BIOSPECTRA
Premium Pharmaceutical Ingredients

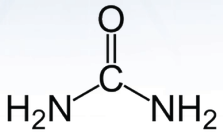
Excipient

ICH-Q7 GMP Manufactured Product

UREA, USP, GMP, Excipient Grade

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 repurified, GMP Urea in its FDA registered, US facility.



CAS #: 57-13-6

Molecular Formula: CH_4N_2O

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-3220 | Previously: UR3220

CH_4N_2O • F.W. 60.06 g/mol. • 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
Alcohol Insoluble Matter		0.04% max.
Appearance and Color		White / Crystals
Assay		98.0 - 102.0%
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	Urea RCA	≤ 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 maximum
	Copper (Cu)	5 ppm maximum
	Iron (Fe)	5 ppm maximum
	Lead (Pb)	5 ppm maximum

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 Urea UREA-3220 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 product.
- Molecular Formula: CH_4N_2O
- Molecular Weight: 60.06 g/mol.
- 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 UREA-3220 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: Carbamide, Carbonyldiamide.

GMP Compliance:

Bio Excipient Grade Urea, UREA-3220 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, 25kg and 50kg pails.