

BIOSPECTRA

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

Effective Date:	22-Dec-2021	22-Dec-2024	: Date of Next Review
Prepared By:	Danielle Gathagan	21-004199 v.1.0	: Supersedes
QA/QC Approval:	Jaron Hughes	Carissa McCollian	: Management Approval
Reason for Revision:	See Revision History in ensur.		

CERTIFICATE OF ANALYSIS

UREA 6M SOLUTION, GMP

MADE WITH USP/EP GRADE UREA AND WATER FOR INJECTION PACKAGED IN A
1200L TOTE, 360 GRAMS PER LITER UREA

BIO EXCIPIENT GRADE / UREA-3120-78

LOT: UREA-0124-00017

$\text{CH}_4\text{N}_2\text{O}$ \wedge 360g/L \wedge CAS# 57-13-6

Manufacture Date: 05/08/24

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Site: 100 Majestic Way, Bangor PA, 18013 Packaging Date: 05/09/24

ANALYSIS	SPECIFICATION	TEST RESULT
Appearance	Colorless Liquid	Colorless Liquid
Identification (IR)	Conforms to Standard	Conforms to Standard
Molarity	5.8 – 6.2M	5.9 M
pH @ 25°C	7 – 10	7
Trace Metals	Arsenic (As)	≤ 5 ppm
	Copper (Cu)	≤ 5 ppm
	Iron (Fe)	≤ 5 ppm
	Lead (Pb)	≤ 5 ppm
		<0.45 ppm
		<0.90 ppm
		<0.90 ppm
		<0.15 ppm

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: BSI-ATM-0079

MANUFACTURING STATEMENT: Material represented by this Certification of Analysis was manufactured using Urea USP/EP Raw Material and Water for Injection.

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.

SHELF LIFE: A Retest Date is to be determined based on the data obtained from the stability study.

Prepared by: Taylor Yunker Date: 5/17/24 Job Title: QA Tech III

Reviewed by: Jaron Hughes Date: 5/17/24 Job Title: QA Supervisor