

BIOSPECTRA

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

Effective Date:	23-Jan-2025	23-Jan-2028	: Date of Next Review
Prepared By:	Amy Yenko	Not Applicable	: Supersedes
QA/QC Approval:	Krista Rehrig	Carissa Albert	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

CERTIFICATE OF ANALYSIS

UREA

BIOTECH, MEETS USP, GMP

BIO PHARMA GRADE / UREA-4221

LOT: UREA-0224-00004

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

Manufacturing Date: 03/03/24 Retest Date: 03/31/26

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS	SPECIFICATION	TEST RESULT
Alcohol Insoluble Matter	$\leq 0.04 \%$	$< 0.01 \%$
Ammonium (NH_4)	$\leq 500 \text{ ppm}$	$< 500 \text{ ppm}$
Appearance and Color	White / Crystals	White / Crystals
Assay	98.0 - 102.0 %	99.4 %
Chloride	$\leq 500 \text{ ppm}$	$< 500 \text{ ppm}$
Enzymes	DNase	None Detected
	Protease	None Detected
	RNase	None Detected
Heavy Metals	$\leq 10 \text{ ppm}$	$< 10 \text{ ppm}$
Identification A, IR	Conforms to Reference Standard	Conforms to Reference Standard
Identification B	Passes Test	Passes Test
Melting Range	132 - 135 °C	134 - 135°C
pH (5M) @ 20°C	7.5 – 9.5	7.7
Impurities	Urea Related Compound A	0.07 %
	Any Individual Unspecified Impurity	$\leq 0.1 \%$
	Total Impurities	$\leq 2.0 \%$
Residue on Ignition	$\leq 0.010 \%$	$< 0.003 \%$
Sulfate	$\leq 500 \text{ ppm}$	$< 500 \text{ ppm}$

	ANALYSIS	SPECIFICATION	TEST RESULT
Trace Metals	Aluminum (Al)	≤ 5 ppm	< 1.5 ppm
	Arsenic (As)	≤ 5 ppm	< 0.45 ppm
	Calcium (Ca)	≤ 10 ppm	< 1.5 ppm
	Copper (Cu)	≤ 5 ppm	< 0.90 ppm
	Iron (Fe)	≤ 5 ppm	< 0.90 ppm
	Lead (Pb)	≤ 5 ppm	< 0.15 ppm
	Magnesium (Mg)	≤ 5 ppm	< 1.5 ppm
	Potassium (K)	≤ 50 ppm	< 15 ppm
	Phosphorus (P)	≤ 50 ppm	< 30 ppm
	Sodium (Na)	≤ 50 ppm	< 15 ppm
	Zinc (Zn)	≤ 5 ppm	< 1.5 ppm

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: BSI-ATM-0006

INTENDED USE: Material represented by this Certificate of Analysis is suitable for use as a 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.

Prepared by: Shirley McCall Date: 1/31/25 Job Title: QA Tech III

Reviewed by: Car Albert Date: 1/31/25 Job Title: Senior Quality Manager