

## UREA 6M SOLUTION

### GMP, EXCIPIENT

CAS #: 57-13-6

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

M.W.: 60.06 g/mol

### UREA-3120

### BIO EXCIPIENT GRADE

ANALYSIS		SPECIFICATIONS
Appearance and Color		Colorless Solution
Identification, IR		Conforms to Reference Standard
Molarity		5.8 – 6.2 M
pH, 25°C		7 – 10
Trace Metals	Arsenic (As)	< = 5 ppm
	Copper (Cu)	< = 5 ppm
	Iron (Fe)	< = 5 ppm
	Lead (Pb)	< = 5 ppm

### General Product Overview

Urea is used as a protein denaturant with low UV absorptivity. In addition to increasing the solubility of hydrophobic molecules, Urea denatures proteins by unfolding them and altering their three-dimensional structure. BioSpectra manufactures GMP, multi-compendial Urea crystal which is combined with water for injection to manufacture the finished 6M Urea Solution.

### Industry Application

Suitable for use as a cGMP chemical in pharmaceutical manufacturing processes and products.

### Key Product Features

- The manufacturing of Urea 6M Solution is performed at BioSpectra's Bangor, PA facility.
- Appears as a colorless solution
- Manufactured in accordance with ICH Q7
- Manufactured in an enzyme free, hormone free and animal free environment
- Contains 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 or derivatives.
- Is not subject to genetic modification
- Synonyms: Carbamide Solution; Carbonyl Diamide Solution

### Storage and Shipping Conditions

Refer to SDS.

### Standard Shelf-Life Policy

Unless otherwise noted on the Shelf-Life Statement and CoA, this product has a 2-year retest date supported by a 3-year ICH Q1 Stability Study (if one is completed).

### Package Sizes

200L drums and 1,000L – 1,200L totes

[Click here to view SDS, CoAs and other supporting regulatory documents on our website.](#)

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