

BIOSPECTRA

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

Effective Date:	15-Sep-2017	15-Sep-2020	: Date of Next Review
Prepared By:	Nicole Fisher	16-001182 v.4.0	: Supersedes
QA/QC Approval:	Crystal Hamelburg	Dora Meissner	: Management Approval
Reason for Revision:	See Revision History in ensur		

UREA

CERTIFICATE OF ANALYSIS

BIO EXCIPIENT GRADE / UR3220-G100

LOT: UR3220-011-0718

NH₂CONH₂ * F.W. 60.06 g/mol. * CAS# 57-13-6

Manufacturing Date: 09/29/2017 Retest Date: 09/30/2019

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360 Packaging Date: 07/23/2018

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%	99.53%	
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.	0.3364%	
Melting Range	132-135 °C	133.3 – 134.6 °C	
Residue on Ignition	0.010% max.	<0.0075%	
	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

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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. Bennett Date: 7/24/18

Reviewed by: C. Spina Date: 7/24/18