



Manufacturers of : Bulk Drugs & Chemicals

METAPHARMACEUTICAL

N DE LOTE:

0110323

**QUALITY CONTROL
CERTIFICATE OF ANALYSIS**

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Product Name : **Metronidazole Benzoate EP**
Batch No. : MBO/13020086
Mfg. Date : Feb -2023
Exp. Date : Jan -2028

CAS# : 13182-89-3
A. R. No. : MBO/23/0100
Date of Release : 13-Feb-2023
Batch Size : 1108 kg's.

Sr. NO.	TESTS	OBSERVATIONS	SPECIFICATION
1	Appearance	White crystalline powder	White or slightly yellowish, crystalline powder or flakes
2	Solubility	Complies	Practically insoluble in water, freely soluble in methylene chloride, soluble in acetone, slightly soluble in alcohol.
3	Identification A. Melting Pont.	101.0°C	Melt Between 99 °C to 102 °C
	B. UV.	Specific Absorbance at the maximum at 232 nm = 551	The light absorption in the range 220 nm and 350 nm the solution shows 2 absorption maxima, at 232 nm and 275 nm. The specific absorbance at maximum at 232 nm is 525 to 575.
	C. IR	Concordant with WRS.	Infrared absorption spectrum of sample directly is concordant with Infrared absorption spectrum of Metronidazole Benzoate working standard.
	D. Primary aromatic amines test.	Complies	An intense orange or red colour precipitates produce.
4	Appearance of solution	Complies	Not more opalescent than reference suspension II and not more intensely coloured than reference solution GY ₃ .
5	Acidity	0.06 ml.	NMT 0.25 ml of 0.02 M NaOH is required to change the colour of the indicator.
6	Related substances	BDL	Impurity A : Not more than 0.1%.
		BDL	Impurity B : Not more than 0.1%.
		BDL	Impurity C : Not more than 0.1%.
		0.03%	Other impurity : Not more than 0.1%.
		0.05%	Total impurities : Not more than 0.2%.
7	Sulphated Ash (%)	0.03%	Not more than 0.1%
8	Loss on drying (%)	0.10%	Not more than 0.5%
9	Assay. (%)	100.19%	Not less than 98.50% and not more than 101.0%
*INHOUSE TESTS :			
1	Particle size	99.67%	40 Mesh not less than 98%

Opinion: The material Complies / ~~Not comply~~ as per EP specification.

*The material Complies / ~~Not comply~~ as per In house specification.

Prepared By : *P. Patil*

Checked By :

Approved By: *P. Patil*

QC Officer
Name: Pavan M. Patil.

QC Officer
Name: Aeshvarya N. Patil

Quality Assurance Head:
Name: Dhansing P. Girase

Date : 13 / 02 / 2023

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