

BIOSPECTRA

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

Effective Date:	04-APR-2024	04-APR-2027	: Date of Next Review
Prepared By:	Carissa Albert	BSI-COA-0139 v.8.1	: Supersedes
QA/QC Approval:	Hannah Kuchmas	Wayne Talamonti	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

CERTIFICATE OF ANALYSIS

TRIS

BIO EXCIPIENT GRADE / TRIS-3255-12

LOT: TRIS-S01-1124-0216

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

Manufacturing Date: 09/23/24 Expiration Date: 09/30/27

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Date: 11/13/24 Packaging Site: 100 Majestic Way, Bangor PA, 18013

Meets or Exceeds USP, EP and JPC Specifications

USP COMPENDIA

ANALYSIS	SPECIFICATION	TEST RESULT
Assay (Dried Basis)	99.0-101.0%	100.0%
Identification A	Passes Test	Passes Test
Identification B	Passes Test	Passes Test
Identification C	Passes Test	Passes Test
Loss on Drying	1.0% max.	0.2%
Melting Range	168-172°C	171 - 172 °C
pH (1 in 20)	10.0 – 11.5	10.9
Residue on Ignition	0.1% max.	< 0.1%

EP COMPENDIA

ANALYSIS	SPECIFICATION	TEST RESULT
Appearance of Solution	Passes Test	Passes Test
Assay (Dried Basis)	99.0-100.5%	100.0%
Chloride (Cl)	≤ 100 ppm	< 100 ppm
Identification A	Passes Test	Passes Test
Identification B (Melting Range)	168-172°C	171 - 172 °C
Identification C	Passes Test	Passes Test
Identification D	Passes Test	Passes Test
Iron (Fe)	10 ppm max.	< 0.30 ppm
Loss on Drying @105°C	0.5% max.	0.2%

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ANALYSIS	SPECIFICATION	TEST RESULT
pH (5%)	10.0-11.5	10.9
Related Substances	≤ 1.0%	< 0.03%
Sulfated Ash	0.1% max.	< 0.1%

JPC ANALYSIS

ANALYSIS	SPECIFICATION	TEST RESULT
Arsenic (As)	1.6 ppm max.	≤ 1.6 ppm
Assay (Dried Basis)	99.0-101.0%	100.0%
Clarity and Color of Solution	Passes Test	Passes Test
Heavy Metals	8 ppm max.	≤ 8 ppm
Identification A	Passes Test	Passes Test
Identification B	Passes Test	Passes Test
Loss on Drying	0.5% max.	0.2%
Melting Point	168-172°C	171 - 172 °C
pH	10.3 – 10.7	10.6
Residue on Ignition	0.1% max.	< 0.1%

ADDITIONAL ANALYSES

ANALYSIS	SPECIFICATION	TEST RESULT
Appearance and Color	White, crystalline powder to needle-like crystals	White, crystalline powder to needle-like crystals
	260nm	0.06 a.u. max
Absorbance (1M)	280nm	0.06 a.u. max
	430nm	0.01 a.u. max
	260nm	0.03 a.u. max.
Absorbance (10%)	280nm	0.02 a.u. max.
	430nm	0.004 a.u. max.
Absorbance (40%)	290nm	0.2 a.u. max.
APHA Color, 20% Solution	20 APHA max.	< 20 APHA
Assay (Ultrapure, Dried Basis)	99.9% min	99.9%
Endotoxins	≤ 2.5 EU/g	< 1.0 EU/g
	DNase	None
Enzymes	Protease	None
	RNase	None

ANALYSIS		SPECIFICATION	TEST RESULT
Heavy Metals (As Pb)		1 ppm max.	≤ 1 ppm
Insoluble Matter		0.005% max.	0.001%
Karl Fischer Water		1.0% max.	0.3%
Loss on Drying		0.3% max.	0.2%
Microbial Content	TAMC	≤ 100 CFU/g	< 10 CFU/g
	TYMC	≤ 100 CFU/g	< 10 CFU/g
Related Substances		0.1% max.	< 0.03%
Residue on Ignition		0.05% max.	< 0.01%
Arsenic (As)		≤ 1.6 ppm	≤ 1.6 ppm
Calcium (Ca)		≤ 1 ppm	≤ 1 ppm
Copper (Cu)		≤ 1 ppm	≤ 1 ppm
Trace Metals	Iron (Fe)	≤ 1 ppm	≤ 1 ppm
	Lead (Pb)	≤ 1 ppm	≤ 1 ppm
	Magnesium (Mg)	≤ 5 ppm	≤ 5 ppm
	Manganese (Mn)	≤ 1 ppm	≤ 1 ppm
	Zinc (Zn)	≤ 1 ppm	≤ 1 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.

RESIDUAL SOLVENTS: 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: Shel McCall Date: 11/22/24 Job Title: QA Tech III

Reviewed by: John Bingham Date: 11/22/24 Job Title: QA Supervisor

