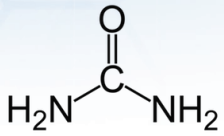
BIOSPECTRA
Premium Pharmaceutical Ingredients

Excipient
ICH-Q7 GMP Manufactured Product

UREA, USP, EP, JP, 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 re-purified, 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-3221 | Previously: UR3221

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.

USP Requirements

ANALYSIS		SPECIFICATIONS
Appearance and Color		White Crystalline Powder
Assay		98.0-102.0%
Chloride		0.007% max.
Elemental Impurities		Complies with USP <232><233>
Identification A (IR)		Passes Test
Identification B (HPLC)		Retention Time Corresponds to Standard
Identification C		Red Purple Color Develops
Identification D		White Precipitate is Formed
In ethanol (96%) Insoluble Parts		0.04% maximum
Organic Impurities	Urea RCA Individual Total	NMT 0.1% NMT 0.1% NMT 2.0%
Residual Solvents		Complies with USP <467>
Sulfated Ash (Residue on Ignition)		0.10% max.
Sulfate		0.010% max.

BIOSPECTRA

US Manufactured Premium, Bulk, GMP Fine Chemicals

Excipient

Urea USP / EP / JP

TECHNICAL PRODUCT SHEET

EP Requirements

ANALYSIS	SPECIFICATIONS
Assay	98.5-101.5%
Appearance of Solution (5% solution; water)	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.
Sulfated Ash	0.10% max.

JP Requirements

ANALYSIS	SPECIFICATIONS
Assay	99.0% minimum
Chloride	0.007% max.
Ethanol-insoluble substances	0.04% max.
Heavy Metals	20 ppm max.
Identification 1	Red Purple Color Develops
Identification 2	White Precipitate is Formed
Melting Point	132.5-134.5°C
Sulfated Ash (Residue on Ignition)	0.1% max.
Sulfate	0.010% max.

ANALYSIS	SPECIFICATIONS
Assay	99.0 – 100.5%
Assay (Dried Basis)	99.0 – 101.0%

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 UREA-3221 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: CH_4N_2O
- 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-3221 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-3221 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 STATEMENT: Based on the manufacturing process and the controlled handling, storage and analysis of this product, this product complies with the requirements and specifications listed in the current USP method <467> Tables 1, 2, 3, or 4.