

UREA

USP, EP, LE*, GMP, EXCIPIENT
CAS #: 57-13-6
Formula: NH₂CONH₂
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 | |
| Enzymes | DNase Protease RNase | None Detected None Detected 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 Total Impurities | < = 0.1% < = 0.1% < = 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 |

*Low Endotoxin

This is not considered a controlled document. We are not responsible for any errors or omissions, and the user is responsible for any decisions based on the information herein.

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.

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.](#)