BIOSPECTRA

100 Majestic Way, Bangor, PA 18013 / www.biospectra.us

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|---|---|---|---|
| Effective Date: | 29-Sep-2021 | 29-Sep-2024 | : Date of Next Review |
| Prepared By: | Jaron Hughes | 16-001182 v.7.0 | : Supersedes |
| QA/QC Approval: | Krista Rehrig | Carissa McCollian | : Management Approval |
| Reason for Revision: | See Revision History in ensur. | | |

# CERTIFICATE OF ANALYSIS

## UREA

## BIO EXCIPIENT GRADE / NEW CODE UREA-3220-25

## (HISTORICAL CODE UR3220-K025)

## LOT: UREA-0121-00014

$NH_2CONH_2$ ⅄ F.W. 60.06 g/mol. ⅄ CAS# 57-13-6

Manufacturing Date: 7/25/21 Retest Date: 7/31/23

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Date: 9/3/21 Packaging Site: 100 Majestic Way, Bangor PA, 18013

Meets or Exceeds USP Specifications

| ANALYSIS | | SPECIFICATION | TEST RESULT |
|---|---|---|---|
| Alcohol Insoluble Matter | | 0.04% max. | <0.04% |
| Appearance and Color | | White / Crystals | White / Crystals |
| Assay | | 98.0-102.0% | 100.3% |
| Enzymes | DNase | None Detected | None Detected |
| | Protease | None Detected | None Detected |
| | RNase | None Detected | None Detected |
| Heavy Metals | | 10 ppm max. | < 10 ppm |
| Identification A(IR) | | Passes Test | Passes Test |
| Identification B | | Passes Test | Passes Test |
| Impurities | Urea RCA | ≤ 0.1% | <0.1% |
| | Total | ≤ 2.0% | 0.1% |
| | Unspecified | ≤ 0.1% | 0.1% |
| Insoluble Matter | | 0.010% max. | <0.001% |
| Loss on Drying | | 1.0% max. | 0.1% |
| Melting Range | | 132-135 °C | 132 - 134°C |
| Residue on Ignition | | 0.010% max. | <0.005% |
| Trace Metals | Arsenic (As) | 5 ppm max. | < 5 ppm |
| | Copper (Cu) | 5 ppm max. | < 5 ppm |
| | Iron (Fe) | 5 ppm max. | < 5 ppm |
| | Lead (Pb) | 5 ppm max. | < 5 ppm |

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: 16-000495

INTENDED USE: Material represented by this Certificate of Analysis is suitable for use as an excipient. It is manufactured in accordance with the ICH Q7 Good Manufacturing Practice Guide. The material represented by this Certificate of Analysis is not suitable to be used as an Active Pharmaceutical Ingredient, Drug Product or Household Item.

RESIDUAL SOLVENTS STATEMENT: Based on the manufacturing process and the controlled handling, storage and analysis of this product, this product complies with the requirements and specifications listed in the current USP method <467> Tables 1, 2, 3, or 4.

Prepared by: _____ Date: 9/29/21 Job Title: QA Specialist

Reviewed by: _____ Date: 9/29/21 Job Title: QA Manager