METAPHARMACEUTICAL

N DE LOTE: 0060725

02/07/2025

SEQENS

CU Chemie Uetikon GmbH
Raiffeisenstraße 4, D-77933 Lahr
Tel. +497821-585-0

F&A PHARMA

Certificate of Analysis

Product:	**METHIMAZOLE** (USP compendial name) **THIAMAZOLE** (Ph. Eur. compendial name)		
CAS-No.:	60-56-0	Ident.-No.: Mat-No.:	M 0400 1900320
Batch-No.:	0080625P	Retest Date:	02 / 2030

Appearance: A white to pale buff crystalline powder with a faint characteristic odour.

Testing	Requirement	Result
Identification		
IR	identical versus reference spectrum	identical
Assay	98.0 - 101.0 %	100.0 %
Loss on drying	nmt. 0.5 %	0.1 %
Residue on ignition	nmt. 0.1 %	0.0 %
Selenium	nmt. 30 ppm	< 30 ppm
Organic impurities (GC)		
Impurity A	nmt. 0.1 %	< 0.02 % (DL)
Impurity B	nmt. 0.1 %	< 0.02 % (DL)
Impurity C	nmt. 0.1 %	< 0.02 % (DL)
Any other impurity	nmt. 0.10 %	0.05 %
Sum of all impurities	nmt. 0.5 %	passed
Ordinary impurities (TLC)		
1-Methyl-2-(methylsulphanyl)-1*H*-imidazolinum rhodanide	nmt. 0.1 %	< 0.1 % (LoD)
Residual solvents	complies with USP <467>	
	nmt. 1000 ppm acetone	346 ppm
	nmt. 1000 ppm ethyl acetate	< 20 ppm
	nmt. 100 ppm methanol	< 20 ppm

COPY QA APPROVED Date 24.06.25 Signature F&A PHARMA-Handels-GmbH

The above information is derived from our quality checks. It does not relieve the purchaser from examining the product upon delivery and gives no assurance of suitability of the product for any particular purpose.

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Additional tests according to Ph. Eur. Thiamazole monograph.

Testing	**Requirement**	**Result**
Melting point	143 - 146° C	145.6° C
Appearance of solution	a) clear solution	conforms
	b) not more intensely colored than reference solution B6	conforms

Remark: **Product is in conformity with the requirements of the current USP and European Pharmacopoeia. The batch was manufactured, packed and tested at the above mentioned site. Batch records have been reviewed for accuracy, completeness, and compliance with established procedures, to determine compliance of the API with the registered manufacturing process, specifications and cGMP requirements.**

Manufacture: February 07, 2025 QA release: March 13, 2025 QC release: April 14, 2025

Issue: June 03, 2025 Q-Manager: i.V. [signature] Head of QC: [signature]

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