BIOSPECTRA

100 Majestic Way, Bangor, PA 18013 / 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-3250-92

(HISTORICAL CODE UR3250-G100)

LOT: UREA-0122-00013

NH_2CONH_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: 9/10/22 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
Enzymes	DNase	None Detected	None Detected
	Protease	None Detected	None Detected
	RNase	None Detected	None Detected
Heavy Metals		10 ppm maximum	< 10 ppm
Identification A(IR)		Passes Test	Passes Test
Identification B		Passes Test	Passes Test
Impurities	Organic	≤ 0.1%	< 0.1%
	Total	≤ 2.0%	< 2.0%
	Unspecified	≤ 0.1%	< 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%
Trace Metals	Arsenic (As)	5 ppm maximum	< 5 ppm
	Copper (Cu)	5 ppm maximum	< 5 ppm
	Iron (Fe)	5 ppm maximum	< 5 ppm
	Lead (Pb)	5 ppm maximum	< 5 ppm

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: _____ Date: 9/14/22 Job Title: QA Specialist

Reviewed by: Carisa Allert Date: 9/14/22 Job Title: QA Manager