

QUALITY CONTROL CERTIFICATE OF ANALYSIS

N DE LOTE:

0280525

PRODUCT NAME : METRONIDAZOLE EP

Batch Size:- 950 Kg

Batch No :- MTZ/ 25010193

AR NO:- FG/25/0209

Mfg Date :- Jan-2025

Analysis Date: 26/01/2025

Expiry Date:- Dec-2029

CAS No :- [443-48-1]

ANALYSIS REPORT

No	Particulars	Standard Limits	Observation
01	Appearance	White or Yellowish, Crystalline Powder.	White to Yellowish, Crystalline Powder.
02	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.
03	Identification(A)	Melting point(2.2.14): 159°C to 163°C	160.9 °C
	Identification(B)	Specific Absorbance (2.2.25): The specific absorbance at maximum is 365 nm to 395 nm	Specific abs : 373
	Identification(C)	Infrared absorption spectrophotometry (2.2.24) IR Spectrum of sample concordant with IR Spectrum of Metronidazole WS or with the reference Spectrum of metronidazole.	IR Spectrum of sample concordant with IR Spectrum of Metronidazole working standard
	Identification(D)	To about 10 mg add about 10 mg of zinc powder R, 1 ml of water R and 0.25 ml of dilute hydrochloric acid R. Heat on a water bath for 5 min. cool. The solution gives the reaction of primary aromatic amines (2.3.1)	To about 10 mg add about 10 mg of zinc powder R, 1 ml of water R and 0.25 ml of dilute hydrochloric acid R. Heat on a water bath for 5 min. cool. The solution gives the reaction of primary aromatic amines (2.3.1)
04	Appearance of Solution	The Solution is not more opalescent than reference suspension II and not more intensely coloured than reference solution GY6 (2.2.2 Method II)	The Solution found less opalescent than reference suspension II, and less intensely coloured than reference solution GY6
05	Related Substances	Any Impurity not more than 0.1% w/w	0.027 % w/w
		Total Impurity not more than 0.2% w/w	0.062 % w/w
06	Sulphated Ash	Maximum 0.1% w/w	0.039 % w/w
07	Loss on Drying	Maximum 0.5% w/w	0.21 % w/w
08	Assay	Not less than 99.0% w/w and not more than 101.0% w/w of C ₆ H ₉ N ₃ O ₃ , calculated with reference to the dried substance	99.67 % w/w

Remark :- The above material passes as per EP Specification

Prepared By: *Deviyani*

Checked By: *Jeneel*

Approved By: *Pinkesh*

QC Officer: *[Signature]*

QC Officer/ Executive: *[Signature]*

QC Head: *[Signature]*

Date: 03.04.25

Date: 03.04.25

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