Aarti Drugs Limited

Manufacturers of : Bulk Drugs & Chemicals

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METAPHARMACEUTICAL

N DE LOTE: 0120224

08/02/2024.

QUALITY CONTROL
CERTIFICATE OF ANALYSIS

PRODUCT NAME : METRONIDAZOLE EP		Batch Size:-	1000 Kg
Batch No :- MTZ/ 3050696		AR NO:-	MTZ/ 230938
Mfg Date :-	May-2023	Analysis Date:	13/05/2023
Expiry Date:-	Apr-2028	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	160.7 °C
	Identification(B)	**Specific Absorbance (2.2.25):** The specific absorbance at maximum is 365 nm to 395 nm	Specific abs : 374
	Identification(C)	**Infrared absorption spectrophotomety (2.2.24)** IR Spectrum of sample concordant with IR Spctrum of Metronidazole WS or with the reference Spectrum of metronidazole.	IR Spectrum of sample concordant with IR Spctrum 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	0.025 % w/w
		Total Impurity not more than 0.2%w/w	0.049 % w/w
06	Sulphated Ash	Maximum 0.1% w/w	0.045 % w/w
07	Loss on Drying	Maximum 0.5% w/w	0.20 % w/w
08	Assay	Not less than 99.0% w/w and not more than 101.0% w/w of C6H9N3O3, calculated with reference to the dried substance	100.00 % w/w

Remark :-The above material passes as per EP Specification

Prepared By:	Bharat	Checked By:	Renuka	Approved By:	Pramod
QC Officer		QC Officer/ Executive		QC Head	
Date:	13.05.23	Date:	13.05.23	Date:	13.05.23