DCN: BSI-COA-0327 v.1.0



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

Effective Date:	22-Jan-2025	22-Jan-2028	: Date of Next Review
Prepared By:	Amy Yencho	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

## BIOTECH, LBLE, GMP BIO PHARMA GRADE / URID-4250

LOT: URID-N02-1024-0016

C<sub>9</sub>H<sub>12</sub>N<sub>2</sub>O<sub>6</sub> F.W. 244.20 g/mol CAS# 58-96-8

Manufacture Date: 10/04/24

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 %	
D' 1 1	TAMC	$\leq 100 \text{ CFU/g}$	< 100 CFU/g	
Bioburden	TYMC	$\leq 100 \text{ CFU/g}$	< 100 CFU/g	
Chloride		≤ 500 ppm	< 500 ppm	
Endotoxin		$\leq 0.5 \; EU/mg$	< 0.5 EU/mg	
Heavy Metals		≤ 10 ppm	< 10 ppm	
Identification, IR		Conforms to Reference Standard	Conforms to Reference Standards	
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	

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

<u>INTENDED USE:</u> 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: Anil McCall	Date:	Ce120125	_ Job Title: _	QA Tech III
Reviewed by: Can Allut	_Date: _	blaolas	_ Job Title:S	enior Quality Manager