

BIOSPECTRA

100 Majestic Way, Bangor, PA 18013 / www.biospectra.us

Effective Date:	29-Sep-2021	29-Sep-2024	: Date of Next Review
Prepared By:	Jaron Hughes	16-001182 v.7.0	: Supersedes
QA/QC Approval:	Krista Rehrig	Carissa McCollan	: Management Approval
Reason for Revision:	See Revision History in ensur.		

CERTIFICATE OF ANALYSIS

UREA

BIO EXCIPIENT GRADE / NEW CODE UREA-3220-10

(HISTORICAL CODE UR3220-K010)

LOT: UREA-0121-00034

NH₂CONH₂ ^ F.W. 60.06 g/mol. ^ CAS# 57-13-6

Manufacturing Date: 7/25/21 Retest Date: 7/31/23

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Date: 11/6/21 Packaging Site: 100 Majestic Way, Bangor PA, 18013

Meets or Exceeds USP Specifications

ANALYSIS	SPECIFICATION	TEST RESULT
Alcohol Insoluble Matter	0.04% max.	<0.04%
Appearance and Color	White / Crystals	White / Crystals
Assay	98.0-102.0%	100.3%
Enzymes	DNase	None Detected
	Protease	None Detected
	RNase	None Detected
Heavy Metals	10 ppm max.	< 10 ppm
Identification A(IR)	Passes Test	Passes Test
Identification B	Passes Test	Passes Test
Impurities	Urea RCA	≤ 0.1%
	Total	≤ 2.0%
	Unspecified	≤ 0.1%
Insoluble Matter	0.010% max.	<0.001%
Loss on Drying	1.0% max.	0.1%
Melting Range	132-135 °C	132 - 134°C
Residue on Ignition	0.010% max.	<0.005%
Trace Metals	Arsenic (As)	5 ppm max.
	Copper (Cu)	5 ppm max.
	Iron (Fe)	5 ppm max.
	Lead (Pb)	5 ppm max.

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: 16-000495

The information contained herein is the property of BioSpectra. The recipient is responsible for its safe-keeping, and the prevention of unauthorized appropriation, use, disclosure and copying.

INTENDED USE: Material represented by this Certificate of Analysis is suitable for use as an excipient. It is manufactured in accordance with the ICH Q7 Good Manufacturing Practice Guide. The material represented by this Certificate of Analysis is not suitable to be used as an Active Pharmaceutical Ingredient, Drug Product or Household Item.

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.

Prepared by: Jason Hughes Date: 11/12/21 Job Title: QA Specialist

Reviewed by: C. Y. Date: 11/12/21 Job Title: QA Manager