

**CLOTRIMAZOL (EUR. PH.)**

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|----------------------------------|--------------------------------|---------------------|
| PRODUCT CODE: 0429 | CAS Nº: 23593-75-1 | ANALYSIS Nº: 078/24 |
| MANUFACTURER BATCH: A22130J027 | CERTIFICATE ID: 41.551 | |
| SUPPLIER BATCH: 23B17-B02-226041 | MANUFACTURING DATE: 01/08/2022 | |
| METAPH BATCH: 0310324 | EXPIRY DATE: 31/07/2027 | |

| 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 % | < 0.01 % |
| Impurity E | =< 0.2 % | < 0.05 % |
| Impurity F | =< 0.1 % | < 0.05 % |
| Unspecified impurities | =< 0.10 % | < 0.05 % |
| Total impurities | =< 0.5 % | < 0.01 % |
| Loss on drying | =< 0.5 % | 0.06 % |
| Sulfated ash | =< 0.1 % | < 0.1 % |
| Assay | 98.5 - 100.5 % | 99.3 % |

COMPLIES WITH

Europea Pharmacopoeia 11.0

REMARKS

Product fully analysed inside the EU.

Clotrimazole 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 supplier'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.

Analysis date: 07/05/2024

Signature: Albert Sánchez López (QP)

Conclusion: Complies

Original certificate available upon request

Manufacturer: 40000451

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