

TRIS

USP, EP, JPC, LBLE, GMP, EXCIPIENT

CAS #: 77-86-1

 Formula: $\text{NH}_2\text{C}(\text{CH}_2\text{OH})_3$

F.W.: 121.14 g/mol

TRIS-3255

Bio EXCIPIENT GRADE

ANALYSIS	SPECIFICATIONS	
Absorbance (1M)	260nm	< = 0.06 a.u.
	280nm	< = 0.06 a.u.
	430nm	< = 0.01 a.u.
Absorbance (10%)	260nm	< = 0.03 a.u.
	280nm	< = 0.02 a.u.
	430nm	< = 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	None Detected
	Protease	None Detected
	RNAse	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	< = 100 CFU/g
	TYMC	< = 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)	< = 1.6 ppm
	Calcium (Ca)	< = 1 ppm
	Copper (Cu)	< = 1 ppm
	Iron (Fe) (EP)	< = 1 ppm
	Lead (Pb) (JPC)	< = 1 ppm
	Magnesium (Mg)	< = 5 ppm
	Manganese (Mn)	< = 1 ppm
	Zinc (Zn)	< = 1 ppm
Water, KF	< = 1.0%	

Refer to page 2 for additional product details.

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General Product Overview

Tromethamine (Tris) 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, 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; Tromethamine

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 pails

[Click here to view SDS, CoAs and other supporting regulatory documents on our website.](#)

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