



CERTIFICATE OF ANALYSIS	
Product Name: THIAMAZOLE	Grade: EP
Batch No.: MET24032/M	A.R. No.: QF24104
Batch Size: 51.11Kg	Date of Mfg.: SEP-2024
Date of Sampling: 19/09/2024	Date of Expiry: AUG-2028
Date of Testing: 21/09/2024	Date of Release : 21/09/2024
Reference Specification No: IP/QCD/FPS/012	

PHARMACOEPEIAL STANDARD			
Sr.No	Test	Specification	Results
1.	Appearance	White or pale brown crystalline powder.	White Crystalline Powder.
2.	Solubility	Freely soluble in water, Freely soluble in methylene chloride, Freely soluble in ethanol (96%)	Complies
3.	Identification	First identification: A, C and Second identification: A, B, D	
	A. Melting Point	143°C and 146 °C	144 °C
	B. Absorbance Ratio	Absorption maximum at 251nm to 211nm is 2.5 to 2.7	Complies
	C. Infrared Absorption Spectroscopy	IR Spectrum of Test sample should be concordant with spectrum obtained with working standard.	Complies
	D. Thin layer Chromatography	The principal spot in chromatograph obtained with the test solution is similar in position and size to principal spot in the chromatogram obtained with reference solution (a)	NA
4.	Appearance of solution	The Solution S is clear and not more than intensely colored then reference solution B6	Complies
5.	Related substance By GC		
	Impurity A	Not More Than 0.1%	ND
	Impurity B	Not More Than 0.1%	ND
	Impurity C	Not More Than 0.1%	ND
	Any other Impurity	Not More Than 0.1%	ND
	Total impurities	Not More Than 0.5%	ND
6.	Loss on drying	Maximum 0.5%	0.20%
7.	Sulfated Ash	Maximum 0.1%	0.02%
8.	Assay by (Potentiometrically)	98.0% to 101.0% (dried substance)	100.1%
IN-HOUSE STANDARD			
9.	Residual solvent		
	Methanol	NMT 3000ppm	ND
	Acetone	NMT 5000ppm	180ppm
	Mesh size test	100 % material passes through 60#	Complies

Note: ND-Not Detected, NA-Not Applicable

Remarks: The above product complies/~~does not comply~~ with prescribed Pharmacopeia (EP 11.3) as well as In-house standard.

QA Sign and Date	Prepared By:	Reviewed By:	Approved By:
Date: 21/09/2024	<i>[Signature]</i> 21/09/2024	<i>[Signature]</i> 21/09/2024	<i>[Signature]</i> 21/09/2024
Name	Sanita Shabale	Pratik Chaudhary	MARY THOMAS
Designation	QA Executive	QC Manager	MANAGER QA



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