

BIOSPECTRA

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

Effective Date:	27-Nov-2019	26-Nov-2022	: Date of Next Review
Prepared By:	Kyle Snyder	19-002973 v.2.0	: Supersedes
QA/QC Approval:	Carissa McCollian	Amy Yenko	: Management Approval
Reason for Revision:	See Revision History in ensur.		

CERTIFICATE OF ANALYSIS

TRIS

BIO EXCIPIENT GRADE / TR3255-G100

LOT: TR3255-001-1119

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

Manufacture Date: 10/26/2018 Retest Date: 10/31/2020

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Date: 11/25/2019 Packaging Site: 100 Majestic Way, Bangor PA, 18013

Meets or Exceeds USP Specifications

USP COMPENDIA

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 – 100.5%	100.2%
Enzymes	RNase	None Detected	None Detected
	DNase	None Detected	None Detected
	Protease	None Detected	None Detected
Identification A		Passes Test	Passes Test
Identification B		Passes Test	Passes Test
Identification C		Passes Test	Passes Test
Insoluble Matter		0.005% max	<0.001%
Karl Fischer Water		2.0% max.	0.1%
Loss on Drying		1.0% max.	0.3%
Melting Range		168-172°C	169 - 170 °C
pH (1 in 20)		10.0 – 11.5	10.8 @ 23.70 °C
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)	≤ 100ppm	<100ppm
Identification B	Passes Test	Passes Test
Identification C	Passes Test	Passes Test
Iron (Fe)	≤ 10ppm	<5ppm
Loss on Drying @105°C	≤ 0.5%	0.3%
pH (5%)	10.0-11.5	10.8 @ 23.70 °C
Related Substances	≤ 1.0%	<1.0%
Sulfated Ash	≤ 0.1%	<0.1%

ANALYSIS	SPECIFICATION	TEST RESULT
Endotoxins	≤ 2.5 EU/g	<1.5 EU/g
Heavy Metals (as Pb)	≤ 1ppm	≤ 1ppm
Microbial Content	TAMC TYMC	<10 CFU/g <10 CFU/g
	Arsenic (As)	5 ppm max. ≤ 5ppm
	Calcium (Ca)	5 ppm max. ≤ 5ppm
	Copper (Cu)	5 ppm max. ≤ 5ppm
Trace Metals	Iron (Fe)	5 ppm max. ≤ 5ppm
	Lead (Pb)	5 ppm max. ≤ 5ppm
	Magnesium (Mg)	5 ppm max. ≤ 5ppm

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: 16-000496

INTENDED USE: Material represented by this Certificate of Analysis is suitable to be used only as the following: ICH Q7 Compliant cGMP Manufactured Excipient for use in further Manufacturing. The material represented by this Certificate of Analysis is not suitable to be used as an Active Pharmaceutical Ingredient, Drug Product or Household Item.

Prepared by:  Date: 11/27/19

Reviewed by:  Date: 11/27/19