

BIOSPECTRA

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

Effective Date:	24-Apr-2020	24-Apr-2023	: Date of Next Review
Prepared By:	Kyle Snyder	18-002383 v.2.0	: Supersedes
QA/QC Approval:	Carissa McCollian	Wendy Santay	: Management Approval
Reason for Revision:	See Revision History in ensur.		

CERTIFICATE OF ANALYSIS

TRIS

BIO EXCIPIENT GRADE / TR3251-K010

LOT: TR3251-012-0121

 $\text{NH}_2\text{C}(\text{CH}_2\text{OH})_3$ ^ F.W. 121.14 g/mol. ^ CAS# 77-86-1

Manufacturing Date: 12/18/20 Retest Date: 12/31/22

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Date: 1/23/21 Packaging Site: 100 Majestic Way, Bangor PA, 18013

Meets or Exceeds USP Specifications

ANALYSIS		SPECIFICATION	TEST RESULT
Absorbance (40%)	290nm	0.2 a.u. max.	<0.2 a.u.
Appearance and Color		White / Crystals	White / Crystals
Assay		99.0 - 101.0%	100.2%
Bioburden	TAMC	≤ 1000 CFU/g	<10 CFU/g
	TYMC	≤ 100 CFU/g	<10 CFU/g
Chloride		0.01% max.	<0.01%
Endotoxin Concentration		≤ 30 EU/g	<1 EU/g
	DNase	None Detected	None Detected
Enzymes	Protease	None Detected	None Detected
	RNase	None Detected	None Detected
Heavy Metals (Pb)		5 ppm max.	< 5 ppm
Identification B		Passes Test	Passes Test
Identification C		Passes Test	Passes Test
Identification (IR)		Passes Test	Passes Test
Insoluble Matter		0.005% max	0.005%
Karl Fischer Water		2% max.	<2%
Loss on Drying		0.6% max.	0.1%
Melting Range		168 – 172°C	170 - 172 °C
Microorganisms	Bile tolerant Gram Neg. Bacteria	Absence in 1g	Absence in 1g
	<i>Escherichia coli</i>	Absence in 1g	Absence in 1g
	<i>Pseudomonas aeruginosa</i>	Absence in 1g	Absence in 1g
	<i>Staphylococcus aureus</i>	Absence in 1g	Absence in 1g

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ANALYSIS		SPECIFICATION	TEST RESULT
Microorganisms	<i>Candida albicans</i>	Absence in 1g	Absence in 1g
	<i>Salmonella sp</i>	Absence in 10g	Absence in 10g
pH (5%)		10.0 – 11.5	10.8 @ 23.4 °C
Related Substances (TLC)		1% max.	<1%
Residue on Ignition		0.1% max.	<0.1%
Trace Metals	Arsenic (As)	5 ppm max.	< 5 ppm
	Calcium (Ca)	5 ppm max.	< 5 ppm
	Copper (Cu)	5 ppm max.	< 5 ppm
	Iron (Fe)	5 ppm max.	< 5 ppm
	Lead (Pb)	5 ppm max.	< 5 ppm
	Magnesium (Mg)	5 ppm max.	< 5 ppm
Nickel (Ni)		15 ppm max.	< 15 ppm

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: 16-000496

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.

OVI STATEMENT: Based on the manufacturing process and the controlled handling, storage and analysis of this product, this product complies with the requirements and specifications listed in the current USP method <467> Tables 1, 2, 3, or 4.

Prepared by: Jason Steghe Date: 1/29/21 Job Title: QA Specialist

Reviewed by: Wing Chan Date: 01/29/21 Job Title: QI Manager