

**BICALUTAMIDA (EUR. PH.)**

PRODUCT CODE: 1851		CAS Nº: 90357-06-5	ANALYSIS Nº: 115/25
MANUFACTURER BATCH:	BICE 0020225	CERTIFICATE ID:	46.308
SUPPLIER BATCH:	----	MANUFACTURING DATE:	01/02/2025
METAPH BATCH:	0010525	EXPIRY DATE:	31/01/2030

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white powder	White powder
Solubility	Practically insoluble in water, freely soluble in acetone, slightly soluble in anhydrous ethanol and in methylene chloride	Complies (*)
Identification	Complies	Complies
Related substances		
Impurity C	=< 0.15 %	Not Detected
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 0.5 %	< 0.05 %
Loss on drying	=< 0.5 %	0.04 %
Sulfated ash	=< 0.1 %	0.04 %
Assay	97.5 - 102.0 %	97.9 %

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.

It shows polymorphism.

Bicalutamide 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

Store in a fresh and dry place.

Analysis date: 04/08/2025

Signature: Albert Sánchez López (QP)

Conclusion: Complies

Original certificate available upon request

Manufacturer: 40001552

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