= 200 ppm	<= 200 ppm	#
Residual solvent: methyl iso butyrate	<= 1000 ppm	<= 1000 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: 15/01/2025

Judgement:
APPROVED

Responsible: B.Chia

Technical director: Montserrat Enrique

Manufacturer: F01039 Coral Drugs Pvt. Ltd.

Manufacturer batch: 5402024012

Product	Name	Capacity	Batch
1145226	FLUTAMIDA	5 g	250046-E-2
1145226	FLUTAMIDA	5 g	250046-E-3
1145227	FLUTAMIDA	25 g	250046-G-1
1145228	FLUTAMIDA	100 g	250046-J-1
1145228	FLUTAMIDA	100 g	250046-J-2
1145231	FLUTAMIDA	1 kg	250046-P-1
1145231	FLUTAMIDA	1 kg	250046-P-2
1370215	FLUTAMIDA (FLB)	5 g	250046-E-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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