

BIOSPECTRA

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

Effective Date:	15-Aug-2022	15-Aug-2025	: Date of Next Review
Prepared By:	Amy Hosein	BSI-COA-0196 v.1.0	: Supersedes
QA/QC Approval:	Carissa McCollian	Amy Yencho	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

CERTIFICATE OF ANALYSIS

URIDINE

BIO EXCIPIENT GRADE / URID-3250-10

LOT: URID-0122-00009

C₉H₁₂N₂O₆ * F.W. 244.20 g/mol * CAS# 58-96-8

Manufacture Date: 6/29/22

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 7/15/22

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
Bioburden	TAMC	≤ 100CFU/g
	TYMC	≤ 100CFU/g
Endotoxin	≤ 0.5 EU/mg	< 0.5 EU/mg
Heavy Metals	≤ 10 ppm	< 10 ppm
HPLC Purity	95.0 – 105.0%	99.9%
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%	99.6%
UV Assay	≥ 98.0%	98.4%

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: A Retest Date is to be determined based on the data obtained from the stability study.

Prepared by: B. B. Date: 8/22/22 Job Title: QA Specialist

Reviewed by: Carissa Allert Date: 8/22/22 Job Title: QA Manager

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