

UREA

USP, EP, LBLE, GMP, EXCIPIENT

CAS #: 57-13-6

Formula: NH_2CONH_2

F.W.: 60.06 g/mol

UREA-3250

Bio EXCIPIENT GRADE

ANALYSIS	SPECIFICATIONS	
Alcohol Insoluble Matter (USP)	< = 0.04%	
Alkalinity (EP)	Passes Test	
Appearance and Color	White Crystals	
Appearance of Solution (EP)	Clear and Colorless	
Assay (USP)	98.0 – 102.0%	
Assay, Dried Basis (EP)	98.5 – 101.5%	
Ammonium (EP)	< = 500 ppm	
Biuret (EP)	< = 0.1%	
Endotoxin	< = 2.5 EU/g	
DNase Enzymes	None Detected	
Protease	None Detected	
RNAse	None Detected	
Identification, IR (USP-A/EP-B)	Conforms to Reference Standard	
Identification B (USP)	Conforms to Reference Standard	
Identification A (EP)	132 - 135 °C	
Identification C (EP)	Passes Test	
Identification D (EP)	Passes Test	
Insoluble Matter	< = 0.010%	
Organic Impurities (USP)	Urea Related Compound A Any Individual Unspecified Impurity	< = 0.1% < = 0.1%
	Total Impurities	< = 2.0%
Loss on Drying (EP)	< = 1.0%	
Residue on Ignition/Sulfated Ash (USP/EP)	< = 0.010%	
Trace Metals	Arsenic (As) Copper (Cu) Iron (Fe) Lead (Pb)	< = 5 ppm < = 5 ppm < = 5 ppm < = 5 ppm

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-3250 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.
- It 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

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

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