

# BIO SPECTRA

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

Effective Date:	12-JUL-2023	12-JUL-2026	: Date of Next Review
Prepared By:	Amy Yenko	BSI-COA-0196 v.1.1	: Supersedes
QA/QC Approval:	Wayne Talamonti	Dora Meissner	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

## CERTIFICATE OF ANALYSIS

### URIDINE

### BIO EXCIPIENT GRADE / URID-3250-93

### LOT: URID-0123-00010

$C_9H_{12}N_2O_6$  ^ F.W. 244.20 g/mol ^ CAS# 58-96-8

Manufacture Date: 6/12/23 Retest Date: 6/30/25

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 6/24/23

Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS	SPECIFICATION	TEST RESULT
Appearance and Color	White to almost white powder	White to almost white powder
Assay (HPLC)	98.0 – 102.0%	100.5%
Bioburden	TAMC $\leq 100$ CFU/g	<100 CFU/g
	TYMC $\leq 100$ CFU/g	<100 CFU/g
Endotoxin	$\leq 0.5$ EU/mg	<0.5 EU/mg
Heavy Metals	$\leq 10$ ppm	<10 ppm
HPLC Purity	$\geq 99\%$	100%
Identification (IR)	Conforms to Spectrum of Reference Standard	Conforms to Spectrum of Reference Standard
Loss on Drying	$\leq 0.5\%$	0.1 %
Residue on Ignition	$\leq 0.1\%$	<0.1 %
Transparency	$\geq 98.0\%$	99.9%
UV Assay	$\geq 98.0\%$	98.8%

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 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 STATEMENT: Retest Date is assigned based on industry standard only.

Prepared by: *Amy Yenko* Date: 7/14/23 Job Title: QA Support Tech

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Reviewed by: Car Allert Date: 7/14/23 Job Title: Assoc. Director of Quality