Aarti Drugs Limited

Manufacturers of : Bulk Drugs & Chemicals

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QUALITY CONTROL

CERTIFICATE OF ANALYSIS

PRODUCT NAME : METRONIDAZOLE EP	Batch Size:- 1000 Kg
Batch No :- MTZ/ 1010169	AR NO:- MTZ/ 10182
Mfg Date :- Jan-2021	Analysis Date: 08-01-2021
Expiry Date:- Dec-2025	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	162 °C
	Identification(B)	**Specific Absorbance (2.2.25):** The specific absorbance at maximum is 365 nm to 395 nm	Specific abs : 376
	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 Spectra Concordant with 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	0.040 % w/w
		Total Impurity not more than 0.2%w/w	0.068 % w/w
06	Sulphated Ash	Maximum 0.1% w/w	0.032 % w/w
07	Loss on Drying	Maximum 0.5% w/w	0.18 % 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	99.42 % w/w

Remark :-The above material passes as per EP Specification

Prepared By: Remuka
QC Officer
Date: 03.03.21

Checked By: Tad-Sad
QC Officer/ Executive
Date: 03.03.21

Approved By: Pimkesh
QC Head
Date: 03.03.21

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