

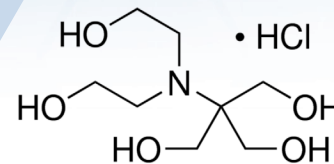
BIS-TRIS HCl, LBLE, GMP Excipient Grade

Low Bioburden, Low Endotoxin, GMP Manufactured

INTENDED FOR USE AS AN EXCIPIENT

BIS-TRIS HCl, is the chlorinated version of BIS-TRIS, a zwitterionic biological buffer often used in biological pharmaceutical manufacturing for extraction, separation and purification, as well as an intermediate in synthetic reactions and as a process aid in peptide synthesis.

Lead Time: If Stock: 1-month/ If No Stock: 3-months
Minimum Order Quantity: If Stock-50kg/ No Stock-150kg



CAS #: 124763-51-5

Molecular Formula:

$C_8H_{19}NO_5 \cdot HCl$

F.W.: 245.70 g/mol

pH 1% @ 25°C: 3.8 - 4.4

BIO PHARMA GRADE | Product Code: BTHY-4250

$C_8H_{19}NO_5 \cdot HCl \cdot F.W.:$ 245.70 g/mol • CAS# 124763-51-5

ANALYSIS		SPECIFICATIONS
Absorbance (0.1M)	260 nm 290 nm	≤0.05 a.u. ≤0.03 a.u.
Appearance and Color		White Crystals
Assay (Titration)		≥99.0%
Bioburden		≤100 CFU/g
Endotoxin		≤50 CFU/g
Enzymes	DNase Protease RNase	None Detected None Detected None Detected
Identification (IR)		Passes Test
pH (1.0% @ 25°C)		3.8 – 4.4
Solubility (0.1M)		Passes Test
Water Content (KF)		≤1.0%



General Product Description:

- Bis-Tris HCl is produced at our cGMP platform in India and then shipped to our Bangor, PA facility where it is tested and repackaged under cGMP conditions.
- Bis-Tris HCl is a White Crystalline product
- Molecular Formula: $C_8H_{19}NO_5 \cdot HCl$
- Molecular Weight: 245.70 g/mol
- CAS Number: 124763-51-5
- There are no known major food allergens (as defined by FDA and WHO) in the manufacture of this product.
- Biospectra certifies that all Bis-Tris HCl BTHY-4250 manufactured at our cGMP platform in India and its raw materials are not derived from or come in contact with animal parts, products and/or byproducts. Bis-Tris HCl manufactured at BioSpectra and any raw materials used in the manufacture of Bis-Tris HCl at BioSpectra are not subject to genetic modification.
- Synonyms: 2,2-Bis(hydroxymethyl)-2,2',2''-nitrioltriethanol, BIS-TRIS hydrochloride, Bis(2-hydroxyethyl)aminotris(hydroxymethyl)methane, 2-Bis(2-hydroxyethyl)amino-2-(hydroxymethyl)-1,3-propanediol

GMP Compliance:

Bio Pharma Grade Bis-Tris HCl BTHY-4250 is suitable for use as an excipient. It is manufactured in accordance with the IPEC-PQG Joint Good Manufacturing Practice Guide For Excipients. This grade of Bis-Tris HCl is not suitable to be used as an Active Pharmaceutical Ingredient, Drug, Drug Product or Household Item.

Retest Date:

The recommended retest period for Bis-Tris HCl is two years from the date of manufacture.

Storage and Shipping Conditions:

Keep container tightly closed in a dry and well-ventilated place.

Package Sizes:

10kg, 25 kg and 50 kg pails.

Country of Origin:

India

This product is then repacked and retested under cGMP at our Bangor USA cGMP FDA Regulated Facility.