

# BIOSPECTRA

100 Majestic Way, Bangor, PA 18013 / [www.biospectra.us](http://www.biospectra.us)

Effective Date:	13-Apr-2021	13-Apr-2024	: Date of Next Review
Prepared By:	Amy Hosein	21-003694 v.2.0	: Supersedes
QA/QC Approval:	Carissa McCollian	Amy Yencho	: Management Approval
Reason for Revision:	See Revision History in ensur.		

## CERTIFICATE OF ANALYSIS

### TRIS HYDROCHLORIDE

### BIO EXCIPIENT GRADE / NEW CODE THCL-3259-92

#### (HISTORICAL CODE TH3259-G100)

#### LOT: THCL-0121-00243

$\text{NH}_2\text{C}(\text{CH}_2\text{OH})_3 \cdot \text{HCl}$  ^ F.W. 157.60 g/mol. ^ CAS# 1185-53-1

Manufacturing Date: 7/7/21      Retest Date: 7/31/23

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Date: 12/15/21 Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS	SPECIFICATION	TEST RESULT
Absorbance (1M)	260 nm	≤ 0.06 a.u.
	280 nm	≤ 0.06 a.u.
	400 nm	≤ 0.01 a.u.
Appearance and Color	White / Crystals	Passes Test
Assay, Dried	99.5 – 101.0%	99.5%
Bioburden	≤ 100 CFU/g	<100 CFU/g
Endotoxin	≤ 2.5 EU/g	<2.0 EU/g
Enzymes	DNase	None Detected
	RNase	None Detected
	Protease	None Detected
Heavy Metals	2 ppm max.	< 2 ppm
Identification	(IR)	Passes Test
	(Chloride)	Passes Test
Insoluble Matter	0.001% max.	0.001%
Loss on Drying @ 105°C	≤ 0.5%	0.3%
Melting Range	150 – 152 °C	151-152°C
pH (1% Aqueous Solution)	4.0 – 5.0	4.8
pH (0.5M) @ 25°C	3.5 – 5.0	4.4
pK <sub>a</sub>	8.0 – 8.4	8.2
Residue on Ignition	0.1% max.	<0.1%

ANALYSIS	SPECIFICATION	TEST RESULT
Solubility 35%	Passes Test	Passes Test
Sulfated Ash (EP)	≤ 300 ppm	<200 ppm
Arsenic (As)	1 ppm max.	<1 ppm
Cadmium (Cd)	1 ppm max.	<1 ppm
Calcium (Ca)	1 ppm max.	1 ppm
Trace Metals	Copper (Cu)	1 ppm max.
	Iron (Fe)	1 ppm max.
	Lead (Pb)	1 ppm max.
	Magnesium (Mg)	1 ppm max.
Water (Karl Fischer)	0.5% max.	0.4 %

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: 16-000042

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: Jason Shukh Date: 12/16/21 Job Title: QA Specialist

Reviewed by: Cir Date: 12/16/21 Job Title: QA Manager