

BIOSPECTRA

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

Effective Date:	26-Sep-2018	26-Sep-2021	: Date of Next Review
Prepared By:	Jamie Storm	Not Applicable	: Supersedes
QA/QC Approval:	Amy Yencho	Dora Meissner via proxy Crystal Hamelburg	: Management Approval
Reason for Revision:	See Revision History in ensur		

UREA

CERTIFICATE OF ANALYSIS

BIO ACTIVE GRADE / UR2220 – G500

LOT: UR2220-003-0918

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

Manufacture Date: 04/25/2018

Retest Date: 10/31/2020

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 09/24/2018 Packaging Site: 100 Majestic Way, Bangor PA, 18013

Meets or Exceeds USP Specifications

ANALYSIS	SPECIFICATION	TEST RESULT
Alcohol Insoluble Matter	0.04% max.	0.0140%
Appearance and Color	White / Crystals	White / Crystals
Assay	98.0-102.0%	100.48%
Enzymes	DNase	None Detected
	RNase	None Detected
	Protease	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%
	Total	< 2.0%
	Unspecified	< 0.1%
Insoluble Matter	0.010% max.	<0.0015%
Loss on Drying	1.0% max.	0.2296%
Melting Range	132-135 °C	133.7 – 134.8 °C
Residue on Ignition		0.010% max.
	Arsenic (As)	5 ppm max.
	Copper (Cu)	5 ppm max.
	Iron (Fe)	5 ppm max.
	Lead (Pb)	5 ppm max.

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: 16-000495

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CAUTION STATEMENT: For use in development only and not for commercial distribution.

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: 9/26/18

Reviewed by: Cynthia M Date: 9/26/18