

BIOSPECTRA

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

Effective Date:	04-Feb-2025	04-Feb-2028	: Date of Next Review
Prepared By:	Taylor Yurick	BSI-COA-0035 v.7.2	: Supersedes
QA/QC Approval:	Jessica DeMaio	Hannah Kuchmas	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

CERTIFICATE OF ANALYSIS

UREA

BIO EXCIPIENT GRADE / UREA-3220

LOT: UREA-S04-1125-0018

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

Manufacturing Date: 11/10/25 Retest Date: 11/30/27

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Site: 100 Majestic Way, Bangor PA, 18013

Meets or Exceeds USP Specifications

ANALYSIS	SPECIFICATION	TEST RESULT
Alcohol Insoluble Matter	0.04% max.	< 0.01%
Appearance and Color	White / Crystals	White / Crystals
Assay	98.0-102.0%	99.9%
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	0.06%
	Total	0.06%
	Unspecified	< 0.05%
Insoluble Matter	0.010% max.	< 0.001%
Loss on Drying	1.0% max.	0.2%
Melting Range	132-135 °C	133 - 135°C
Residue on Ignition	0.010% max.	0.008%
Trace Metals	Arsenic (As)	< 0.45 ppm
	Copper (Cu)	< 0.15 ppm
	Iron (Fe)	< 0.30 ppm
	Lead (Pb)	< 0.30 ppm

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: BSI-ATM-0006

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INTENDED USE: Material represented by this Certificate of Analysis is suitable for use as an excipient. It is manufactured in accordance with the ICH Q7 Good Manufacturing Practice Guide. 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, 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: Anil McCall Date: 8/11/26 Job Title: QA Techn

Reviewed by: James Bingham Date: 8/11/26 Job Title: QA Supervisor