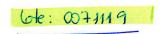


Order No.: 2019-1/427



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

Certificate of Analysis

Product:

METHIMAZOLE (USP compendial name)

THIAMAZOLE

(Ph. Eur. compendial name)

CAS-No.:

60-56-0

Ident.-No.:

M 0400

Batch-No.:

0202019P

Retest Date:

05 / 2024

Additional tests according to Ph. Eur. Thiamazole monograph.

Testing	Requirement	Result
Melting point	143 - 146° C	145.5° C
Appearance of solution	a) clear solution	conforms
	b) not more intensely colored than reference solution B6	conforms
Heavy metals	nmt. 10 ppm	passed

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: May 21, 2019

QA release: August 27, 2019

QC release: August 27, 2019

Issue: November 18, 2019

Q-Manager: W. Prellowelt Head of QC: i.A. Alisa Blvm

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.



Order No.: 2019-1/427

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

Certificate of Analysis

Product: METHIMAZOLE (USP compendial name)

THIAMAZOLE (Ph. Eur. compendial name)

CAS-No.: 60-56-0 Ident.-No.: M 0400

Batch-No.: 0202019P Retest Date: 05 / 2024

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 Impurity B Impurity C Any other impurity Sum of all impurities Ordinary impurities (TLC) 1-Methyl-2-(methylsulphanyl)- 1 <i>H</i> -imidazolinum rhodanide Residual solvents	nmt. 0.1 % nmt. 0.1 % nmt. 0.10 % nmt. 0.10 % nmt. 0.5 % nmt. 0.1 % complies with USP <467> nmt. 1000 ppm acetone nmt. 1000 ppm ethyl acetate nmt. 100 ppm methanol	< 0.02 % (DL) < 0.02 % (DL) 0.03 % < 0.02 % (DL) passed < 0.1 % (LoD) 188 ppm < 20 ppm < 20 ppm

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