

BIOSPECTRA

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

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

CERTIFICATE OF ANALYSIS
TRIS HYDROCHLORIDE
BIO EXCIPIENT GRADE / NEW CODE THCL-3259-25
(HISTORICAL CODE TH3259-K025)
LOT: THCL-0121-00139

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

Manufacturing Date: 08/16/21 Retest Date: 08/31/23

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Date: 08/31/21 Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS	SPECIFICATION	TEST RESULT	
Absorbance (1M)	260 nm	≤ 0.06 a.u.	0.01 a.u.
	280 nm	≤ 0.06 a.u.	< 0.06 a.u.
	400 nm	≤ 0.01 a.u.	< 0.01 a.u.
Appearance and Color	White / Crystals	Passes Test	
Assay, Dried	99.5 – 101.0%	99.5%	
Bioburden	≤ 100 CFU/g	< 10 CFU/g	
Endotoxin	≤ 2.5 EU/g	< 2.0 EU/g	
Enzymes	DNase	None Detected	None Detected
	RNase	None Detected	None Detected
	Protease	None Detected	None Detected
Heavy Metals	2 ppm max.	< 2 ppm	
Identification	(IR)	Passes Test	Passes Test
	(Chloride)	Passes Test	Passes Test
Insoluble Matter	0.001% max.	< 0.001%	
Loss on Drying @ 105°C	≤ 0.5%	0.1%	
Melting Range	150 – 152 °C	150-152°C	
pH (1% Aqueous Solution)	4.0 – 5.0	4.9	
pH (0.5M) @ 25°C	3.5 – 5.0	4.0	
pK _a	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	< 300 ppm
	Arsenic (As)	< 1 ppm
	Cadmium (Cd)	< 1 ppm
	Calcium (Ca)	1 ppm
Trace Metals	Copper (Cu)	< 1 ppm
	Iron (Fe)	< 1 ppm
	Lead (Pb)	< 1 ppm
	Magnesium (Mg)	< 1 ppm
Water (Karl Fischer)	0.5% max.	0.3 %

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: Jack S. L. Date: 09/09/21 Job Title: CAPA Specialist

Reviewed by: Jason Hughes Date: 9/9/21 Job Title: QA Specialist