BIOSPECTRA

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

Effective Date:	28-Feb-2018	28-Feb-2021	: Date of Next Review
Prepared By:	Jamie Storm	16-001939 v.1.0	: Supersedes
QA/QC Approval:	Nicole Fisher	Dora Meissner	: Management Approval
Reason for Revision:	See Revision History in ensur		

UREA

CERTIFICATE OF ANALYSIS

BIO ACTIVE GRADE / UR2220 – K025

LOT: UR2220-005-1218

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

Manufacture Date: 04/16/2018 Retest Date: 04/30/2020

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 12/10/2018 Packaging Site: 100 Majestic Way, Bangor PA, 18013

Meets or Exceeds USP Specifications

ANALYSIS		SPECIFICATION	TEST RESULT
Alcohol Insoluble Matter		0.04% max.	0.0100%
Appearance and Color		White / Crystals	White / Crystals
Assay		98.0-102.0%	99.80%
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.	<0.0015%
Loss on Drying		1.0% max.	0.2197%
Melting Range		132-135 °C	133.8 – 135.0 °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

CAUTION STATEMENT: For manufacturing, processing, or repacking in the preparation of a new drug or new animal drug limited by Federal law to investigational use.

INTENDED USE: Material represented by this Certificate of Analysis is suitable to be used only as the following: ICH Q7 Compliant cGMP Manufactured Active Pharmaceutical Ingredient for use in Drug Product Manufacturing. 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 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. Bennett Date: 12/11/18

Reviewed by: Anna Mills Date: 12/11/18