

METRONIDAZOL (EUR. PH.)

PRODUCT CODE: 1294	CAS Nº: 443-48-1	ANALYSIS Nº: 141/25
MANUFACTURER BATCH: MTZ/25010193	CERTIFICATE ID: 46.604	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 01/01/2025	
METAPH BATCH: 0280525	EXPIRY DATE: 30/12/2029	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or yellowish, crystalline powder	Yellowish crystalline powder
Solubility	Slightly soluble in water, in acetone, in alcohol and in methylene chloride	Complies (*)
Identification C	Complies	Complies
Appearance of solution	Not more opalescent than ref. susp. II and not more intensely coloured than ref. sol. GY6	Complies
Related substances		
Any impurity	=< 0.1 %	0.01 %
Total impurities	=< 0.2 %	0.01 %
Loss on drying	=< 0.5 %	0.2 %
Sulfated ash	=< 0.1 %	0.02 %
Assay	99.0 - 101.0 %	100.8 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

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

Metronidazole is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

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. Store it in a cool and dry place.

Analysis date: 06/08/2025
 Signature: Albert Sánchez López (QP)
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40000160
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