

BIOSPECTRA

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

Effective Date:	22-Jan-2025	22-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
URIDINE
BIOTECH, LBLE, GMP
BIO PHARMA GRADE / URID-4250
LOT: URID-N02-1024-0016
 $C_9H_{12}N_2O_6$ * F.W. 244.20 g/mol * CAS# 58-96-8
 Manufacture Date: 10/4/24 Retest Date: 10/31/26
 Manufacturing Site: 100 Majestic Way, Bangor PA, 18013
 Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS	SPECIFICATION	TEST RESULT
Ammonium	≤ 1500 ppm	< 1500 ppm
Appearance and Color	White to almost white powder	White to almost white powder
Assay	98.0 - 102.0 %	100.5 %
Bioburden	TAMC	≤ 100 CFU/g
	TYMC	≤ 100 CFU/g
Chloride	≤ 500 ppm	< 500 ppm
Endotoxin	≤ 0.5 EU/mg	< 0.5 EU/mg
Heavy Metals	≤ 10 ppm	< 10 ppm
Identification, IR	Conforms to Reference Standard	Conforms to Reference Standard
Insoluble Matter	≤ 0.1 %	< 0.1 %
Loss on Drying	≤ 0.5 %	0.1 %
Purity	≥ 99.0 %	100.0 %
Residue on Ignition	≤ 0.1 %	0.1 %
Solubility (Color)	Colorless	Colorless
Solubility (Turbidity)	Clear	Clear
Total Phosphorus	≤ 160 ppm	< 30 ppm


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ANALYSIS	SPECIFICATION	TEST RESULT	
	Aluminum (Al)	≤ 5 ppm	< 1.5 ppm
	Calcium (Ca)	≤ 100 ppm	2.2 ppm
	Copper (Cu)	≤ 5 ppm	< 1.5 ppm
	Iron (Fe)	≤ 30 ppm	< 1.5 ppm
Trace Metals	Potassium (K)	≤ 50 ppm	< 15 ppm
	Magnesium (Mg)	≤ 30 ppm	< 1.5 ppm
	Sodium (Na)	≤ 200 ppm	< 15 ppm
	Lead (Pb)	≤ 50 ppm	< 0.15 ppm
	Zinc (Zn)	≤ 5 ppm	< 1.5 ppm
Transparency		≥ 98.0 %	99.8 %
UV Assay		≥ 98.0 %	100.0 %

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: BSI-ATM-0086

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:  Date: 2/3/25 Job Title: QA Technician I

Reviewed by:  Date: 2/3/25 Job Title: Senior Quality Manager