

TIAMAZOL (METIMAZOL) (EUR. PH.)

PRODUCT CODE: 010084	CAS Nº: 60-56-0	ANALYSIS Nº: 115/24
MANUFACTURER BATCH: MET24010/M	CERTIFICATE ID: 42.007	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 01/03/2024	
METAPH BATCH: 0280424	EXPIRY DATE: 28/02/2028	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or pale brown, crystalline powder	White crystalline powder
Solubility	Freely soluble in water, freely soluble in methylene chloride, freely soluble or soluble in ethanol (96 %)	Complies (*)
Melting point	143 - 146 °C	146 °C
Identification A	Complies	Complies
Identification C	Complies	Complies
Appearance of solution	Clear and not more intensely coloured than ref. sol. B6	Complies
Related substances		
Impurity A	=< 0.1 %	< 0.02 %
Impurity B	=< 0.1 %	< 0.02 %
Impurity C	=< 0.1 %	Not Detected
Any other impurity	=< 0.1 %	< 0.1 % (#)
Total impurities	=< 0.5 %	0.1 %
Loss on drying	=< 0.5 %	0.3 %
Sulfated ash	=< 0.1 %	< 0.1 %
Assay	98.0 - 101.0 %	99.8 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

(#) Impurities detailed underneath:

RT (1.74 min) = 0.05 %

RT (5.94 min) = 0.05 %

RT (8.02 min) = 0.02 %

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

(*) 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 in a well-ventilated place. Protect from direct sunlight.

Analysis date: 23/05/2024
 Signature: Albert Sanchez Lopez (QP)
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40001170

