**Aarti Drugs Limited**

Manufacturers of : Bulk Drugs & Chemicals

**CORPORATE OFFICE :** Plot No. 109-D, Mahendra Industrial Estate, Ground Floor, Road No. 29, Sion (East), Mumbai - 400 022. India
Tel.: 91 22 2407 2249 • Fax : 91 22 2407 0144 / 2407 3462
E-mail : sales@aartidrugs.com • Website : www.aartidrugs.com
**MANUFACTURING SITE :** Plot No. 2902, 2904, 2601-2605, 2509, G.I.D.C., Sarigam, Dist. Valsad - 396155.
Tel : (0260) 2780269 • Fax. : (0260) 2780268

# QUALITY CONTROL
## CERTIFICATE OF ANALYSIS

| | | | |
|---|---|---|---|
| **PRODUCT NAME : METRONIDAZOLE EP** | | Batch Size:- | 1000 Kg |
| **Batch No :-MTZ/ 2101973** | | AR NO:- | MTZ/ 21995 |
| Mfg Date :- | Oct-2022 | Analysis Date: | 15/10/2022 |
| Expiry Date:- | Sep-2027 | 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 : 382 |
| | 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 | 0.033 % w/w |
| | | Total Impurity not more than 0.2%w/w | 0.071 % w/w |
| 06 | Sulphated Ash | Maximum 0.1% w/w | 0.039 % w/w |
| 07 | Loss on Drying | Maximum 0.5% w/w | 0.17 % 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 | 100.18 % w/w |

**Remark :-The above material passes as per EP Specification**

Prepared By: Renuka
QC Officer
Date: 15.10.22

Checked By: Tatsat
QC Officer/ Executive
Date:

Approved By: Pankaj
QC Head
Date: 15.10.22

Nº lote ACOFARMA: 232152
Firma y fecha: 27/04/23