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

Product: Metronidazole USP			
Batch No.	RMZP210062	**LIMS A.R. No.**	ROFP2100750
Mfg. Date	Feb-2021	**Product Code**	10001023
~~Exp. Date/Retest date~~	Jan-2026	**Batch Quantity**	519.45 Kgs
Specification Id	GA/APIS/MTZ17/3.00	**Date Of Release**	Apr 29, 2021
STP No.	GA/APISTP/MTZ17/4.00	**Customer / Country**	LGM PHARMA

29/04/21

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%	0.14 %
5	**Residue on ignition (%w/w)**	Not more than 0.1%	0.03 %
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+D)**	NMT 0.05%	Maximum: 0.00 %
6.4	**Impurity E**	NMT 0.05%	Maximum: 0.00 %
6.5	**Impurity F**	NMT 0.05%	Maximum: 0.00 %
6.6	**Impurity G**	NMT 0.05%	Maximum: 0.00 %

Remarks: APPROVED (Sample Conforms to above Specification)
—

Initiated By	Checked By	Approved By
Nivrutti.Phatangare (QC Incharge)	Mahesh.Kutre (QC Incharge)	Nitin.Thamke (Manager)
Apr 29 2021 3:04PM	Apr 29 2021 3:04PM	Apr 29 2021 3:07PM

Printed by: Mahesh.Kutre — **Printed on: Apr 29 2021 3:07PM**

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CNo: C10000001189

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6.7	Unspecified impurity	NMT 0.05%	Average: 0.01 %
6.8	**Total Impurities**	NMT 0.20%	Average: 0.03 %
7	**Assay by HPLC**	Between 99.0% and 101.0%	100.0 %
8	**ADDITIONAL TESTS**		
8.1	**Acetic acid content by GC**	Not More than 5000ppm	Average: 8 ppm

Remarks: APPROVED (Sample Conforms to above Specification)

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Nivrutti.Phatangare (QC Incharge)	Mahesh.Kutre (QC Incharge)	Nitin.Thamke (Manager)
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Printed by: Mahesh.Kutre	**Printed on: Apr 29 2021 3:07PM**
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