



TECHNICAL DATA SHEET

151416-TDS-ENG-2024

MICONAZOL (EUR. PH.)		
DESCRIPTION DCI: miconazole		DESCRIPTION DOE: MICONAZOL
CAS Nº: 22916-47-8	EC Nº: 245-324-5	AEMPS CODE: 1967A
MOL. WEIGHT: 416,1	MOL. FORMULA: C ₁₈ H ₁₄ Cl ₄ N ₂ O	ARTICLE CODE: 151416

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

COMPLIES WITH

European Pharmacopeia 11.0

STORAGE

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

REMARKS

It shows polymorphism.

Miconazole 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.