



**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 Ph.Eur			
Batch No.	RMTZP60107	LIMS A.R. No.	ROFP1601531
Mfg. Date	Sep-2016	Product Code	10000043
Exp. Date/Retest date	Aug-2021	Batch Quantity	350.00
Specification Id	GA/APIS/MTZ04/07	Date Of Release	Oct 07, 2016
STP No.	GA/APISTP/MTZ04/05	Customer / Country	METAPHARMACEUTICAL, SPAIN

S. No.	TEST	SPECIFIED	ACTUAL
1	Characters		
1.1	Appearance	A White or yellowish, crystalline powder	A Yellowish, crystalline powder
1.2	Solubility	Slightly soluble in water, in acetone, in alcohol and in methylene chloride	Slightly soluble in water, in acetone, in alcohol and in methylene chloride
2	Identification		
2.1	Melting Point	Between 159°C and 163° C	Test Melting Point not performed , since Identification by IR is performed
2.2	By UV	The solution shows an absorption maximum at 277nm and minimum at 240nm. The specific absorbance at the maximum is 365 to 395	Test UV not performed , since Identification by IR is performed
2.3	By IR	Spectrum of sample should be concordant with the spectrum obtained from working standard	Spectrum of sample concordant with the spectrum obtained from working standard
2.4	Reaction of primary aromatic amine	An intense orange or red colour and usually precipitate of the same colour are produced	Test Reaction of primary aromatic amine not performed , since Identification by IR is performed
3	Appearance of Solution	The solution is not more opalescent than reference solution II and not more intensely colored than reference solution GY6	The solution is less opalescent than reference solution II and less intensely colored than reference solution GY6
4	Related substances by HPLC (% w/w)		

Remarks: APPROVED (Sample Conforms to above Specification)

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<b>Initiated By</b>		<b>Checked By</b>	<b>Approved By</b>	
Lalit.Patil (QC Incharge)		Dilip.Shelake (QC In-Charge)	Mahendra.Chavan (Manager)	
Oct 8 2016 12:32PM		Oct 8 2016 12:34PM	Oct 8 2016 2:02PM	
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**UNICHEM - A TRUSTED NAME IN PHARMACEUTICALS**

RQA/F/007/02



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4.1	Impurity A	NMT 0.1%	Average: 0.01 %
4.2	Any individual unknown impurity	NMT 0.05%	Average: 0.00 %
4.3	Total impurities	NMT 0.2%	Average: 0.01 %
5	Heavy Metals	NMT 20 ppm	Less than 20 ppm
6	Loss on drying(%w/w)	NMT 0.5%	0.17 %
7	Sulphated ash (%w/w)	NMT 0.1%	0.02 %
8	Assay by potentiometry (%w/w) (on dried basis)	Between 99.0% and 101.0%	100.2 %
9	Glyoxal Content by HPLC	NMT 0.7ppm	0.07 ppm

Remarks: APPROVED (Sample Conforms to above Specification)

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