BIOSPECTRA

US Manufactured Premium, Bulk, GMP Fine Chemicals

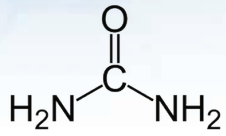
Excipient

Urea USP / EP

TECHNICAL PRODUCT SHEET

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 / UR3250

CH_4N_2O • 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.

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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 UR3250 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 UR3250 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

Key Compliance Attributes of BioSpectra Grades	Bio Excipient Grade ICH Q7 Compliant Manufactured
Suitable for Research and Diagnostic	Yes
Each Batch 100% Analyzed	Yes
Management of Change	Yes
Validated Analytical Methods	Yes
Compendial Testing	Yes
Trace Metals Analyzed	Yes
Two Year Stability	Yes
BioSpectra Supply Chain Audit Trail	Yes
Product Origin Statement	Yes
Customer Quality Audits	Yes
Customized Additional Specifications	Yes
Multi-Compendial Testing	Yes
Enzyme Tested	Yes
Validated Manufacturing Process	Yes
US Manufactured at BioSpectra	Yes
IPEC cGMP Compliant Manufactured	Yes
Suitable for use as Excipient	Yes
Microbial / Endotoxin Tested	Yes
Manufactured in FDA Registered Facility	Available
Customized Manufacturing Schedule	Available
Custom Regulatory Packet	Available
Accelerated Stability	Available
Type IV Drug Master File	Available
Video Conference access to BioSpectra Sites	Available
Complete access to Product Traceability	Available
Access to Supply Chain Information	Yes
ICH Q7 Qualified Utilities	Yes
ICH Q7 Compliant Manufactured	Yes

GMP Compliance:

Bio Excipient Grade Urea, UR3250 is manufactured in accordance with ICH Q7 compliant cGMP guidelines and is suitable for use “downstream” in the manufacture of drug products including use in further manufacturing of parenteral grade products. This grade of Urea is not sterile and requires terminal sterilization. It is not intended for use as an API, final Drug Product or Household item.

Expiration/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.