

BIO SPECTRA

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

Effective Date:	24-Jul-2020	24-Jul-2023	: Date of Next Review
Prepared By:	Amy Hosein	19-002973 v.7.0	: Supersedes
QA/QC Approval:	Carissa McCollian	Amy Yencho	: Management Approval
Reason for Revision:	See Revision History in ensur.		

CERTIFICATE OF ANALYSIS

TRIS

BIO EXCIPIENT GRADE / TR3255-G500

LOT: TR3255-014-0820

NH₂C(CH₂OH)₃; * F.W. 121.14 g mol. * CAS# 77-86-1
 Manufacturing Date: 5/3/20 Retest Date: 5/31/22
 Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360
 Packaging Date: 8/25/20 Packaging Site: 100 Majestic Way, Bangor PA, 18013
 Meets or Exceeds USP, EP and JPC Specifications

USP COMPENDIA

ANALYSIS	SPECIFICATION	TEST RESULT
Appearance and Color	White, crystalline powder to needle-like crystals	White, crystalline powder to needle-like crystals
Assay (Dried Basis)	99.0-101.0%	100.2%
Identification A	Passes Test	Passes Test
Identification B	Passes Test	Passes Test
Identification C	Passes Test	Passes Test
Loss on Drying	1.0% max.	0.3%
Melting Range	168-172°C	169 - 171 °C
pH (1 in 20)	10.0 – 11.5	10.7
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%	100.2%
Chloride (Cl)	≤ 100 ppm	<100 ppm
Identification A	Passes Test	Passes Test
Identification B (Melting Range)	168-172°C	169 - 171 °C
Identification C	Passes Test	Passes Test
Identification D	Passes Test	Passes Test
Iron (Fe)	10 ppm max.	<10 ppm
Loss on Drying @105°C	0.5% max.	0.3%
pH (5%)	10.0-11.5	10.7
Related Substances	≤ 1.0%	<1.0%

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Sulfated Ash	0.1% max.	<0.1%
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JPC ANALYSIS		
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ANALYSIS	SPECIFICATION	TEST RESULT
Arsenic (As)	1.6 ppm max.	≤ 1.6ppm
Assay (Dried Basis)	99.0-101.0%	100.2%
Clarity and Color of Solution	Passes Test	Passes Test
Heavy Metals	8 ppm max.	≤ 8ppm
Identification A	Passes Test	Passes Test
Identification B	Passes Test	Passes Test
Loss on Drying	0.5% max.	0.3%
Melting Point	168-172°C	169 - 171 °C
pH	10.3 – 10.7	10.4
Residue on Ignition	0.1% max.	<0.1%

ANALYSIS	SPECIFICATION	TEST RESULT
	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	100.2%
Endotoxins	≤ 2.5 EU/g	<1.2 EU/g
	DNase	None
Enzymes	Protease	None
	RNase	None
Heavy Metals (As Pb)	1 ppm max.	≤ 1 ppm
Insoluble Matter	0.005% max.	<0.005%
Karl Fischer Water	1.0% max.	0.1%
Loss on Drying	0.3% max.	0.3%
	TAMC	≤ 100 CFU/g
Microbial Content	TYMC	≤ 100 CFU/g
Related Substances	0.1% max.	<0.1%
Residue on Ignition	0.05% max.	<0.05%
	Arsenic (As)	< 1.6 ppm
	Calcium (Ca)	< 1 ppm
Trace Metals	Copper (Cu)	< 1 ppm
	Iron (Fe)	< 1 ppm
	Lead (Pb)	< 1 ppm

	ANALYSIS	SPECIFICATION	TEST RESULT
Trace Metals	Magnesium (Mg)	< 5 ppm	< 5ppm
	Manganese (Mn)	< 1 ppm	< 1ppm
	Zinc (Zn)	< 1 ppm	< 1ppm

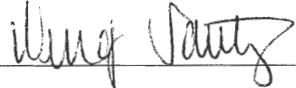
COUNTRY OF ORIGIN: U.S.A.

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.

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:  Date: 8/25/20 Job Title: QA Supervisor

Reviewed by:  Date: 08/25/20 Job Title: QA Manager