

Tromethamine, U.S.P.
Multi-Compendial

Tris (Base)



Material No.: 4102-01
Batch No.: 0000134833
Manufactured Date: 2015/06/12
Expiration Date: 2017/06/11

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 ₄ H ₁₁ NO ₃)	99.0 – 101.0 %	99.3
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	10.5
USP – Loss on Drying	<= 1.0 %	< 0.1
USP – Residue on Ignition	<= 0.1 %	< 0.1
USP – Heavy Metals (as Pb)	<= 0.001 %	< 0.001
USP – Melting Range(Lower)	168 – 172 °C	171
USP – Melting Range(Upper)	168 – 172 °C	172
EP/BP – Assay (C ₄ H ₁₁ NO ₃) (dried basis)	99.0 – 100.5 %	99.3
EP/BP – Identification B	Passes Test	PT
EP/BP – Identification C	Passes Test	PT
EP/BP – Appearance of Solution	Passes Test	PT
EP/BP – pH	10.0 – 11.5	10.6
EP/BP – Related Substances	<= 1.0 %	< 1.0
EP/BP – Chloride (Cl)	<= 100 ppm	< 100
EP/BP – Heavy Metals (as Pb)	<= 10 ppm	< 10
EP/BP – Iron (Fe)	<= 10 ppm	< 10
EP/BP – Loss on Drying at 105°C	<= 0.5 %	< 0.1
EP/BP – Ash (sulfated)	<= 0.1 %	< 0.1

Test	Specification	Result
JPC 1997 – Assay (C ₄ H ₁₁ NO ₃) (dried basis)	>= 99.0 %	100.2
JPC 1997 – Identification A	Passes Test	PT
JPC 1997 – Identification B	Passes Test	PT
JPC 1997 – pH	10.3 – 10.7	10.3
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 %	< 0.1
JPC 1997 – Residue on Ignition	<= 0.10 %	0.04
Assay (C ₄ H ₁₁ NO ₃) (dried basis)	>= 99.9 %	100.0
Absorbance of a 1M Solution – 260 nm	<= 0.06	0.01
Absorbance of a 1M Solution – 280 nm	<= 0.06	0.01
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, Inc., by BioSpectra, Inc., Stroudsburg, PA

Metallic Residues: No metal catalysts or metal reagents, as defined by EMA Guideline EMEA/CHMP/SWP/4446/2000, are used in the production of this material.

Country of Origin: US
Packaging Site: Paris Mfg Ctr & DC
Manufacturer: P0064001
Manufacturer source batch: TR7201-052-0615



Phillipsburg, NJ 9001:2008, 14001:2004, FSSC 22000
Paris, KY 9001:2008
Mexico City, Mexico 9001:2008
Deventer, The Netherlands 9001:2008, 14001:2004, 13485:2003
Gliwice, Poland 9001:2008
Selangor, Malaysia 9001:2008
Dehradun, India, 9001:2008, 14001:2004, 13485:2003
Mumbai, India, 9001:2008, 17025:2005
Panoli, India 9001:2008



Jamie Ethier
Vice President Global Quality

For questions on this Certificate of Analysis please contact Technical Services at 855.282.6867 or +1.610.573.2600
Avantor™ Performance Materials Inc.

3477 Corporate Parkway, Suite #200, Center Valley, PA 18034. U.S.A. Phone: 610.573.2600 . Fax: 610.573.2610