

MICONAZOL NITRATO (EUR. PH.)

PRODUCT CODE: 1295	CAS Nº: 22832-87-7	ANALYSIS Nº: 072/25
MANUFACTURER BATCH: H20241102	CERTIFICATE ID: 45.575	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 05/11/2024	
METAPH BATCH: 0240325	EXPIRY DATE: 04/11/2028	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white powder	White powder
Solubility	Very slightly soluble in water, sparingly soluble in methanol, slightly soluble in ethanol (96 %)	Complies (*)
Identification A	Complies	Complies
Identification B	Complies	Complies
Melting point		
Result A	178 - 184 °C	180 °C
Result B	Complies	Complies
Appearance of solution	Clear and not more intensely coloured than ref. sol. Y7	Complies
Optical rotation	-0.10° / +0.10°	+0.0°
Related substances		
Impurity C	<= 0.2 %	Not Detected
Sum of impurities F and G	<= 0.2 %	< 0.05 %
Unspecified impurities	<= 0.1 %	0.07 %
Total impurities	<= 0.5 %	0.07 %
Loss on drying	<= 0.5 %	0.2 %
Sulfated ash	<= 0.1 %	0.05 %
Assay	99.0 - 101.0 %	100.4 %

COMPLIES WITH

European Pharmacopoeia 11.2

REMARKS

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

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".

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

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

Analysis date: 25/04/2025
 Signature: Albert Sánchez López (QP)
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40001544
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