

BIOSPECTRA

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

Effective Date:	30-Nov-2017	30-Nov-2020	: Date of Next Review
Prepared By:	Jamie Storm	16-001181 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 PHARMA GRADE / UR4220-K025

LOT: UR4220-033-0818

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

Manufacture Date: 07/30/2018

Retest Date: 07/31/2020

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Date: 08/14/2018

Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS	SPECIFICATION	TEST RESULT	
Alcohol Insoluble Matter	0.04% maximum	<0.0040%	
Appearance and Color	White / Crystals	White / Crystals	
Assay	98.0-102.0%	99.79%	
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	Passes Test	Passes Test	
Identification B	Passes Test	Passes Test	
Identification (IR)	Passes Test	Passes Test	
Insoluble Matter	0.010% maximum	<0.0010%	
Loss on Drying	1.0% maximum	0.1941%	
Melting Range	132-135 °C	132.9 – 134.3 °C	
Residue on Ignition	0.010% maximum	<0.0075%	
Sulfate	0.001% maximum	<0.001%	
	Arsenic (As)	5 ppm maximum	< 5 ppm
	Copper (Cu)	5 ppm maximum	< 5 ppm
	Iron (Fe)	5 ppm maximum	< 5 ppm
	Lead (Pb)	5 ppm maximum	< 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: IPEC Compliant GMP Manufactured Chemical, for use in further Manufacturing or as a Reagent for Laboratory and Research. 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 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: S. Denton Date: 8/15/18

Reviewed by: H. Beumer Date: 8/15/18