

# BIOSPECTRA

100 Majestic Way, Bangor, PA 18013 / [www.biospectra.us](http://www.biospectra.us)

Effective Date:	2-Apr-2020	2-Apr-2023	: Date of Next Review
Prepared By:	Jessica DeMaio	16-001181 v.6.0	: Supersedes
QA/QC Approval:	Kyle Snyder	Jenna Miller	: Management Approval
Reason for Revision:	See Revision History in ensur.		

## CERTIFICATE OF ANALYSIS

### UREA

BIO PHARMA GRADE / UR4220-K010

LOT: UR4220-039-0620

NH<sub>2</sub>CONH<sub>2</sub> \* F.W. 60.06 g/mol. \* CAS# 57-13-6

Manufacturing Date: 2/19/19 Retest Date:2/28/21

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Date: 6/4/20 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
	Protease	None Detected
	RNase	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%
	Total	NMT 2.0%
	Unspecified	NMT 0.1%
Residue on Ignition	0.010% maximum	<0.010%
Sulfate		0.001% maximum
	Arsenic (As)	5 ppm maximum
	Copper (Cu)	5 ppm maximum
	Iron (Fe)	5 ppm maximum
	Lead (Pb)	5 ppm maximum

COUNTRY OF ORIGIN: U.S.A.

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TEST METHOD REFERENCE: DCN: 16-000495

INTENDED USE: Material represented by this Certificate of Analysis is suitable for use as a GMP process chemical. It is manufactured in accordance with the IPEC-PQG Joint Good Manufacturing Practice Guide. 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: C. [Signature] Date: 06/15/20 Job Title: QA Supervisor

Reviewed by: Wendy [Signature] Date: 06/05/20 Job Title: QA Manager