



**UNICHEM**  
**LABORATORIES LTD.**

Plot No. 99, M.I.D.C., Dhatav, Roha, Dist. Raigad - 402 116. (India)  
Phone : + 91-2194-263561, 62, 49.  
Fax : + 91-2194-263545.

## Certificate of Analysis

20/08/23

Product: Metronidazole USP			
Batch No.	RMZP230235	LIMS A.R. No.	ROFP2301510
Mfg. Date	Jul-2023	Product Code	10001023
Exp. Date/Retest date	Jun-2028	Batch Quantity	520.06 Kgs
Specification Id	GA/APIS/MTZ17/6.00	Date Of Release	Aug 23, 2023
STP No.	GA/APISTP/MTZ17/7.00	Customer / Country	SUAN FARMA

S. No.	TEST	SPECIFIED	ACTUAL
1	Description	White to pale yellow, odourless crystals or crystalline powder. It is stable in air, but darkens on exposure to light	White, odourless crystalline powder. It is stable in air, but darkens on exposure to light
2	Solubility	Sparingly soluble in water and alcohol; slightly soluble in ether and chloroform. Soluble in dilute hydrochloric acid	Sparingly soluble in water and alcohol; slightly soluble in ether and chloroform. Soluble in dilute hydrochloric acid
3	Identification		
3.1	By IR		
3.1.1	Identification by IR	The IR Spectrum of sample should be concordant with that of reference/working standard Metronidazole	The IR Spectrum of sample concordant with that of working standard Metronidazole
3.2	By HPLC	In the test for Assay, the retention time of principle peak in chromatogram of the sample preparation correspond to that in the chromatogram of the standard preparation	In the test for Assay, the retention time of principle peak in chromatogram of the sample preparation correspond to that in the chromatogram of the standard preparation
4	Loss on drying	Not More than 0.5%	0.11 %
5	Residue on ignition (%w/w)	Not more than 0.1%	0.04 %
6	Related substances by HPLC (% w/w)		
6.1	Impurity A	NMT 0.05%	Maximum: 0.00 %
6.2	Impurity B	NMT 0.05%	Maximum: 0.00 %
6.3	Impurity C	NMT 0.05%	Maximum: 0.00 %
6.4	Impurity D	NMT 0.05%	Maximum: 0.00 %
6.5	Impurity E	NMT 0.05%	Maximum: 0.00 %
6.6	Impurity F	NMT 0.05%	Maximum: 0.00 %

Remarks: APPROVED (Sample Conforms to above Specification)

Prepared By	Checked By	Approved By
Avinash.Nehe	Ganesh.Jagadale	Nitin.Thamke
Aug 30 2023 9:20AM	Aug 30 2023 9:20AM	Aug 30 2023 9:33AM

Printed by: Nitin.Thamke

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ROA/F/007/02



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80/02/23 ✓

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6.7	Impurity G	NMT 0.05%	Maximum: 0.00 %
6.8	Unspecified impurity	NMT 0.05%	Maximum: 0.01 %
6.9	Total Impurities	NMT 0.20%	Maximum: 0.03 %
7	Assay by HPLC (%w/w)(on dried basis)	Between 99.0% and 101.0%	99.7 %
8	Additional test		
8.1	Acetic acid content by GC	Not More than 5000ppm	Maximum: 1 ppm
8.2	Content of NDBA by GCMS	NMT 6.6ppb	Not detected
9	ADDITIONAL TEST AS PER CUSTOMER REQUIREMENT		
9.1	Particle size Malvern	For Information	d (0.1) = 20.0 µm, d (0.5) = 99.5 µm, d (0.9) = 264 µm.

Remarks: APPROVED (Sample Conforms to above Specification)

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