

# BIOSPECTRA

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

## TRIS (TROMETHAMINE) SPECIFICATION SHEET BIO EXCIPIENT GRADE/TR3252

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

USP COMPENDIA		
ANALYSIS		SPECIFICATIONS
Appearance and Color		White/Crystals
Assay		99.0 – 101.0%
Endotoxin		≤2.5 EU/g
Identification A		Passes Test
Identification B		Passes Test
Identification C		Passes Test
Loss on Drying		≤1.0%
Melting Range		168 - 172 °C
pH (1 in 20)		10.0 – 11.5
Residue on Ignition		≤0.1%
Microbial Content	TAMC	≤500 CFU/g
	TYMC	≤200 CFU/g
	Total Bioburden	≤500 CFU/g

EP COMPENDIA	
ANALYSIS	SPECIFICATIONS
Appearance of Solution	Passes Test
Assay	99.0-100.5%
Chloride (Cl)	≤100 ppm
Identification A	Passes Test
Identification B	168 - 174°C
Identification C	Passes Test
Iron (Fe)	<10ppm
Loss on Drying at 105°C	≤0.5%
pH	10.0 – 11.5
Related Substances	≤1.0%
Sulfated Ash	≤0.1%

**RESIDUAL SOLVENTS STATEMENT:** 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.

**FREE FLOWING MATERIAL STATEMENT:** This material was manufactured utilizing multiple proprietary purification, drying and packaging processes to increase the free-flowing nature of the product in the final package. The final packaging configuration is also designed to help maintain those characteristics.

**TRUSCAN STATEMENT:** Identification A (EP) is the alternate method for Identification by TruScan to confirm the identity of this product.