BIOSPECTRA

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

Effective Date:	04-Feb-2025	04-Feb-2028	: Date of Next Review
Prepared By:	Taylor Yurick	BSI-COA-0196 v.1.2	: Supersedes
QA/QC Approval:	Jessica DeMaio	Hannah Kuchmas	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

CERTIFICATE OF ANALYSIS

URIDINE

BIO EXCIPIENT GRADE / URID-3250

LOT: URID-N02-0425-0013

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

Manufacture Date: 3/26/25 Retest Date: 3/31/27

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Site: 100 Majestic Way, Bangor PA, 18013

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

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: _____ Date: 4/24/25 Job Title: QA Tech I

Reviewed by: _____ Date: 4/24/25 Job Title: QA Tech III