

BIOSPECTRA

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

Effective Date:	12-JUL-2023	12-JUL-2026	: Date of Next Review
Prepared By:	Amy Yencho	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-3250-25

LOT: URID-N02-1224-0021

$C_9H_{12}N_2O_6$ * F.W. 244.20 g/mol * CAS# 58-96-8
 Manufacture Date: 10/10/24 Retest Date: 10/31/26
 Manufacturing Site: 100 Majestic Way, Bangor PA, 18013
 Packaging Date: 12/10/24
 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%	100.7%
Bioburden	TAMC ≤ 100 CFU/g	< 100 CFU/g
	TYMC ≤ 100 CFU/g	< 100 CFU/g
Endotoxin	≤ 0.5 EU/mg	< 0.5 EU/mg
Heavy Metals	≤ 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	$\geq 98.0\%$	99.8%
UV Assay	$\geq 98.0\%$	99.6%

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.

Prepared by: *David McCall* Date: 12/17/24 Job Title: QA Tech III

Reviewed by: *Joan Anglin* Date: 12/17/24 Job Title: QA Supervisor

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