

## **TECHNICAL DATA SHEET**

010084-TDS-ENG-2025

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: C4H6N2S		ARTICLE CODE: 010084	

ATTRIBUTES	SHOULD BE

Appearance White or pale brown, crystalline powder

Solubility Freely soluble in water and in methylene chloride, freely soluble or soluble in

ethanol (96 %)

Melting point 143 - 147 °C
Identification A Complies
Identification C Complies

Appearance of solution Clear and not more intensely coloured than ref. sol. B6

Related substances

Unspecified impurities = < 0.1 %Total impurities = < 0.2 %Loss on drying = < 0.5 %Sulfated ash = < 0.1 %Assay 99.0 - 101.0 %

## **COMPLIES WITH**

European Pharmacopoeia 11.8

## 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.