



MERIDIAN BIOCHEMICALS INC.

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CERTIFICATE OF ANALYSIS

Certificate No. COA-2026-03142 | Issue Date: 14 March 2026

LOT NO. MB24-071-A

Product Code: MB-TRIS-500	CAS No.: 77-86-1	Container Size: 500 g
Mfg. Date: 14 Mar 2026	Retest Date: 13 Mar 2028	Molecular Wt.: 121.14 g/mol

Product Identity & Description

Product Name: Tris(hydroxymethyl)aminomethane (Tris Base), Ultra Pure Molecular Biology Grade
Molecular Formula: C₄H₁₁NO₃
Intended Use: Buffer component for molecular biology, enzymology, and electrophoresis applications. Not for use in food, drug, or medical device manufacture unless independently qualified by the end user.
Sampling Statement: Samples were drawn from 4 of 22 drums comprising Lot MB24-071-A in accordance with the statistically justified sampling plan of ASTM E122 [2] and internal procedure QC-SOP-102, and were tested against the methods indicated below.

Specification vs. Result — Primary Assay & Physicochemical Tests

Test	Specification	Method	Result	Status
Appearance	White to off-white, free-flowing crystalline powder	Visual inspection, USP <790>	Conforms	✓
Identity (IR Spectrum)	Conforms to reference spectrum	FT-IR, USP <197>	Conforms	✓
Assay (non-aqueous titration, dry basis)	99.0% – 101.0%	Perchloric acid titration	99.8%	✓
Melting Range	168°C – 172°C	USP <741> capillary method	169.4°C – 170.1°C	✓
pH (0.1 M aqueous solution, 25°C)	10.4 – 10.8	Potentiometric, ASTM D1293 [3]	10.6	✓
Water Content (Karl Fischer)	≤ 0.5% w/w	Karl Fischer titration, USP <921>	0.18%	✓

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Certificate of Analysis — Lot MB24-071-A (continued)

Test	Specification	Method	Result	Status
Loss on Drying (105°C, 3 h)	≤ 0.3% w/w	Gravimetric	0.11%	✓
Residue on Ignition	≤ 0.05% w/w	USP <281>	0.021%	✓
Heavy Metals (as Pb)	≤ 5 ppm	USP <231>, ICP-OES	<1 ppm	✓
Iron (Fe)	≤ 5 ppm	ICP-OES	0.8 ppm	✓
Chloride (Cl ⁻)	≤ 5 ppm	Ion chromatography	<2 ppm	✓
Sulfate (SO ₄ ²⁻)	≤ 10 ppm	Ion chromatography	3.1 ppm	✓
Ammonium (NH ₄ ⁺)	≤ 20 ppm	Nessler colorimetric	6 ppm	✓
UV Absorbance (10% aq. solution, 280 nm)	≤ 0.020 AU	UV-Vis spectrophotometry	0.008 AU	✓

Trace Elemental Analysis (ICP-MS)

Trace-metal testing is performed at the ultra-pure grade limits required for downstream enzymatic and cell-based applications, where residual divalent cations can inhibit nucleases, polymerases, and ligases.

Element	Specification	Method	Result	Status
Zinc (Zn)	≤ 50 ppb	ICP-MS	12 ppb	✓
Copper (Cu)	≤ 20 ppb	ICP-MS	4 ppb	✓
Nickel (Ni)	≤ 20 ppb	ICP-MS	<2 ppb	✓
Chromium (Cr)	≤ 20 ppb	ICP-MS	3 ppb	✓
Cadmium (Cd)	≤ 5 ppb	ICP-MS	<1 ppb	✓
Arsenic (As)	≤ 10 ppb	ICP-MS	<1 ppb	✓
Mercury (Hg)	≤ 5 ppb	ICP-MS, cold-vapour	<0.5 ppb	✓

Nuclease & Protease Activity (Molecular Biology Grade Testing)

Enzymatic contamination testing confirms suitability of this lot for RNA/DNA handling buffers, in-vitro transcription, and cell culture reagent formulation.

Parameter	Method	Result	Status
DNase Activity	Fluorescence-based DNA degradation assay, SOP QC-ENZ-07	None Detected	✓
RNase Activity	Fluorescent RNA-substrate cleavage assay, SOP QC-ENZ-09	None Detected	✓
Protease Activity	Azocasein digestion assay, 24 h, 37°C	None Detected	✓

Test Methods & Applicable Standards

All testing reported in this Certificate of Analysis was performed by the Meridian Biochemicals Quality Control Laboratory, which operates under a quality management system aligned with the general requirements for the competence of testing and calibration laboratories described in ISO/IEC 17025 [1].

Compendial test methods are drawn from the current United States Pharmacopeia–National Formulary General Chapters, including Heavy Metals [4], Residue on Ignition [5], Melting Range or Temperature [6], and Water Determination [7]. Where no compendial method exists, internally validated methods are used, each qualified for specificity, accuracy, and precision under document control reference QC-VAL-2024-014.

- ✓ Instruments used in generating this Certificate are maintained on a documented calibration schedule traceable to national measurement standards.
- ✓ Reference standards and reagents used in testing are within their assigned expiry and are verified against certified reference materials at first use.
- ✓ Raw data, chromatograms, and spectra supporting each result are retained in the laboratory information management system under Lot MB24-071-A and are available upon reasonable request.
- ✓ Out-of-specification results, had any occurred, would trigger investigation under SOP QC-SOP-118 prior to lot disposition; no such investigation was required for this lot.

References

- [1] General requirements for the competence of testing and calibration laboratories. Technical Report ISO/IEC 17025:2017, International Organization for Standardization, Geneva, Switzerland, 2017.
- [2] Standard practice for calculating sample size to estimate, with a specified tolerable error, the average for characteristic of a lot or process. Technical Report ASTM E122-17, ASTM International, West Conshohocken, PA, USA, 2017.
- [3] Standard test methods for pH of water. Technical Report ASTM D1293-18, ASTM International, West Conshohocken, PA, USA, 2018.
- [4] General chapter <231> heavy metals. Technical Report USP–NF General Chapters, United States Pharmacopeial Convention, Rockville, MD, USA, 2023.
- [5] General chapter <281> residue on ignition. Technical Report USP–NF General Chapters, United States Pharmacopeial Convention, Rockville, MD, USA, 2023.
- [6] General chapter <741> melting range or temperature. Technical Report USP–NF General Chapters, United States Pharmacopeial Convention, Rockville, MD, USA, 2023.
- [7] General chapter <921> water determination. Technical Report USP–NF General Chapters, United States Pharmacopeial Convention, Rockville, MD, USA, 2023.

Storage, Handling & Shelf Life

- Store at 15°C – 30°C in the original, tightly closed container, protected from moisture and direct sunlight.
- Tris base is hygroscopic; reseal the container promptly after each use and dispense with a dry scoop.
- Retest Date: 13 Mar 2028. Material may be requalified by QC beyond this date upon customer request.
- ⚠ Mild eye and respiratory irritant in dust form. Use appropriate personal protective equipment (gloves, safety glasses) when handling, per Safety Data Sheet MB-TRIS-500-SDS.

Certificate Validity & Sample Retention

This Certificate of Analysis applies solely to the lot number identified above and shall not be reproduced except in full without the written consent of Meridian Biochemicals Inc. A retained sample of this lot is held by the Quality Control Laboratory for twenty-four (24) months from the issue date in accordance with SOP QC-SOP-114, available for re-examination should any question of conformance arise.

Quality Control Authorization

Role	Name & Title	Signature	Date
Prepared by	Priya Nandakumar QC Analyst II	<i>P. Nandakumar</i>	13 Mar 2026
Reviewed by	Dorian Achebe QC Supervisor	<i>D. Achebe</i>	14 Mar 2026
Approved by	Elena Kowalski QC Manager (Authorized Signatory)	<i>E. Kowalski</i>	14 Mar 2026

✓ **DISPOSITION: RELEASED FOR DISTRIBUTION**

Based on the analytical results recorded above, Lot MB24-071-A conforms to all specifications defined in Meridian Biochemicals product specification MB-TRIS-500-SPEC Rev. 6 and is approved for release and distribution.



This Certificate of Analysis applies solely to the lot number identified above. Retained samples for this lot are held for twenty-four (24) months from the issue date in accordance with SOP QC-SOP-114. For Research Use Only — not intended for use in diagnostic or therapeutic procedures unless independently validated by the end user.