

**FLUTAMIDA (EUR. PH.)**

PRODUCT CODE: 0980	CAS Nº: 13311-84-7	ANALYSIS Nº: 084/25
MANUFACTURER BATCH: 2085736	CERTIFICATE ID: 45.822	
SUPPLIER BATCH: 0101222	MANUFACTURING DATE: 18/01/2022	
METAPH BATCH: 0010425	RETEST DATE: 17/01/2027	

ATTRIBUTES	SHOULD BE	IS
Appearance	Pale yellow, crystalline powder	Pale yellow, crystalline powder (*)
Solubility	Practically insoluble in water, freely soluble in acetone and in ethanol (96 %), practically insoluble in heptane	Complies (*)
Melting point	about 112 °C	112.5 °C
Identification	Complies	Complies
Related substances		
Impurity A	=< 0.2 %	0.07 %
Impurity B	=< 0.2 %	< 0.05 %
Impurity C	=< 0.2 %	< 0.05 %
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 0.5 %	0.07 %
Loss on drying	=< 0.5 %	0.02 %
Sulfated ash	=< 0.1 %	0.06 %
Assay	97.5 - 102.0 %	97.8 %

**COMPLIES WITH**

European Pharmacopoeia 11.0

**REMARKS**

Product fully analyzed within the EU, in compliance with the current regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

Flutamide is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

All data controlled by Metapharmaceutical Industrial SL.

(\*) Data adapted from the manufacturer's certificate of analysis.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

**STORAGE**

Keep container tightly closed. Store in a dry place and protect from sunlight.

Analysis date: 19/05/2025  
Signature: Albert Sánchez López (QP)  
Conclusion: Complies  
Original certificate available upon request

Manufacturer: 40000306  
FERMION OY  
Koivu-Mankkaan tie 6A,  
FI-02200 Espoo  
(Finlandia)