

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



Material No.: 4101-07
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 ₄ H ₁₁ NO ₃)	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 ₄ H ₁₁ NO ₃) (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 ₄ H ₁₁ NO ₃) (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
JPC 1997 – 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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Test	Specification
JPC 1997 – Residue on Ignition	≤ 0.10 %
Assay (C ₄ H ₁₁ NO ₃) (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 ₂ 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 ppm
Trace Impurities – Barium (Ba)	≤ 5 ppm
Trace Impurities – Bismuth (Bi)	≤ 5 ppm
Trace Impurities – Calcium (Ca)	≤ 10 ppm
Trace Impurities – Cadmium (Cd)	≤ 5 ppm
Trace Impurities – Chromium (CR)	≤ 5 ppm
Trace Impurities – Cobalt (Co)	≤ 5 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 ppm
Trace Impurities – Potassium (K)	≤ 50 ppm
Trace Impurities – Sodium (Na)	≤ 50 ppm
Trace Impurities – Strontium (Sr)	≤ 5 ppm
Trace Impurities – Vanadium (V)	≤ 5 ppm
Trace Impurities – Zinc (Zn)	≤ 5 ppm

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Test

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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

For questions on this Product Specification please contact Technical Services at 855.282.6867 or +1.610.386.1700
Avantor Performance Materials, LLC

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