



Material No.: 2084-06
Batch No.: 0000181847
Manufactured Date: 2015/07/17
Retest Date: 2020/07/15

Certificate of Analysis

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

| Test | Specification | Result |
|--|--------------------|---------|
| USP – Assay (C ₆ H ₁₄ N ₂ O ₂ · HCl) (dried basis) | 98.5 – 101.5 % | 100.5 |
| USP – Identification | Passes Test | PT |
| USP – Specific Rotation [α] _D ²⁵ ^D (+) | 20.4 – 21.4 Degree | 21.0 |
| USP – Loss on Drying at 105°C | <= 0.4 % | 0.2 |
| USP – Residue on Ignition | <= 0.1 % | < 0.1 |
| USP – Sulfate (SO ₄) | <= 0.03 % | < 0.03 |
| USP – Iron (Fe) | <= 0.003 % | < 0.003 |
| USP – Related Compounds – Individual Impurities | <= 0.5 % | < 0.5 |
| USP – Related Compounds – Total Impurities | <= 2.0 % | < 2.0 |
| USP – Chloride (Cl) | 19.0 – 19.6 % | 19.4 |
| FCC – Assay (C ₆ H ₁₄ N ₂ O ₂ · HCl) (dried basis) | 98.5 – 101.5 % | 98.8 |
| FCC – Identification | Passes Test | PT |
| FCC – Lead (Pb) | <= 5 mg/kg | < 5 |
| FCC – Loss on Drying at 105°C | <= 1.0 % | 0.2 |
| FCC – Residue on Ignition | <= 0.2 % | < 0.1 |
| FCC – Specific Rotation [α] _D ²⁰ ^D (+) | 20.3 – 21.5 Degree | 21.2 |
| FCC – Insoluble Foreign Matter | Passes Test | PT |
| EP/BP – Assay (C ₆ H ₁₄ N ₂ O ₂ · HCl) (dried basis) | 98.5 – 101.0 % | 98.7 |
| EP/BP – Identification A | Passes Test | PT |
| EP/BP – Identification B | Passes Test | PT |
| EP/BP – Identification E | Passes Test | PT |
| EP/BP – Appearance of Solution | Passes Test | PT |

For questions on this Certificate of Analysis please contact Technical Services at 855.282.6867 or +1.610.573.2600
Avantor Performance Materials, LLC.

3477 Corporate Parkway, Center Valley, PA 18034. U.S.A. Phone: 610.573.2600 . Fax: 610.573.2610

| Test | Specification | Result |
|---|--------------------|---------|
| EP/BP – Specific Rotation $[\alpha]^{20\text{D}} (+)$ | 21.0 – 22.5 Degree | 21.6 |
| EP/BP–Ninhydrin–Positive Substances–Each | <= 0.2 % | < 0.1 |
| EP/BP–Ninhydrin–Positive Substances–Total Impurities | <= 1.0 % | < 0.1 |
| EP/BP – Sulfate (SO ₄) | <= 300 ppm | < 300 |
| EP/BP – Ammonium (NH ₄) | <= 0.02 % | < 0.02 |
| EP/BP – Iron (Fe) | <= 30 ppm | < 30 |
| EP/BP – Loss on Drying at 105°C | <= 0.5 % | 0.1 |
| EP/BP – Ash (sulfated) | <= 0.1 % | < 0.1 |
| JP – Assay (C ₆ H ₁₄ N ₂ O ₂ · HCl) (dried basis) | 98.5 – 101.0 % | 98.8 |
| JP – Identification A | Passes Test | PT |
| JP – Identification B | Passes Test | PT |
| JP – Optical Rotation (+) | 19.0 – 21.5 Degree | 21.1 |
| JP – pH (1 in 10) | 5.0 – 6.0 | 5.7 |
| JP – Clarity and Color of Solution | Passes Test | PT |
| JP – Sulfate (SO ₄) | <= 0.028 % | < 0.028 |
| JP – Ammonium (NH ₄) | <= 0.02 % | < 0.02 |
| JP – Heavy Metals (as Pb) | <= 10 ppm | < 10 |
| JP – Arsenic (As) | <= 2 ppm | < 2 |
| JP – Related Substances | Passes Test | PT |
| JP – Loss on Drying at 105°C | <= 1.0 % | 0.2 |
| JP – Residue on Ignition | <= 0.10 % | < 0.01 |
| Endotoxin Concentration, IU/mg, For Information Only | | < 0.003 |

Bulk Food Chemical

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 Conditions: Store in well-closed, light-resistant containers

Country of Origin: JP

Packaging Site: Paris Mfg Ctr & DC

Manufacturer: P0062001

Manufacturer source batch: 150238

Phillipsburg, NJ 9001:2008, 14001:2004, FSSC 22000
 Paris, KY 9001:2008
 Mexico City, Mexico 9001:2008
 Deventer, The Netherlands 9001:2008, 14001:2004, 13485:2003
 Gliwice, Poland 9001:2008, 13485:2012
 Selangor, Malaysia 9001:2008
 Dehradun, India, 9001:2008, 14001:2004, 13485:2003
 Mumbai, India, 9001:2008
 Panoli, India 9001:2008

Jamie Ethier
 Vice President Global Quality

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