

BIOSPECTRA

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

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|----------------------|--|--------------------|-----------------------|
| 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 Yenko | : Management Approval |
| Reason for Revision: | See Revision History in MasterControl. | | |

CERTIFICATE OF ANALYSIS

URIDINE

BIO EXCIPIENT GRADE / URID-3250-10

LOT: URID-0122-00010

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

Manufacture Date: 7/5/22

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 7/16/22

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% | < 0.5 % |
| Residue on Ignition | ≤ 0.1% | < 0.1 % |
| Transparency | ≥ 98.0% | 99.7% |
| UV Assay | ≥ 98.0% | 100.1% |

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: BH Date: 8/22/22 Job Title: QA Specialist

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

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