



TECHNICAL DATA SHEET

00066-TDS-ENG-2024

ANASTROZOL (EUR. PH.)		
DESCRIPTION DCI: anastrozole		DESCRIPTION DOE: ANASTROZOL
CAS Nº: 120511-73-1	EC Nº: 601-715-6	AEMPS CODE: 2729A
MOL. WEIGHT: 293,37	MOL. FORMULA: C ₁₇ H ₁₉ N ₅	ARTICLE CODE: 00066

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

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

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

REMARKS

Anastrozole 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.