BIOSPECTRA
Premium Pharmaceutical Ingredients

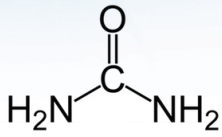
GMP Solution
ICH-Q7 GMP Manufactured Product

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

Lead Time: 3-months
Minimum Order Quantity: 4000L

BIO EXCIPIENT GRADE | Product Code: UREA-3120

CH_4N_2O • 360 g/L • CAS# 57-13-6

Made in the USA

These are general specifications. BioSpectra will customize our products to meet your quality based requirements.

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) Copper (Cu) Iron (Fe) Lead (Pb)	≤ 5 ppm ≤ 5 ppm ≤ 5 ppm ≤ 5 ppm

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

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.

BioSpectra, Inc. 100 Majestic Way Bangor, PA 18013 610-599-3400

BIOSPECTRA Key Compliance Attributes of BioSpectra Grades	Bio Excipient Grade 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.