

## **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**

1	Analysis	SPECIFICATIONS
	Alcohol Insoluble Matter	<u>&lt;</u> 0.04%
	Ammonium (NH4)	<u>&lt;</u> 500 ppm
	Appearance and Color	White / Crystals
	Assay	98.0 - 102.0%
	Chloride	<u>&lt;</u> 500 ppm
	Enzymes DNase RNase	None Detected None Detected None Detected
	Heavy Metals	<u>&lt;</u> 10 ppm
1	Identification A, IR	Conforms to Reference Standard
	Identification B	Passes Test
	Melting Range	132-135°C
	pH (5M) @ 20°C	7.5 – 9.5
	Urea Related Compound A	<u>&lt;</u> 0.1%
	Impurities Any Individual Unspecified Impurity	<u>&lt;</u> 0.1%
Ê	Total Impurities	<u>&lt;</u> 2.0%
	Residue on Ignition	<u>&lt;</u> 0.010%
	Sulfate	<u>&lt;</u> 500 ppm
	Aluminum (Al) Arsenic (As) Calcium (Ca) Copper (Cu) Iron (Fe) Trace Metals Lead (Pb) Magnesium (Mg) Potassium (K)	<ul> <li>5 ppm</li> <li>5 ppm</li> <li>10 ppm</li> <li>5 0 ppm</li> </ul>
	Phosphorous (P) Sodium (Na) Zinc (Zn)	<u>&lt;</u> 50 ppm <u>&lt;</u> 50 ppm <u>&lt;</u> 5 ppm

### **Country of Origin: USA**

### 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