BIOSPECTRA
Premium Pharmaceutical Ingredients

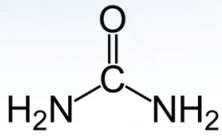
**GMP Solution**
**ICH-Q7 GMP Manufactured Product**

# Urea 6M, GMP Excipient Grade

**MADE WITH USP/EP GRADE UREA AND WATER FOR INJECTION**

## INTENDED FOR USE AS AN EXCIPIENT GRADE SOLUTION

Urea is used as a protein denaturant with low UV absorptivity. In addition to increasing solubility of hydrophobic molecules, unfolding proteins and altering their three-dimensional structures, Urea also renatures protein structures. BioSpectra manufactures repurified, GMP Urea. This multi-compendial certified Urea crystal is combined with WFI grade water to manufacture the finished 6M Urea Solution.



**CAS #:** 57-13-6
**Molecular Formula:** $CH_4N_2O$
360 grams per Liter Urea
**pH of a 6M soln., 25°C** = 7-10

## BIO EXCIPIENT GRADE | Product Code: UREA-3120

$CH_4N_2O$ • 360 g/L • CAS# 57-13-6

Made in the USA

MANUFACTURING STATEMENT: Manufactured using Urea raw material purified (in process) to Meet USP/EP compendial specifications.

| ANALYSIS | | SPECIFICATIONS |
|---|---|---|
| Appearance | | Colorless Liquid |
| Identification (IR) | | Conforms to Standard |
| Molarity | | 5.8 – 6.2 M |
| pH @ 25°C | | 7 - 10 |
| Trace Metals | Arsenic (As)<br>Copper (Cu)<br>Iron (Fe)<br>Lead (Pb) | ≤ 5 ppm<br>≤ 5 ppm<br>≤ 5 ppm<br>≤ 5 ppm |

MANUFACTURING STATEMENT: Manufactured using USP/EP Urea raw material and Water for Injection.

## GMP Compliance:

Bio Excipient Grade Urea 6M solution, UREA-3120 is suitable for use as an excipient. It is manufactured in accordance with the ICH-Q7 Good Manufacturing Practice Guide. This grade of Urea 6M solution is not suitable to be used as an Active Pharmaceutical Ingredient, Drug Product or Household Item.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| BIOSPECTRA<br>**Key Compliance Attributes of BioSpectra Grades** | **Bio Excipient Grade**<br>**ICH-Q7 Compliant Manufactured** |
|---|---|
| Suitable for Research and Diagnostic | ✓ |
| Each Batch 100% Analyzed | ✓ |
| Management of Change | ✓ |
| Validated Analytical Methods | ✓ |
| Compendial Testing | ✓ |
| Trace Metals Analyzed | ✓ |
| Stability Testing Program | ✓ |
| BioSpectra Supply Chain Audit Trail | ✓ |
| Product Origin Statement | ✓ |
| Customer Quality Audits | ✓ |
| Validated Manufacturing Process | ✓ |
| US Manufactured at BioSpectra | ✓ |
| IPEC cGMP Compliant Manufactured | ✓ |
| Customized Additional Specifications | ✓ |
| Multi-Compendial Testing | ✓ |
| Low Bioburden Low Endotoxin (LBLE) | ✓ |
| Enzyme Tested | ✓ |
| Suitable for use as Excipient | ✓ |
| Microbial / Endotoxin Tested | ✓ |
| Manufactured in FDA Registered Facility | ✓ |
| Customized Manufacturing Schedule | ✓ |
| Custom Regulatory Packet | ✓ |
| Accelerated Stability | ✓ |
| Video Conference access to BioSpectra Sites | ✓ |
| Complete access to Product Traceability | ✓ |
| Access to Supply Chain Information | ✓ |
| ICH-Q7 Qualified Utilities | ✓ |
| ICH-Q7 Compliant Manufactured | ✓ |
| Type IV Drug Master File | ✓ |

✓ indicates an attribute or level of compliance which is granted or available based on the purchase of the product grade.

**Bio Excipient Grade:** Intended for use as ICH-Q7 Compliant Excipient

**LBLE:** LBLE applies when product specifications include requirements for Bioburden Testing (TAMC/TYMC and/or Endotoxin).

LBLE stands for Low Bioburden, Low Endotoxin non-sterile products suitable for further use in parenteral manufacturing and other sterile applications.

## General Product Description:

The manufacturing of Bio Excipient Grade Urea 6M soln., UREA-3120 is performed at BioSpectra's Bangor, PA facility and is conducted in a multi-purpose processing area using multi-purpose equipment.

- Urea 6M solution is a colorless liquid.
- Molecular Formula: $CH_4N_2O$
- Molecular Weight: 60.06 g/mol.
- 6M solution: 360 g/liter
- pH: 7-10
- CAS Number: 57-13-6.
- There are no known major food allergens (as defined by FDA and WHO) in the manufacture of this product.
- BioSpectra certifies that all Urea 6M solution, UREA-3120 manufactured at BioSpectra and its raw materials are not derived from or come in contact with animal parts, products, and/or byproducts.
- Urea 6M solution manufactured at BioSpectra and any raw materials used in the manufacture of Urea at BioSpectra are not subject to genetic modification.
- Manufactured with WFI water.
- Synonyms: Carbamide Solution, Carbonyl Diamide Solution

## Retest Date:

The recommended retest period for Urea 6M solution is two years from the date of manufacture.

## Storage and Shipping Conditions:

Store in a tightly closed container. Store in dry, well-ventilated area with temperature between 15-30° C. Store away from incompatible substances.

## Package Sizes:

200 Liter drums, 1,000 - 1,200 L totes.