

## CERTIFICATE OF ANALYSIS

### CIMETIDINE, USP\*

**Batch/Lot Number :** 168359  
**Manufacturing Date :** 09/18/2019  
**Expiration Date :** 08/31/2024  
**Retest Date :** NOT APPLICABLE  
**CAS:** 51481-61-9

† All dates in this document are in format mm/dd/yyyy unless otherwise specified

| TESTS                      | SPECIFICATIONS                                                                                                                                                                                      | RESULTS        |
|----------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
| ASSAY ON DRIED BASIS       | 98.0 - 102.0 %                                                                                                                                                                                      | 98.8 %         |
| DESCRIPTION                | White to off-white, crystalline powder; odorless, or having a slight mercaptan odor.                                                                                                                | CONFORMS       |
| IDENTIFICATION A: <197A>   | IR: Reference to standard spectrum                                                                                                                                                                  | POSITIVE       |
| IDENTIFICATION B:          | UV: Reference to standard spectrum                                                                                                                                                                  | POSITIVE       |
| MELTING RANGE <741>        | 139° - 144°C                                                                                                                                                                                        | 142 ° - 143 °C |
| LOSS ON DRYING <731>       | <= 1.0 %                                                                                                                                                                                            | 0.06 %         |
| RESIDUE ON IGNITION <281>  | <= 0.2 %                                                                                                                                                                                            | 0.06 %         |
| CHROMATOGRAPHIC PURITY     | <= 0.2 % (Single impurity)                                                                                                                                                                          | <= 0.2 %       |
|                            | <= 1.0 % (Total impurities)                                                                                                                                                                         | 0.3 %          |
| ELEMENTAL IMPURITIES <232> | Meets the requirements.                                                                                                                                                                             | CONFORMS       |
| RESIDUAL SOLVENTS <467>    | Meets the requirements.                                                                                                                                                                             | CONFORMS       |
| SOLUBILITY                 | Soluble in alcohol and in polyethylene glycol 400; freely soluble in methanol; sparingly soluble in isopropyl alcohol; slightly soluble in water and in chloroform; practically insoluble in ether. |                |
| **PACKAGING AND STORAGE**  | Preserve in tight, light-resistant containers.                                                                                                                                                      |                |

\*TESTED ON 01/22/2020

Lot number has been changed from  
10401920030 to 168359.

The above mentioned product conforms to the specifications of USP.

The above test results are a direct transcription of information provided to MEDISCA from the Certificate of Analysis provided by the manufacturer / supplier. Additional testing conducted by MEDISCA is represented by an asterisk. This lot was manufactured by M: ZZ1937.

**Dated :** 01/22/2020