

Tromethamine, U.S.P.
Multi-Compendial

Tris (Base)



Material No.: 4102-01
Batch No.: 0000182984
Manufactured Date: 2017/05/24
Expiration Date: 2019/05/24

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 %	99.6
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	10.7
USP – Loss on Drying	<= 1.0 %	0.2
USP – Residue on Ignition	<= 0.1 %	< 0.1
USP – Heavy Metals (as Pb)	<= 0.001 %	< 0.001
USP – Melting Range(Lower)	168 – 172 °C	169
USP – Melting Range(Upper)	168 – 172 °C	170
EP/BP – Assay (C ₄ H ₁₁ NO ₃) (dried basis)	99.0 – 100.5 %	100.0
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	10.7
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 %	0.2
EP/BP – Ash (sulfated)	<= 0.1 %	< 0.1

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

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

Test	Specification	Result
JPC 1997 – Assay (C ₄ H ₁₁ NO ₃) (dried basis)	>= 99.0 %	99.9
JPC 1997 – Identification A	Passes Test	PT
JPC 1997 – Identification B	Passes Test	PT
JPC 1997 – pH	10.3 – 10.7	10.5
JPC 1997 – Melting Point	168 – 172 °C	169
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 %	0.2
JPC 1997 – Residue on Ignition	<= 0.10 %	< 0.01
Assay (C ₄ H ₁₁ NO ₃) (dried basis)	>= 99.9 %	99.9
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, LLC., 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: TR7201-155-0517

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, 13485:2012
 Selangor, Malaysia 9001:2008
 Dehradun, India, 9001:2008, 14001:2004, 13485:2003
 Mumbai, India, 9001:2008
 Panoli, India 9001:2008

James Ethier
 Jamie Ethier
 Vice President Global Quality

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