

# BIOSPECTRA

100 Majestic Way, Bangor, PA 18013 / [www.biospectra.us](http://www.biospectra.us)

Effective Date:	16-Apr-2021	16-Apr-2024	: Date of Next Review
Prepared By:	Shana Geffken	19-003109 v.2.1	: Supersedes
QA/QC Approval:	Jess DeMaio	Hannah Bernier	: Management Approval
Reason for Revision:	See Revision History in ensur.		

## CERTIFICATE OF ANALYSIS

### UREA

### BIO EXCIPIENT GRADE / NEW CODE UREA-3250-93

### (HISTORICAL CODE UR3250-G500)

### LOT: UREA-0122-00041

$\text{NH}_2\text{CONH}_2$  \* F.W. 60.06 g/mol. \* CAS# 57-13-6

Manufacturing Date: 8/15/21 Retest Date: 8/31/23

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Date: 9/17/22 Packaging Site: 100 Majestic Way, Bangor PA, 18013

Meets or Exceeds USP / EP / BP Specifications

### USP REQUIREMENTS

ANALYSIS	SPECIFICATION	TEST RESULT
Alcohol Insoluble Matter	0.04% maximum	< 0.04%
Appearance and Color	White / Crystals	White / Crystals
Assay	98.0-102.0%	99.9%
Endotoxin	2.5 EU/g maximum	< 2.0 EU/g
	DNase	None Detected
Enzymes	Protease	None Detected
	RNase	None Detected
Heavy Metals	10 ppm maximum	< 10 ppm
Identification A(IR)	Passes Test	Passes Test
Identification B	Passes Test	Passes Test
	Organic	< 0.1%
Impurities	Total	< 2.0%
	Unspecified	< 0.1%
Insoluble Matter	0.010% maximum	< 0.001%
Loss on Drying	1.0% maximum	0.2%
Melting Range	132-135°C	133 - 134°C
Residue on Ignition	0.010% maximum	< 0.005%
	Arsenic (As)	< 5 ppm
Trace Metals	Copper (Cu)	< 5 ppm
	Iron (Fe)	< 5 ppm
	Lead (Pb)	< 5 ppm

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.

## EP REQUIREMENTS

ANALYSIS	SPECIFICATION	TEST RESULT
Assay	98.5 – 101.5%	99.9%
Appearance of Solution	Clear and Colorless	Clear and Colorless
Alkalinity	Passes Test	Passes Test
Ammonium	500 ppm maximum	<500 ppm
Biuret	0.1% maximum	< 0.1%
Heavy Metals	10 ppm maximum	< 10 ppm
Identification A	132 – 135°C	133 – 134°C
Identification B (IR)	Passes Test	Passes Test
Identification C	Passes Test	Passes Test
Identification D	Passes Test	Passes Test
Loss on Drying	1.0% maximum	0.2%
Residue on Ignition	0.1% maximum	< 0.1%

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: 16-000495

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 requirement and specifications listed in the current USP method <467> Tables 1,2,3, or 4.

Prepared by: B. B. Date: 9/20/22 Job Title: QA Specialist

Reviewed by: Carrie Allert Date: 9/20/22 Job Title: QA Manager