

**METRONIDAZOL (EUR. PH.)**

PRODUCT CODE: 1294	CAS Nº: 443-48-1	ANALYSIS Nº: 171/22
MANUFACTURER BATCH: MTZ/2061189	CERTIFICATE ID: 35.550	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 01/06/2022	
METAPH BATCH: 0070722	EXPIRY DATE: 30/05/2027	

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 %	< 0.05 %
Total impurities	=< 0.2 %	< 0.05 %
Loss on drying	=< 0.5 %	0.08 %
Sulfated ash	=< 0.1 %	0.03 %
Assay	99.0 - 101.0 %	99.39 %

**COMPLIES WITH**

European Pharmacopoeia 10.0

**REMARKS**

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

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.

(\*) Data adapted from the certificate of analysis of the manufacturer.

All methods of analysis are validated by official pharmacopeias 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: 20/09/2022  
 Signature: Ferran Gonzalez de Rivera Rier  
 Conclusion: Complies  
 Original certificate available upon request

Manufacturer: 40000297  
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