

Tromethamine, U.S.P.
Multi-Compendial

Tris (Base)



Material No.: 4102-05
Batch No.: 0000275589
Manufactured Date: 2020/11/17
Expiration Date: 2022/11/17
Release Date: 2021/02/01
Revision No: 1

Certificate of Analysis

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	Result
USP – Assay ($C_4H_{11}NO_3$)	99.0 – 101.0 %	100.2
USP – Identification A	Passes Test	PT
USP – Identification B	Passes Test	PT
USP – Identification C	Passes Test	PT
USP – pH (1 in 20)	10.0 – 11.5	10.8
USP – Loss on Drying	≤ 1.0 %	< 1.0
USP – Residue on Ignition	≤ 0.1 %	< 0.1
USP – Melting Range(Lower)	168 – 172 °C	170
USP – Melting Range(Upper)	168 – 172 °C	171
EP/BP – Assay ($C_4H_{11}NO_3$) (dried basis)	99.0 – 100.5 %	99.9
EP/BP – Identification B (melting point)	168 – 174 °C	171
EP/BP – Identification C	Passes Test	PT
EP/BP – Appearance of Solution	Passes Test	PT
EP/BP – pH	10.0 – 11.5	10.8
EP/BP – Related Substances	≤ 1.0 %	< 1.0
EP/BP – Chloride (Cl)	≤ 100 ppm	< 100
EP/BP – Iron (Fe)	≤ 10 ppm	< 10
EP/BP – Loss on Drying at 105°C	≤ 0.5 %	< 0.5
EP/BP – Ash (sulfated)	≤ 0.1 %	< 0.1
JPC 1997 – Assay ($C_4H_{11}NO_3$) (dried basis)	≥ 99.0 %	99.9
JPC 1997 – Identification A	Passes Test	PT

For questions on this Certificate of Analysis please contact Technical Services at 855.282.6867 or +1.610.386.1700
Avantor Performance Materials, LLC
100 Matsonford Rd, Suite 200, Radnor, PA 19087. U.S.A. Phone: 610.386.1700

Test	Specification	Result
JPC 1997 – Identification B	Passes Test	PT
JPC 1997 – pH	10.3 – 10.7	10.4
JPC 1997 – Melting Point	168 – 172 °C	171
JPC 1997 – Clarity and Color of Solution	Passes Test	PT
JPC 1997 – Heavy Metals (as Pb)	<= 8 ppm	< 8
JPC 1997 – Arsenic (As)	<= 1.6 ppm	< 1.6
JPC 1997 – Loss on Drying	<= 0.5 %	< 0.5
JPC 1997 – Residue on Ignition	<= 0.10 %	< 0.10
Assay (C ₄ H ₁₁ NO ₃) (dried basis)	>= 99.9 %	100.0
Absorbance of a 1M Solution – 260 nm	<= 0.06	< 0.06
Absorbance of a 1M Solution – 280 nm	<= 0.06	< 0.06
Absorbance of a 1M Solution – 400 nm	<= 0.01	< 0.01
Endotoxin Concentration (EU/g)	<= 2.5	< 1.0
Iron (Fe)	<= 1 ppm	< 1
Lead (Pb)	<= 1 ppm	< 1

Bulk Pharmaceutical Chemical

CAUTION: For Manufacturing, processing or repackaging

Ultrapure Bioreagent Specifications

No Class 1,2,3 or other solvents are used or produced in the manufacturing or purification of the product.

Manufactured exclusively for Avantor Performance Materials, LLC., by

BioSpectra, Inc., Stroudsburg, PA

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.

Country of Origin: US
Packaging Site: Paris Mfg Ctr & DC
Manufacturer: P0064001
Manufacturer source batch: TR7201-418-1120


Jamie Ethier
Vice President Global Quality