

## UREA

USP, EP, LE\*, GMP, EXCIPIENT

CAS #: 57-13-6

Formula:  $\text{NH}_2\text{CONH}_2$

F.W.: 60.06 g/mol

### UREA-3250

### BIO EXCIPIENT GRADE

ANALYSIS		SPECIFICATIONS
Alcohol Insoluble Matter (USP)		< = 0.04%
Alkalinity (EP)		Passes Test
Appearance and Color		White Crystals
Appearance of Solution (EP)		Clear and Colorless
Assay (USP)		98.0 – 102.0%
Assay, Dried Basis (EP)		98.5 – 101.5%
Ammonium (EP)		< = 500 ppm
Biuret (EP)		< = 0.1%
Endotoxin		< = 2.5 EU/g
Enzymes	DNase	None Detected
	Protease	None Detected
	RNase	None Detected
Identification, IR (USP-A/EP-B)		Conforms to Reference Standard
Identification B (USP)		Conforms to Reference Standard
Identification A (EP)		132 - 135 °C
Identification C (EP)		Passes Test
Identification D (EP)		Passes Test
Insoluble Matter		< = 0.010%
Organic Impurities (USP)	Urea Related Compound A	< = 0.1%
	Any Individual Unspecified Impurity	< = 0.1%
	Total Impurities	< = 2.0%
Loss on Drying (EP)		< = 1.0%
Residue on Ignition/Sulfated Ash (USP/EP)		< = 0.010%
Trace Metals	Arsenic (As)	< = 5 ppm
	Copper (Cu)	< = 5 ppm
	Iron (Fe)	< = 5 ppm
	Lead (Pb)	< = 5 ppm

\*Low Endotoxin

### General Product Overview

Urea is used in biochemistry and molecular biology 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.

### Industry Application

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

### Key Product Features

- The manufacturing of Urea, UREA-3250 is performed at BioSpectra's Stroudsburg, PA facility.
- Appears as white crystals
- 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.
- It is not subject to genetic modification
- Synonyms: Carbamide, Carbonyl Diamide

### 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

10kg, 25kg and 50kg pails

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

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