



TECHNICAL DATA SHEET

0980-TDS-ENG-2025

FLUTAMIDA (EUR. PH.)		
DESCRIPTION DCI: flutamide		DESCRIPTION DOE: FLUTAMIDA
CAS Nº: 13311-84-7	EC Nº: 236-341-9	AEMPS CODE: 429A
MOL. WEIGHT: 276,22	MOL. FORMULA: C ₁₁ H ₁₁ F ₃ N ₂ O ₃	ARTICLE CODE: 0980

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

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

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

REMARKS

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

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.