



INNOVA PHARMACTIVE PVT. LTD.

NS-13-16, NAGPUR INDUSTRIAL ESTATE CO-OP SOCIETY LTD,

UPPALWADI, NAGPUR 440026.(INDIA)

CIN No.: U24100MH2010PTC204654 Email ID: innovapharmactive@gmail.com

CERTIFICATE OF ANALYSIS

Product Name : METHIMAZOLE USP	
Batch No.: MET23031/M	A.R. No.: QF23101
Batch Size: 60.16Kg	Date of Mfg.: SEP-2023
Date of Sampling: 24/09/2023	Date of Expiry: AUG-2027
Date of Release: 26/09/2023	Reference: IP/QCD/FPS/003

Sr.No	Test	Specification	Results
1.	Description	White to pale buff crystalline powder, having a faint characteristic odour.	White to pale buff Crystalline Powder
2.	Solubility	Its solution are practically neutral to litmus Freely soluble in water, in alcohol (96% ethanol) and in chloroform, slightly soluble in ether	Complies
3.	Identification:		
	Spectroscopic Identification Test:		
	A) Infrared Spectroscopy	IR Spectrum of Test sample should be concordant with the reference spectrum of the Methimazole WS.	Complies
4.	Loss on drying	Not More Than 0.5%	0.20%
5.	Impurities: Residue on ignition	Not More Than 0.1%	0.02%
6.	Organic Impurities by GC (In-house)		
	A. Methimazole related compound A	Not More Than 0.1%	ND
	B.1-Methylimidazole	Not More Than 0.1%	ND
	C. Methimazole related compound C	Not More Than 0.1%	ND
	D. Any Other Individual Impurity	Not More Than 0.1%	ND
	E. Total Impurities	Not More Than 0.5%	ND
7.	Assay (By Potentiometer)	Not less than 98.0% and Not More Than 101.0% of Methimazole, Calculated on dried basis	100.0%
8.	Additional test		
	A) Residual solvent (In-house)		
	Methanol	Not More Than 3000ppm	ND
	Acetone	Not More Than 5000ppm	209ppm
	B) Mesh size test (In-house)	100% Material passes through 60#	Complies

Note: ND- Not Detected

Remarks: The above sample complies / does not comply to the prescribed standards of quality in respect of above tests as per USP 2023.

ISSUED QA Sign Date 26/09/2023	Sign and Date	Prepared By:	Reviewed By:	Approved By:
	Name	Name	Name	Name
	Designation	Designation	Designation	Designation

Quality Assurance Department

IP/QAD/SOP/052/F01.01

