BIOSPECTRA
Bulk cGMP Fine Chemical Manufacturer

EXCIPIENT
ICH Q7 GMP MANUFACTURED PRODUCT

TRIS/TROMETHAMINE

MEETS USP/EP/JPC, BET*, GMP

CAS #: 77-86-1 **Formula: $NH_2C(CH_2OH)_3$** **F.W.: 121.14 g/mol**

TRIS-3255

BIO EXCIPIENT GRADE

ANALYSIS		SPECIFICATIONS
Absorbance (1M)	260nm 280nm 430nm	< = 0.06 a.u. < = 0.06 a.u. < = 0.01 a.u.
Absorbance (10%)	260nm 280nm 430nm	< = 0.03 a.u. < = 0.02 a.u. < = 0.004 a.u.
Absorbance (40%)	290nm	< = 0.2 a.u.
APHA Color (20% Solution)		< = 20 APHA
Appearance and Color		White, Crystalline Powder to Needle Like Crystals
Appearance of Solution (EP)		Passes Test
Assay, Dried Basis (USP/EP/JPC)		99.0 – 100.5%
Assay, Dried Basis (Ultrapure)		> = 99.9%
Chloride (EP)		< = 100 ppm
Clarity and Color of Solution (JPC)		Passes Test
Endotoxin		< = 2.5 EU/g
Enzymes	DNase Protease RNase	None Detected None Detected None Detected
Identification, IR (USP-A /EP-C)		Conforms to Reference Standard
Identification A (EP), pH 5% (USP/EP)		10.0 – 11.5
Identification A (JPC)		Passes Test
Identification B (USP)		Passes Test
Identification B (EP), Melting Range (USP/JPC)		168 – 172˚C

ANALYSIS		SPECIFICATIONS
Identification B (JPC)		Passes Test
Identification C (USP)		Passes Test
Identification D (EP)		Conforms to Reference Standard
Insoluble Matter		< = 0.005%
Loss on Drying (USP/EP/JPC)		< = 0.3%
Microbial Content	TAMC TYMC	< = 100 CFU/g < = 100 CFU/g
pH (1 in 100) (JPC)		10.3 – 10.7
Related Substances (EP)		< = 0.1%
Residue on Ignition/Sulfated Ash (USP/EP/JPC)		< = 0.05%
Trace Metals	Arsenic (As) (JPC) Calcium (Ca) Copper (Cu) Iron (Fe) (EP) Lead (Pb) (JPC) Magnesium (Mg) Manganese (Mn) Zinc (Zn)	< = 1.6 ppm < = 1 ppm < = 1 ppm < = 1 ppm < = 1 ppm < = 5 ppm < = 1 ppm < = 1 ppm
Water, KF		< = 1.0%

*Bioburden and Endotoxin Tested

Refer to page 2 for additional product details.

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General Product Overview

Tris/Tromethamine is commonly used as a buffer and excipient in downstream biological applications during the manufacture of drug products. Tris is considered a Good's buffer because it has low UV absorptivity, minimal reactivity, stable pH and is soluble in water.

Industry Application

Suitable for use as a cGMP chemical in pharmaceutical manufacturing processes and products.

Key Product Features

- The manufacturing of Tris/Tromethamine, TRIS-3255 is performed at BioSpectra's Stroudsburg, PA facility.
- Appears as a white, crystalline powder to needle like crystals
- Manufactured in accordance with ICH Q7
- Manufactured in an enzyme free, hormone free and animal free environment
- Contains no known major food allergens (as defined by FDA and WHO)
- The final product and its raw materials are not derived from nor come into contact with animal parts, animal products, and/or animal byproducts or derivatives.
- Is not subject to genetic modification
- Synonyms: Trometamol; THAM; Tris (Hydroxymethyl) Aminomethane; Trisaminol; Trismethylolaminomethane; 2-Amino-2 (Hydroxymethyl) propane-1,3-diol

Storage and Shipping Conditions

Refer to SDS.

Standard Shelf-Life Policy

Unless otherwise noted on the Shelf-Life Statement and CoA, this product has a 2-year retest date supported by a 3-year ICH Q1 Stability Study (if one is completed).

Package Sizes

10kg, 25kg and 50kg

Click here to view SDS, CoAs and other supporting regulatory documents on our website.