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 McCollian	: Management Approval
Reason for Revision:	See Revision History in ensur.		

CERTIFICATE OF ANALYSIS

UREA

BIO EXCIPIENT GRADE / NEW CODE UREA-3220-93

(HISTORICAL CODE UR3220-G500)

LOT: UREA-0124-00023

NH_2CONH_2 ⅄ F.W. 60.06 g/mol. ⅄ CAS# 57-13-6

Manufacturing Date: 02/23/24 Retest Date: 02/28/26

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Date: 07/31/24 Packaging Site: 100 Majestic Way, Bangor PA, 18013

Meets or Exceeds USP Specifications

ANALYSIS		SPECIFICATION	TEST RESULT
Alcohol Insoluble Matter		0.04% max.	<0.01%
Appearance and Color		White / Crystals	White / Crystals
Assay		98.0-102.0%	99.2%
Enzymes	DNase	None Detected	None Detected
	Protease	None Detected	None Detected
	RNase	None Detected	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%	0.05%
	Total	≤ 2.0%	0.05%
	Unspecified	≤ 0.1%	<0.05%
Insoluble Matter		0.010% max.	0.002%
Loss on Drying		1.0% max.	0.1%
Melting Range		132-135 °C	133 - 135°C
Residue on Ignition		0.010% max.	<0.010%
Trace Metals	Arsenic (As)	5 ppm max.	<0.45 ppm
	Copper (Cu)	5 ppm max.	<0.90 ppm
	Iron (Fe)	5 ppm max.	<0.90 ppm
	Lead (Pb)	5 ppm max.	<0.15 ppm

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

Prepared by: Amil McCall Date: 8/5/24 Job Title: QA Tech I

Reviewed by: Jason Bingham Date: 8/5/24 Job Title: QA Supervisor