

UREA

USP, GMP, EXCIPIENT
CAS #: 57-13-6
Formula: NH₂CONH₂
F.W.: 60.06 g/mol
UREA-3220
Bio EXCIPIENT GRADE

ANALYSIS	SPECIFICATIONS	
Alcohol Insoluble Matter (USP)	< = 0.04%	
Appearance and Color	White Crystals	
Assay (USP)	98.0 – 102.0%	
Enzymes	DNase	None Detected
	Protease	None Detected
	RNase	None Detected
Identification A, IR (USP)	Conforms to Reference Standard	
Identification B (USP)	Conforms to Reference Standard	
Insoluble Matter	< = 0.010%	
Loss on Drying	< = 1.0%	
Melting Range	132 – 135 °C	
Organic Impurities (USP)	Urea Related Compound A	< = 0.1%
	Any Individual Unspecified Impurity	< = 0.1%
	Total Impurities	< = 2.0%
Residue on Ignition (USP)	< = 0.010%	
Trace Metals	Arsenic (As)	< = 5 ppm
	Copper (Cu)	< = 5 ppm
	Iron (Fe)	< = 5 ppm
	Lead (Pb)	< = 5 ppm

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

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. BioSpectra manufactures GMP Urea in its FDA registered, US facility.

Industry Application

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

Key Product Features

- The manufacturing of Urea, UREA-3220 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
- 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

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