

BIOSPECTRA

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

Effective Date:	05-Apr-2024	05-Apr-2027	: Date of Next Review
Prepared By:	Hannah Kuchmas	BSI-COA-0091 v.4.1	: Supersedes
QA/QC Approval:	Taylor Yurick	Jessica DeMaio	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

CERTIFICATE OF ANALYSIS

TRIS

BIO EXCIPIENT GRADE / TRIS-3251-95

LOT: TRIS-0124-00154

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

Manufacturing Date: 07/19/24 Expiration Date: 07/31/27

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Date: 08/16/24 Packaging Site: 100 Majestic Way, Bangor PA, 18013

Meets or Exceeds USP Specifications

ANALYSIS	SPECIFICATION	TEST RESULT	
Absorbance (1M)	260nm	≤ 0.06 a.u.	< 0.06 a.u.
	280nm	≤ 0.06 a.u.	< 0.06 a.u.
	430nm	≤ 0.01 a.u.	< 0.01 a.u.
Absorbance (10%)	260nm	≤ 0.03 a.u.	< 0.03 a.u.
	280nm	≤ 0.02 a.u.	< 0.02 a.u.
	430nm	≤ 0.004 a.u.	< 0.004 a.u.
Absorbance (40%)	290nm	≤ 0.2 a.u.	< 0.2 a.u.
APHA Color, 20% Solution	≤ 20 APHA	< 20 APHA	
Appearance and Color	White/Crystals	Passes Test	
Appearance of Solution (EP)	Passes Test	Passes Test	
Assay (Dried Basis) (USP/EP/ChP/JPC)	99.0 – 100.5%	99.6%	
Assay (Ultrapure, Dried Basis)	≥ 99.9%	100.2 %	
Chloride (ChP/EP)	≤ 100 ppm	<100 ppm	
Clarity and Color of Solution (ChP/JPC)	Passes Test	Passes Test	
Endotoxins	≤ 2.5 EU/g	< 1.2 EU/g	
Enzymes	DNase	None Detected	None Detected
	Protease	None Detected	None Detected
	RNase	None Detected	None Detected
Heavy Metals (as Pb) (ChP/JPC)	≤ 1 ppm	< 0.30 ppm	
Identification IR (USP-A/ChP-3/EP-C)	Passes Test	Passes Test	
Identification A (JPC)	Passes Test	Passes Test	
Identification B (USP/ChP-1)	Passes Test	Passes Test	
Identification B (JPC)	Passes Test	Passes Test	
Identification C (USP)	Passes Test	Passes Test	
Identification D (EP/ChP-2)	Passes Test	Passes Test	
Insoluble Matter	≤ 0.005%	0.003%	
Karl Fischer Water	≤ 1.0%	0.2%	

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ANALYSIS		SPECIFICATION	TEST RESULT
Loss on Drying (USP/ChP/EP/JPC)		≤ 0.3%	0.2%
Melting Range (USP/ChP/IDB-EP/JPC)		168 – 172°C	171 - 172 °C
Methanol		≤ 3000 ppm	< 153 ppm
TAMC		≤ 100 CFU/g	< 10 CFU/g
TYMC		≤ 100 CFU/g	< 10 CFU/g
Bile tolerant Gram Neg. Bacteria		Absence in 1g	Absence in 1g
Microbial Content	<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
	<i>Candida albicans</i>	Absence in 1g	Absence in 1g
	<i>Salmonella sp</i>	Absence in 10g	Absence in 10g
pH (5%) (USP/IDA-EP/ChP)		10.0 – 11.5	10.8
pH (1 in 100) (JPC)		10.3 – 10.7	10.5
Related Substances (ChP/EP)		≤ 0.1%	< 0.1%
Residue on Ignition/Sulfated Ash (USP/ChP/EP/JPC)		≤ 0.05%	< 0.01%
Arsenic (As)		≤ 1.6 ppm	< 0.45 ppm
Calcium (Ca)		≤ 1 ppm	< 0.60 ppm
Copper (Cu)		≤ 1 ppm	< 0.15 ppm
Iron (Fe)		≤ 1 ppm	< 0.30 ppm
Trace Metals	Lead (Pb)	≤ 1 ppm	< 0.30 ppm
	Magnesium (Mg)	≤ 5 ppm	< 0.60 ppm
	Manganese (Mn)	≤ 1 ppm	< 0.60 ppm
	Nickel (Ni)	≤ 15 ppm	< 0.75 ppm
	Zinc (Zn)	≤ 1 ppm	< 0.60 ppm

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: BSI-ATM-0007

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: Amil McCall Date: 8/28/24 Job Title: QA Tech 1

Reviewed by: Jason Bligh Date: 8/28/24 Job Title: QA Supervisor