

<b>MICONAZOL (EUR. PH.)</b>			
PRODUCT CODE: 151416		CAS Nº: 22916-47-8	ANALYSIS Nº: 260/24
MANUFACTURER BATCH:	024H046	CERTIFICATE ID:	43.749
SUPPLIER BATCH:	----	MANUFACTURING DATE:	01/08/2024
METAPH BATCH:	0131024	EXPIRY DATE:	30/07/2029

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white powder	White powder
Solubility	Very slightly soluble in water, freely soluble in methanol, soluble in ethanol (96 %)	Complies (*)
Identification A	Complies	Complies
Identification B	Complies	Complies
Melting point		
Result A	83 - 87 °C	84.6 °C
Result B	< 2.0 °C	1°C
Appearance of solution	Clear and not more intensely coloured than reference solution Y6	Complies
Optical rotation	-0.10° / +0.10°	+0.0 °
Related substances		
Unspecified impurities	=< 0.10 %	< 0.10 %
Total of impurities	=< 0.30 %	< 0.3 %
Loss on drying	=< 0.50 %	0.08 %
Sulfated ash	=< 0.10 %	0.07 %
Assay	99.0 - 101.0 %	99.7 %

#### COMPLIES WITH

European Pharmacopeia 11.0

#### REMARKS

It shows polymorphism.

Product fully analyzed within the EU, in compliance with the current regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

Miconazole 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 tightly closed, in a dry and cool place and protected from the light.

Analysis date: 04/03/2025  
 Signature: Albert Sánchez López (QP)  
 Conclusion: Complies  
 Original certificate available upon request

Manufacturer: 40000299  
 FDC LIMITED  
 142-48 S.V. ROAD.  
 400102 MUMBAI  
 MAHARASHTRA(India)

