



## TECHNICAL DATA SHEET

1295-TDS-ENG-2024

MICONAZOL NITRATO (EUR. PH.)		
DESCRIPTION DCI: MICONAZOLE NITRATE		DESCRIPTION DOE: MICONAZOL NITRATO
CAS Nº: 22832-87-7	EC Nº: 245-256-6	AEMPS CODE: 1967NI
MOL. WEIGHT: 479,14	MOL. FORMULA: C <sub>18</sub> H <sub>14</sub> Cl <sub>4</sub> N <sub>2</sub> O·HNO <sub>3</sub>	ARTICLE CODE: 1295

ATTRIBUTES	SHOULD BE
Appearance	White or almost white powder
Solubility	Very slightly soluble in water, sparingly soluble in methanol, slightly soluble in ethanol (96 %)
Identification A	Complies
Identification B	Complies
Melting point	
Result A	178 - 184 °C
Result B	Complies
Appearance of solution	Clear and not more intensely coloured than ref. sol. Y7
Optical rotation	-0.10° / +0.10°
Related substances	
Impurity C	<= 0.2 %
Sum of impurities F and G	<= 0.2 %
Unspecified impurities	<= 0.1 %
Total impurities	<= 0.5 %
Loss on drying	<= 0.5 %
Sulfated ash	<= 0.1 %
Assay	99.0 - 101.0 %

### COMPLIES WITH

European Pharmacopoeia 11.2

### STORAGE

Keep the container tightly closed, in a cool, dry place. Protected from air and light.

### REMARKS

Miconazole Nitrate is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

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.