

BICALUTAMIDA (EUR. PH.)

PRODUCT CODE: 1851	CAS Nº: 90357-06-5	ANALYSIS Nº: 100/24
MANUFACTURER BATCH: BT24010009	CERTIFICATE ID: 41.838	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 28/01/2024	
METAPH BATCH: 0120424	RETEST DATE: 27/01/2029	

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 %	< 0.05 %
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 0.5 %	< 0.05 %
Loss on drying	=< 0.5 %	0.3 %
Sulfated ash	=< 0.1 %	< 0.1 %
Assay	97.5 - 102.0 %	99.4 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

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.

(*) 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: 07/05/2024
 Signature: Albert Sánchez López (QP)
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40000997
 HETERO LABS LIMITED (Unit-I)
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