

Certificate of Analysis

Product:	METHIMAZOLE (USP compendial name) THIAMAZOLE (Ph. Eur. compendial name)		
CAS-No.:	60-56-0	Ident.-No.:	M 0400
Batch-No.:	0072918P	Retest Date:	07 / 2023

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

<u>Testing</u>	<u>Requirement</u>	<u>Result</u>
Identification		
IR	identical versus reference spectrum	identical
Assay	98.0 - 101.0 %	99.5 %
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 %	< 0.02 % (DL)
Sum of all impurities	nmt. 0.5 %	passed
Ordinary impurities (TLC)		
1-Methyl-2-(methylsulphonyl)-1H-imidazolinum rhodanide	nmt. 0.1 %	< 0.1 % (LoD)
Residual solvents	complies with USP <467>	
	nmt. 1000 ppm acetone	413 ppm
	nmt. 1000 ppm ethyl acetate	< 20 ppm
	nmt. 100 ppm methanol	< 20 ppm

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.

<u>Testing</u>	<u>Requirement</u>	<u>Result</u>
Melting point	143 - 146° C	145.9° 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.

Manufacture: July 18, 2018

QA release: August 14, 2018

QC release: August 14, 2018

Issue: January 03, 2019

Q-Manager: i.v. Brillkult

Head of QC: i.A. Misa Blum

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