BIOSPECTRA

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

Effective Date:	23-Aug-2019	23-Aug-2022	: Date of Next Review
Prepared By:	Jessica DeMaio	16-001182 v.5.0	: Supersedes
QA/QC Approval:	Jenna Miller	Dora Meissner	: Management Approval
Reason for Revision:	See Revision History in ensur		

CERTIFICATE OF ANALYSIS

UREA

BIO EXCIPIENT GRADE / UR3220-K025

LOT: UR3220-007-0917

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

Manufacturing Date: 9/29/2017 Expiration Date: 9/30/2020

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360 Packaging Date: 9/30/2017

Packaging Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Meets or Exceeds USP Specifications

ANALYSIS		SPECIFICATION	TEST RESULT
Alcohol Insoluble Matter		0.04% max.	<0.0060%
Appearance and Color		White / Crystals	White / Crystals
Assay		98.0-102.0%	100.15%
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%	<0.1%
	Total	< 2.0%	<2.0%
	Unspecified	< 0.1%	<0.1%
Insoluble Matter		0.010% max.	<0.0015%
Loss on Drying		1.0% max.	0.1831%
Melting Range		132-135 °C	133.4 – 134.7 °C
Residue on Ignition		0.010% max.	<0.0075%
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

INTENDED USE: Material represented by this Certificate of Analysis is suitable to be used only as the following: ICH Q7 Compliant cGMP Manufactured Excipient for use in further manufacturing. 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 and storage of this product, there is no potential for any of the residual solvents listed in the current USP method <467> Tables 1, 2, 3, or 4 to be present at the specified limits; furthermore, if tested this product would comply with USP/NF requirements.

Prepared by: H. Brewer Date: 10/11/19

Reviewed by: [signature] Date: 10/1/19