BIOSPECTRA

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

Effective Date:	13-Dec-2019	13-Dec-2022	: Date of Next Review
Prepared By:	Carissa McCollian	16-001181 v.5.0	: Supersedes
QA/QC Approval:	Hannah Bernier	Mark Uhlig	: Management Approval
Reason for Revision:	See Revision History in ensur		

CERTIFICATE OF ANALYSIS

UREA

BIO PHARMA GRADE / UR4220-K025

LOT: UR4220-040-0220

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

Manufacture Date: 2/19/2019 Retest Date: 2/28/2021

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360 Packaging Date: 2/27/2020

Packaging Site: 100 Majestic Way, Bangor PA, 18013

MEETS USP SPECIFICATIONS

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%
Chloride		0.0005% maximum	<0.0005%
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
Insoluble Matter		0.010% maximum	<0.002%
Loss on Drying		1.0% maximum	0.1%
Melting Range		132-135 °C	134 - 135°C
Impurities	Organic	NMT 0.1%	<0.1%
	Total	NMT 2.0%	<2.0%
	Unspecified	NMT 0.1%	<0.1%
Residue on Ignition		0.010% maximum	<0.010%
Sulfate		0.001% maximum	<0.001%
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

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: 16-000495

INTENDED USE: Material represented by this Certificate of Analysis is suitable to be used only as the following: IPEC Compliant GMP Manufactured Chemical, for use in further Manufacturing or as a Reagent for Laboratory and Research. The material represented by this Certificate of Analysis is not suitable to be used as an Active Pharmaceutical Ingredient, Drug, Drug Product or Household Item.

RESIDUAL SOLVENT 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: [signature] / QA Supervisor Date: 3/2/20

Reviewed by: [signature] / QA Manager Date: 3/2/20