

Tromethamine, U.S.P.  
Multi-Compendial  
Tris (Base)  
Tris (Base)



Material No.: 4101-09  
Revision No.: 0

## Product Specification

Meets B.P. Chemical Specifications, Meets E.P. Chemical Specifications, Meets JPC (1997) Chemical Specifications, Meets U.S.P Requirements, GMP Manufactured Product

Test	Specification
USP - Assay (C <sub>4</sub> H <sub>11</sub> NO <sub>3</sub> )	99.0 - 101.0 %
USP - Identification A	Passes Test
USP - Identification B	Passes Test
USP - Identification C	Passes Test
USP - pH (1 in 20)	10.0 - 11.5
USP - Residue on Ignition	≤ 0.1 %
USP - Loss on Drying	≤ 0.5 %
USP - Melting Range(Lower)	168 - 172 °C
USP - Melting Range(Upper)	168 - 172 °C
EP/BP - Assay (C <sub>4</sub> H <sub>11</sub> NO <sub>3</sub> ) (dried basis)	99.0 - 100.5 %
EP/BP - Identification B	Passes Test
EP/BP - Identification C	Passes Test
EP/BP - Appearance of Solution	Passes Test
EP/BP - pH	10.0 - 11.5
EP/BP - Related Substances	≤ 1.0 %
EP/BP - Chloride (Cl)	≤ 100 ppm
EP/BP - Iron (Fe)	≤ 10 ppm
EP/BP - Loss on Drying at 105°C	≤ 0.5 %
EP/BP - Ash (sulfated)	≤ 0.1 %
JPC 1997 - Assay (C <sub>4</sub> H <sub>11</sub> NO <sub>3</sub> ) (dried basis)	≥ 99.0 %
JPC 1997 - Identification A	Passes Test
JPC 1997 - Identification B	Passes Test
JPC 1997 - pH	10.3 - 10.7
JPC 1997 - Melting Point	168 - 172 °C
JP - Clarity and Color of Solution	Passes Test
JPC 1997 - Heavy Metals (as Pb)	≤ 8 ppm
JPC 1997 - Arsenic (As)	≤ 1.6 ppm
JPC 1997 - Loss on Drying	≤ 0.5 %

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For questions on this Product Specification please contact Technical Services at 855.282.6867 or +1.610.386.1700  
Avantor Performance Materials, LLC  
100 Mansford Rd, Suite 200, Radnor, PA 19087. U.S.A. Phone 610.386.1700

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Test	Specification
JPC 1997 - Residue on Ignition	≤ 0.10 %
Assay (C <sub>4</sub> H <sub>11</sub> NO <sub>3</sub> ) (dried basis)	≥ 99.9 %
Absorbance of a 1M Solution - 260 nm	≤ 0.06
Absorbance of a 1M Solution - 280 nm	≤ 0.06
Absorbance of a 1M Solution - 400 nm	≤ 0.01
Endotoxin Concentration (EU/g)	≤ 2.5
Iron (Fe)	≤ 1 ppm
Lead (Pb)	≤ 1 ppm
Water (H <sub>2</sub> O)(by Karl Fischer titrn)	≤ 0.5 %
Enzyme Activity - DNase Activity	Passes Test
Enzyme Activity - RNase Activity	Passes Test
Enzyme Activity - Protease Activity	Passes Test
Trace Impurities - Arsenic (As)	≤ 1 ppm
Trace Impurities - Aluminum (Al)	≤ 5.000 ppm
Trace Impurities - Barium (Ba)	≤ 5 ppm
Trace Impurities - Bismuth (Bi)	≤ 5 ppm
Trace Impurities - Calcium (Ca)	≤ 10.0 ppm
Trace Impurities - Cadmium (Cd)	≤ 5.000 ppm
Trace Impurities - Chromium (CR)	≤ 5 ppm
Trace Impurities - Cobalt (Co)	≤ 5.000 ppm
Trace Impurities - Copper (Cu)	≤ 5 ppm
Trace Impurities - Lithium (Li)	≤ 5 ppm
Trace Impurities - Magnesium (Mg)	≤ 5 ppm
Trace Impurities - Mercury (Hg)	≤ 5 ppm
Trace Impurities - Molybdenum (Mo)	≤ 5 ppm
Trace Impurities - Nickel (Ni)	≤ 5.000 ppm
Trace Impurities - Potassium (K)	≤ 50 ppm
Trace Impurities - Sodium (Na)	≤ 50.000 ppm
Trace Impurities - Strontium (Sr)	≤ 5 ppm
Trace Impurities - Vanadium (V)	≤ 5.000 ppm
Trace Impurities - Zinc (Zn)	≤ 5.000 ppm

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GMP Manufactured Product  
Bulk Pharmaceutical Chemical  
CAUTION: For Manufacturing, processing or repackaging  
No Class 1,2,3 or other solvents are used or produced in the manufacturing or purification of the product.  
Elemental Impurities (USP 232, EP 5.20) - Information on elemental impurities for this product is available on the associated Product Regulatory Data Sheet and elemental impurity profile report.

Packaging Site: Paris Mfg Ctr & DC

  
Jamie Ethier  
Vice President Global Quality

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