

# **GMP BIOTECH PRODUCT**

# UREA **BIOTECH, USP, GMP**

CAS #: 57-13-6

Formula: CH<sub>4</sub>N<sub>2</sub>O

F.W.: 60.06 g/mol

# **UREA-4221**

**BIO PHARMA GRADE** 

#### **SPECIFICATIONS** ANALYSIS Alcohol Insoluble Matter < 0.04% Ammonium (NH<sub>4</sub>) < 500 ppm Appearance and Color White / Crystals 98.0 - 102.0% Assay Chloride < 500 ppm</p> **DNase** None Detected Enzymes Protease None Detected **RNase** None Detected **Heavy Metals** < 10 ppm Conforms to Reference Identification A. IR Standard Identification B Passes Test 132-135°C **Melting Range** pH (5M) @ 20°C 7.5 - 9.5 Urea Related < 0.1% Compound A Any Individual Impurities < 0.1% **Unspecified** Impurity **Total Impurities** < 2.0% **Residue on Ignition** < 0.010% Sulfate <u>< 500 ppm</u> Aluminum (Al) <u><</u> 5 ppm <u><</u> 5 ppm Arsenic (As) < 10 ppm Calcium (Ca) Copper (Cu) < 5 ppm Iron (Fe) < 5 ppm</p> <u><</u> 5 ppm **Trace Metals** Lead (Pb) Magnesium (Mg) < 5 ppmPotassium (K) < 50 ppm</p> Phosphorous (P) < 50 ppm Sodium (Na) <u>< 50 ppm</u>

# **Country of Origin: USA**

Zinc (Zn)

<u><</u> 5 ppm

## Intended for Use in Biopharmaceutical & **Biotechnological Applications and Products**

This is a high purity, GMP, Reagent grade product, purified under full cGMP conditions. Urea is used in biochemistry and molecular biology as a protein denaturant with low UV absorptivity. In addition to increasing solubility of hydrophobic molecules, unfolding proteins and altering their threedimensional structures. Urea also renatures protein structures.

#### **General Product Description**

- Appears as a white crystalline product
- Manufactured under an ICH-Q7 Quality Managed cGMP System
- Manufactured in an enzyme free, hormone free and animal free environment
- No known major food allergens (as defined by FDA) and WHO)
- The final product and its raw materials are not derived from nor come into contact with animal parts, animal products, and/or animal byproducts/derivatives.
- · Is not subject to genetic modification
- Synonyms: Carbamide, Carbonyl diamide.
- Visit the product page on our website (www.biospectra.us) for additional information, supporting regulatory documents, and CofAs.

## Storage and Shipping Conditions Refer to SDS.

## **Standard Shelf Life Policy**

Each Certificate of Analysis will contain a 2-year retest/recertification date supported by a 3-year ICH Q1 Stability Study (if one is completed).

## Package Sizes

100g, 500g, 1kg, 5kg, 10kg, 25kg, 50kg

Standard Lead Time

1-2 weeks