



Material No.: 2068-06
Batch No.: 0000191336
Manufactured Date: 2017/02/14
Retest Date: 2022/02/13

Certificate of Analysis

Meets B.P. Chemical Specifications, Meets E.P. Chemical Specifications, Meets F.C.C. Requirements, Meets N.F. Requirements,
GMP Manufactured Product, Food GMP Manufactured Product

| Test | Specification | Result |
|--|--------------------|---------|
| FCC – Assay (C ₄ H ₈ N ₂ O ₃) (dried basis) | 98.0 – 101.5 % | 99.9 |
| FCC – Identification | Passes Test | PT |
| FCC – Lead (Pb) | <= 5 ppm | < 5 |
| FCC – Loss on Drying | 11.5 – 12.5 % | 11.9 |
| FCC – Residue on Ignition | <= 0.1 % | < 0.1 |
| FCC – Specific Rotation [A] ²⁰ ^D (+) | 33.0 – 36.5 Degree | 35.5 |
| Endotoxin Concentration, IU/mg, For Information Only | | < 0.001 |
| NF – Assay (dried basis) | 98.0 – 101.5 % | 99.9 |
| NF – Identification | Passes Test | PT |
| NF – Specific Rotation @ 20 °C (+) | 33.0 – 36.5 Degree | 35.5 |
| NF – Loss on Drying at 130°C | 11.5 – 12.5 % | 11.9 |
| NF – Residue on Ignition | <= 0.1 % | < 0.1 |
| NF – Chromatographic Purity: Individual Impurities | <= 0.5 % | < 0.5 |
| NF – Chromatographic Purity: Total Impurities | <= 1.0 % | < 1.0 |
| NF – Lead (Pb) | <= 5 ppm | < 5 |
| NF – Total Aerobic Microbial Count, cfu/g | <= 1000 | < 10 |
| NF – Total Yeast and Mold Count, cfu/g | <= 100 | < 10 |
| EP/BP – Assay (dried basis) | 99.0 – 101.0 % | 99.9 |
| EP/BP – Identification A | Passes Test | PT |
| EP/BP – Identification B | Passes Test | PT |
| EP/BP – Appearance of Solution | Passes Test | PT |
| EP/BP – Specific Rotation @ 20 °C (+) | 33.7 – 36.0 Degree | 35.5 |

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 – Ninhydrin-Positive Substances | <= 0.5 % | < 0.5 |
| EP/BP – Chloride (Cl) | <= 200 ppm | < 200 |
| EP/BP – Sulfate (SO ₄) | <= 200 ppm | < 200 |
| EP/BP – Ammonium (NH ₄) | <= 0.1 % | < 0.1 |
| EP/BP – Iron (Fe) | <= 10 ppm | < 10 |
| EP/BP – Loss on Drying at 130° C | 10.5 – 12.5 % | 11.9 |
| EP/BP – Sulfated Ash | <= 0.1 % | < 0.1 |
| EP/BP – pH | 4.0 – 6.0 | 5.2 |

Bulk Food Chemical

Bulk Pharmaceutical Chemical

CAUTION: For Manufacturing, processing or repackaging

Residual solvents: Only the Class 2 solvent methanol is likely to be present from use in the manufacturing process. Methanol content is controlled to <200 ppm as a manufacturing process limit.

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: 170176

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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