

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: UR3220-010-0118

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: 1/30/2018

Packaging Site: 100 Majestic Way, Bangor PA, 18013

Meets or Exceeds USP Specifications

ANALYSIS	SPECIFICATION	TEST RESULT
Alcohol Insoluble Matter	0.04% max.	<0.0060%
Appearance and Color	White / Crystals	White / Crystals
Assay	98.0-102.0%	100.15%
Enzymes	DNase	None Detected
	Protease	None Detected
	RNase	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%
	Total	< 2.0%
	Unspecified	< 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%
	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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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. Bauer Date: 10/11/19

Reviewed by: Cal Date: 10/11/19