



## TECHNICAL DATA SHEET

1298-TDS-ENG-2024

METRONIDAZOL BENZOATO (EUR. PH.)		
DESCRIPTION DCI: METRONIDAZOLE BENZOATE		DESCRIPTION DOE: METRONIDAZOL BENZOATO
CAS Nº: 13182-89-3	EC Nº: 236-131-7	AEMPS CODE: 1966BE
MOL. WEIGHT: 275,26	MOL. FORMULA: C <sub>13</sub> H <sub>13</sub> N <sub>3</sub> O <sub>4</sub>	ARTICLE CODE: 1298

ATTRIBUTES	SHOULD BE
Appearance	White or slightly yellowish, crystalline powder or flakes
Solubility	Practically insoluble in water, freely soluble in methylene chloride, soluble in acetone, slightly soluble in ethanol (96 %)
Identification C	Complies
Appearance of solution	Not more opalescent than ref. susp. II and not more intensely coloured than ref. sol. GY3
Acidity	=< 0.25 mL of 0.02 M NaOH
Related substances	
Impurity A	=< 0.1 %
Impurity B	=< 0.1 %
Impurity C	=< 0.1 %
Any other impurity	=< 0.1 %
Total impurities	=< 0.2 %
Loss on drying	=< 0.5 %
Sulfated ash	=< 0.1 %
Assay	98.5 - 101.0 %
Particle size distribution	
40 mesh	=> 98 %

### COMPLIES WITH

European Pharmacopoeia 11.0

### STORAGE

Keep the container in a dry and cool place. Protect from light.

### REMARKS

Metronidazole Benzoate 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.