Lot: 0071119

SEQENS

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: i.V. Brellenthin Head of QC: i.A. Alisa Bihm

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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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 %	0.03 %
Any other impurity	nmt. 0.10 %	< 0.02 % (DL)
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	188 ppm
	nmt. 1000 ppm ethyl acetate	< 20 ppm
	nmt. 100 ppm methanol	< 20 ppm

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