

**ANASTROZOL (EUR. PH.)**

PRODUCT CODE: 00066	CAS Nº: 120511-73-1	ANALYSIS Nº: 037/25
MANUFACTURER BATCH: AL23050016	CERTIFICATE ID: 45.183	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 09/05/2023	
METAPH BATCH: 0110225	RETEST DATE: 08/05/2028	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white powder	White powder
Solubility	Very slightly soluble in water, freely soluble in anhydrous ethanol, practically insoluble in cyclohexane	Complies (*)
Identification	Complies	Complies
Related substances		
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 0.2 %	0.07 %
Water	=< 0.3 %	0.29 %
Sulfated ash	=< 0.1 %	0.05 %
Assay	98.0 - 102.0 %	99.4 %

**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.

Anastrozole 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**

Keep in a well-ventilated place. Store it tightly closed.

Analysis date: 27/02/2025  
Signature: Albert Sánchez López (QP)  
Conclusion: Complies  
Original certificate available upon request

Manufacturer: 40000997  
HETERO LABS LIMITED (Unit-I)  
Survey nº10, I.D.A. Gaddapotharam, Jinnaram  
Mandal,  
502319 Sangareddy District Telangana