BIOSPECTRA

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

Effective Date:	15-APR-2020	15-APR-2023	: Date of Next Review
Prepared By:	Amy Hosein	v.1.0	: Supersedes
QA/QC Approval:	Wendy Santay	Dora Meissner	: Management Approval
Reason for Revision:	See Revision History in ensur.		

CERTIFICATE OF ANALYSIS

UREA

BIO ACTIVE GRADE / UR2220 – K050

LOT: UR2220-014-0820

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

Manufacture Date: 8/16/20 Retest Date: 8/31/23

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 8/19/20 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%	100.2%
Enzymes	DNase	None Detected	None Detected
	RNase	None Detected	None Detected
	Protease	None Detected	None Detected
Heavy Metals		10 ppm max.	<10ppm
Identification A (IR)		Passes Test	Passes Test
Identification B		Passes Test	Passes Test
Impurities	Urea RCA	< 0.1%	<0.1%
	Total	< 2.0%	<2.0%
	Unspecified	< 0.1%	<0.1%
Insoluble Matter		0.010% max.	<0.002%
Loss on Drying		1.0% max.	0.1%
Melting Range		132-135 °C	134 - 135 °C
Residue on Ignition		0.010% max.	0.010%
Trace Metals	Arsenic (As)	5 ppm max.	< 5 ppm
	Copper (Cu)	5 ppm max.	< 5 ppm
	Iron (Fe)	5 ppm max.	< 5 ppm
	Lead (Pb)	5 ppm max.	< 5 ppm

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: 16-000495

CAUTION STATEMENT: For manufacturing, processing, or repacking.

CAUTION STATEMENT: Rx only.

INTENDED USE: Material represented by this Certificate of Analysis is suitable for use as a non-Sterile Active Pharmaceutical Ingredient 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 a Sterile or Injectable Active Pharmaceutical Ingredient, Drug Product or Household Item.

RESIDUAL SOLVENTS: 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: _____ Date: 9/18/20 Job Title: QA Supervisor

Reviewed by: _____ Date: 9/18/20 Job Title: QA Specialist