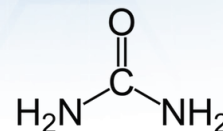


UREA, LBLE, USP, EP, GMP Excipient Grade

Low Bioburden, Low Endotoxin, Multicompendial, GMP Manufactured

INTENDED FOR USE AS AN EXCIPIENT

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 three-dimensional structures, Urea also renatures protein structures. BioSpectra manufactures re-purified, GMP Urea in its FDA registered US facility.



CAS #: 57-13-6

Molecular Formula: CH₄N₂O

Solubility in Water (g/L):
480@20°C

F.W.: 60.06 g/mol

pH @ 20°C: 7.2 (10% soln.)

BIO EXCIPIENT GRADE | Product Code: UREA-3250 | Previously: UR3250

CH₄N₂O • F.W. 60.06 g/mol • CAS# 57-13-6



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

ANALYSIS		SPECIFICATIONS
Alcohol Insoluble Matter		0.04% max.
Appearance and Color		White / Crystals
Assay		98.0 - 102.0%
Endotoxin		2.5 EU/g max.
Enzymes	DNase	None Detected
	Protease	None Detected
	RNase	None Detected
Heavy Metals		10 ppm max.
Identification A (IR)		Passes Test
Identification B		Passes Test
Impurities	Organic	≤ 0.1%
	Total	≤ 2.0%
	Unspecified	≤ 0.1%
Insoluble Matter		0.010% max.
Loss on Drying		1.0% max.
Melting Range		132 - 135 °C
Residue on Ignition		0.010% max.
Trace Metals	Arsenic (As)	5 ppm max.
	Copper (Cu)	5 ppm max.
	Iron (Fe)	5 ppm max.
	Lead (Pb)	5 ppm max.



Urea USP / EP

TECHNICAL PRODUCT SHEET

EP Compendia

ANALYSIS	SPECIFICATIONS
Assay	98.5 – 101.5%
Appearance of Solution	Clear and Colorless
Alkalinity	Passes Test
Ammonium	500 ppm max.
Biuret	0.1% max.
Heavy Metals	10 ppm max.
Identification A	132 - 135°C
Identification B (IR)	Passes Test
Identification C	Passes Test
Identification D	Passes Test
Loss on Drying	1.0% max.
Residue on Ignition	0.1% max.

General Product Description:

- The manufacturing of Bio Excipient Grade UREA-3250 is performed at BioSpectra's Stroudsburg, PA facility and is conducted in a dedicated processing area using only dedicated equipment.
- Urea is a White Crystalline powder.
- Molecular Formula: $\text{CH}_4\text{N}_2\text{O}$
- Molecular Weight: 60.06 g/mol.
- CAS #: 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 UREA-3250 manufactured at BioSpectra and its raw materials are not derived from or come in contact with animal parts, products and/or byproducts.
- Urea manufactured at BioSpectra and any raw materials used in the manufacture of Urea at BioSpectra are not subject to genetic modification.
- Synonyms: Urea, Carbamide, Carbonyldiamide

GMP Compliance:

Bio Excipient Grade Urea, UREA-3250 is suitable for use as an excipient. It is manufactured in accordance with the ICH-Q7 Good Manufacturing Practice Guide. This grade of Urea is not suitable to be used as an Active Pharmaceutical Ingredient, Drug Product or Household Item.

Retest Date:

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

Storage and Shipping Conditions:

- Ship and Store between 15° and 30°C.
- Store in clean and dry area.
- Store in the original container.

Package Sizes:

10kg and 25kg pails and 50kg drums.

Product Statements:

RESIDUAL SOLVENTS: Based on the manufacturing process and the controlled handling, storage and analysis of this product, this product complies with the requirement and specifications listed in the current USP method <467> Tables 1, 2, 3, or 4.