

## Product Specification

Meets B.P. Chemical Specifications, Meets E.P. Chemical Specifications, Meets J.P. Chemical Specifications, Meets U.S.P Requirements, GMP Manufactured Product

| Test   | Specification  |
|--|----------------|
| USP – Assay (C <sub>6</sub> H <sub>14</sub> N <sub>4</sub> O <sub>2</sub> · HCl) (dried basis)   | 98.5 – 101.5 % |
| USP – Identification   | Passes Test    |
| USP – Specific Rotation [A] <sup>20</sup> ^D (+)   | 21.4 – 23.6 °  |
| USP – Loss on Drying at 105°C  | ≤ 0.2 %        |
| USP – Residue on Ignition  | ≤ 0.1 %        |
| USP – Sulfate (SO <sub>4</sub> )   | ≤ 0.03 %       |
| USP – Related Compounds – Individual Impurities  | ≤ 0.5 %        |
| USP – Related Compounds – Total Impurities   | ≤ 2.0 %        |
| USP – Chloride (Cl)  | 16.5 – 17.1 %  |
| EP/BP – Assay (C <sub>6</sub> H <sub>14</sub> N <sub>4</sub> O <sub>2</sub> · HCl) (dried basis) | 98.5 – 101.0 % |
| EP/BP – Identification A   | Passes Test    |
| EP/BP – Identification B   | Passes Test    |
| EP/BP – Identification E   | Passes Test    |
| EP/BP – Appearance of Solution   | Passes Test    |
| EP/BP – Specific Rotation [A] <sup>20</sup> ^D (+)   | 21.0 – 23.5 °  |
| EP/BP–Ninhydrin–Positive Substances–Each   | ≤ 0.2 %        |
| EP/BP–Ninhydrin–Positive Substances–Total Impurities   | ≤ 0.5 %        |
| EP/BP – Sulfate (SO <sub>4</sub> )   | ≤ 300 ppm      |
| EP/BP – Ammonium (NH <sub>4</sub> )  | ≤ 0.02 %       |
| EP/BP – Iron (Fe)  | ≤ 10 ppm       |
| EP/BP – Loss on Drying   | ≤ 0.5 %        |
| EP/BP – Ash (sulfated)   | ≤ 0.1 %        |
| JP – Assay (C <sub>6</sub> H <sub>14</sub> N <sub>4</sub> O <sub>2</sub> · HCl) (dried basis)    | 98.5 – 101.0 % |
| JP – Identification  | Passes Test    |
| JP – Optical Rotation (+)  | 21.5 – 23.5 °  |
| JP – pH (1 in 10)  | 4.7 – 6.2      |
| JP – Clarity and Color of Solution   | Passes Test    |
| JP – Sulfate (SO <sub>4</sub> )  | ≤ 0.028 %      |

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| Test   | Specification |
|--|---------------|
| JP - Ammonium (NH <sub>4</sub> )                     | ≤ 0.02 %      |
| JP - Heavy Metals (as Pb)                            | ≤ 20 ppm      |
| JP - Arsenic (As)                                    | ≤ 2 ppm       |
| JP - Related Substances                              | Passes Test   |
| JP - Loss on Drying at 105°C                         | ≤ 0.20 %      |
| JP - Residue after Ignition                          | ≤ 0.10 %      |
| Endotoxin Concentration, IU/mg, For Information Only |               |

GMP Manufactured Product

Bulk Pharmaceutical Chemical

CAUTION: For Manufacturing, processing or repackaging

No Class 1,2,3 or other solvents are used or produced in the manufacturing or purification of the product.

Elemental Impurities (USP (232), EP 5.20) - Information on elemental impurities for this product is available on the associated Product Regulatory Data Sheet and elemental impurity profile report.

Storage Condition: Preserve in well-closed containers. Store in well-closed, light-resistant containers

Packaging Site: Paris Mfg Ctr & DC



Jamie Ethier  
Vice President Global Quality

For questions on this Product Specification please contact Technical Services at 855.282.6867 or +1.610.386.1700

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