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

Effective Date:	14-MAR-2024	14-MAR-2027	: Date of Next Review
Prepared By:	Amy Yencho	Not Applicable	: Supersedes
QA/QC Approval:	Carissa Albert	Dora Meissner	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

CERTIFICATE OF ANALYSIS

URIDINE

BIO EXCIPIENT GRADE / URID-3250-25

LOT: URID-0124-00006

$C_9H_{12}N_2O_6$ ⅄ F.W. 244.20 g/mol ⅄ CAS# 58-96-8
Manufacture Date: 02/26/24 Retest Date: 02/28/25
Manufacturing Site: 100 Majestic Way, Bangor PA, 18013
Packaging Date: 03/20/24
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%	100.6%
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 currently undergoing a Prospective Validation which has been approved for release based on the analysis for this product code. It is intended for use as an Excipient at the completion of the Prospective Validation and 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: Amil McCall Date: 3/26/24 Job Title: QA Tech I

Reviewed by: Jora Bergh Date: 3/26/24 Job Title: QA Supervisor

The information contained herein is the confidential property of BioSpectra. The recipient is responsible for its safe-keeping and the prevention of unauthorized appropriation, use, disclosure and copying.