



TECHNICAL DATA SHEET

1851-TDS-ENG-2023

BICALUTAMIDA PH.EUR		
DESCRIPTION DCI: BICALUTAMIDE		DESCRIPTION DOE: BICALUTAMIDA
CAS N°: 90357-06-5	EC N°: 618-534-3	AEMPS CODE: 2713A
MOL. WEIGHT: 430.40	MOL. FORMULA: C ₁₈ H ₁₄ F ₄ N ₂ O ₄ S	ARTICLE CODE: 1851

ATTRIBUTES	SHOULD BE
Appearance	White or almost white powder
Solubility	Practically insoluble in water, freely soluble in acetone, slightly soluble in anhydrous ethanol and in methylene chloride
Identification	Complies
Related substances	
Impurity C	=< 0.15 %
Unspecified impurities	=< 0.10 %
Total impurities	=< 0.5 %
Loss on drying	=< 0.5 %
Sulfated ash	=< 0.1 %
Assay	97.5 - 102.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Store in a fresh and dry place.

REMARKS

It shows polymorphism (5.9).

Bicalutamide 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.