

TECHNICAL DATA SHEET

0429-TDS-ENG-2025

CLOTRIMAZOL (EUR. PH.)		
DESCRIPTION DCI: CLOTRIMAZOLE		DESCRIPTION DOE: CLOTRIMAZOL
CAS Nº: 23593-75-1	EC Nº: 245-764-8	AEMPS CODE: 679A
MOL. WEIGHT: 344,84	MOL. FORMULA: C ₂₂ H ₁₇ ClN ₂	ARTICLE CODE: 0429

ATTRIBUTES	SHOULD BE
Appearance	White or pale yellow, crystalline powder
Solubility	Practically insoluble in water, soluble in ethanol (96 %) and in methylene chloride
Identification B	Complies
Related substances	
Impurity A	=< 0.2 %
Impurity B	=< 0.2 %
Impurity D	=< 0.2 %
Impurity E	=< 0.2 %
Impurity F	=< 0.1 %
Unspecified impurities	=< 0.10 %
Total impurities	=< 0.5 %
Loss on drying	=< 0.5 %
Sulfated ash	=< 0.1 %
Assay	98.5 - 100.5 %

COMPLIES WITH

Europea Pharmacopoeia 11.0

STORAGE

Store it in a cool and dry place. Protect from light and moisture.

REMARKS

Clotrimazole 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.