

CERTIFICATE OF ANALYSIS

Product Name : THIAMAZOLE EP	
Batch No.: MET21016/M	A.R. No.: QF21094
Batch Size: 60.19Kg	Date of Mfg.: NOV-2021
Date of Sampling: 05/12/2021	Date of Expiry: OCT-2025
Date of Release: 09/12/2021	Reference: IP/QCD/FPS/012

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 or soluble in ethanol (96%).	Complies
3.	Identification Test:- First identification: A, C and Second identification: A, B, D		
	A. Melting point	Between 143°C and 146 °C	145°C
	B. Absorbance Ratio	Absorption maximum at 251nm to 211nm is 2.5 to 2.7	Complies
	C. Infrared Absorption	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 resulting solution is clear and not more intensely colored than 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	Not more than 0.5%	0.21%
7.	Sulfated Ash	Not more than 0.1%	0.03%
8.	Assay (By Potentiometrically)	98.0% to 101.0% (dried substance)	100.1%
9.	Additional test :-		
	• Residual solvent		
	Methanol	NMT 3000ppm	ND
	Acetone	NMT 5000ppm	223ppm
	• Mesh size test	100 % material passes through 60#	Complies

Remarks: The above sample **complies / does not comply** to the prescribed standards of quality in respect of above tests as per EP 10.0.

QA Sign	Sign and Date	Prepared By:	Reviewed By:	Approved By:
Date 16/12/2021	Name	Manita Dhabale	Asun Gaidwal	Manita Choudhary
	Designation	Officer QA.	Manager QC	Dy. Manager QA