

<b>CLOTRIMAZOL (EUR. PH.)</b>			
PRODUCT CODE: 0429		CAS Nº: 23593-75-1	ANALYSIS Nº: 213/25
MANUFACTURER BATCH:	HCZ09425	CERTIFICATE ID:	47.317
SUPPLIER BATCH:	----	MANUFACTURING DATE:	01/04/2025
METAPH BATCH:	0090725	RETEST DATE:	30/03/2030

ATTRIBUTES	SHOULD BE	IS
Appearance	White or pale yellow, crystalline powder	White crystalline powder
Solubility	Practically insoluble in water, soluble in ethanol (96 %) and in methylene chloride	Complies (*)
Identification B	Complies	Complies
Related substances		
Impurity A	=< 0.2 %	< 0.05 %
Impurity B	=< 0.2 %	< 0.05 %
Impurity D	=< 0.2 %	< 0.05 %
Impurity E	=< 0.2 %	Not Detected
Impurity F	=< 0.1 %	< 0.05 %
Unspecified impurities	=< 0.10 %	0.05 %
Total impurities	=< 0.5 %	0.05 %
Loss on drying	=< 0.5 %	0.2 %
Sulfated ash	=< 0.1 %	0.08 %
Assay	98.5 - 100.5 %	99.0 %

#### COMPLIES WITH

Europea 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.

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

Release date: 18/11/2025  
Signature: Albert Sánchez López (QP)  
Conclusion: Complies



Manufacturer: 40001460  
HALCYON LABS PVT.LTD  
Plot No. 409, Phase - IV,  
G.I.D.C. Industrial Estate, Naroda  
382 330 Ahmedabad

Original certificate available upon request

Page 1 of 1

A073\_ENG\_03