



## TECHNICAL DATA SHEET

010084-TDS-ENG-2024

TIAMAZOL (METIMAZOL) (EUR. PH.)		
DESCRIPTION DCI: METHIMAZOL		DESCRIPTION DOE: METIMAZOL
CAS Nº: 60-56-0	EC Nº: 200-482-4	AEMPS CODE: 1951B
MOL. WEIGHT: 114,17	MOL. FORMULA: C <sub>4</sub> H <sub>6</sub> N <sub>2</sub> S	ARTICLE CODE: 010084

ATTRIBUTES	SHOULD BE
Appearance	White or pale brown, crystalline powder
Solubility	Freely soluble in water, freely soluble in methylene chloride, freely soluble or soluble in ethanol (96 %)
Melting point	143 - 146 °C
Identification A	Complies
Identification C	Complies
Appearance of solution	Clear and not more intensely coloured than ref. sol. B6
Related substances	
Impurity A	=< 0.1 %
Impurity B	=< 0.1 %
Impurity C	=< 0.1 %
Any other impurity	=< 0.1 %
Total impurities	=< 0.5 %
Loss on drying	=< 0.5 %
Sulfated ash	=< 0.1 %
Assay	98.0 - 101.0 %

### COMPLIES WITH

European Pharmacopoeia 11.0

### STORAGE

Keep the container tightly closed in a well-ventilated place. Protect from direct sunlight.

### REMARKS

Thiamazole 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.