DCN: BSI-COA-0196 v.1.2



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-3250-92 LOT: URID-0124-00012

C₉H₁₂N₂O₆ \star F.W. 244.20 g/mol \star CAS# 58-96-8 Manufacture Date: 05/31/23 Retest Date: 05/31/25 Manufacturing Site: 100 Majestic Way, Bangor PA, 18013 Packaging Date: 07/19/24

Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS	2	SPECIFICATION	TEST RESULT
Appearance and Color		White to almost white powder	White to almost white powder
Assay (HPLC)		98.0 - 102.0%	100.3%
Bioburden TAMC TYMC		\leq 100CFU/g \leq 100CFU/g	<100CFU/g <100CFU/g
Endotoxin		\leq 0.5 EU/mg	<0.5EU/mg
Heavy Metals		$\leq 10 \text{ ppm}$	<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%	<0.5 %
Residue on Ignition		$\leq 0.1\%$	<0.1 %
Transparency		\geq 98.0%	99.8%
UV Assay		≥ 98.0%	99.2%

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: BSI-ATM-0086

<u>INTENDED USE:</u> 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.

MUCK Date: 123 24 Job Title: QA Prepared by: _____ Date: ____/23/27____ Job Title: ____A Reviewed by:

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