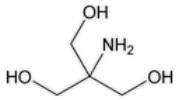
Status: Currently Official on 17-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-B20A752E-D2B5-44BA-B96A-E262D1242067_4_en-US
DOI: https://doi.org/10.31003/USPNF_M86510_04_01
DOI Ref: c914m

Tromethamine



$C_4H_{11}NO_3$ 121.14

1,3-Propanediol, 2-amino-2-(hydroxymethyl)-;

2-Amino-2-(hydroxymethyl)-1,3-propanediol CAS RN®: 77-86-1.

DEFINITION

Tromethamine contains NLT 99.0% and NMT 101.0% of tromethamine ($C_4H_{11}NO_3$), calculated on the dried basis.

IDENTIFICATION

Change to read:

• **A.** ▲Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: **197M**▲ (CN 1-May-2020)

• **B.**

Sample solution: 1 in 5

Analysis: To 4.5 mL of a saturated solution of salicylaldehyde add 0.5 mL of glacial acetic acid, and mix. Add 4.0 mL of the *Sample solution*, and mix.

Acceptance criteria: A yellow color is produced.

• **C.**

Sample solution: 1 in 5

Analysis: To 0.5 mL of a solution (4 in 10) of ceric ammonium nitrate in 2 N nitric acid add 3 mL of water and 0.5 mL of the *Sample solution*, and mix.

Acceptance criteria: The color changes from light yellow to orange.

ASSAY

• **Procedure**

Sample: 250 mg

Analysis: Dissolve the *Sample* in 100 mL of water, add bromocresol purple TS, and titrate with 0.1 N hydrochloric acid VS to a yellow endpoint. Each mL of 0.1 N hydrochloric acid is equivalent to 12.11 mg of tromethamine ($C_4H_{11}NO_3$).

Acceptance criteria: 99.0%–101.0% on the dried basis

IMPURITIES

• **Residue on Ignition ⟨281⟩:** NMT 0.1%

SPECIFIC TESTS

• **Melting Range or Temperature ⟨741⟩:** 168°–172°

• **pH ⟨791⟩**

Sample solution: 1 in 20

Acceptance criteria: 10.0–11.5

• **Loss on Drying ⟨731⟩**

Analysis: Dry at 105° for 3 h.

Acceptance criteria: NMT 1.0%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers.

- **USP Reference Standards** ⟨11⟩
  USP Tromethamine RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
TROMETHAMINE	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 35(2)

Current DocID: GUID-B20A752E-D2B5-44BA-B96A-E262D1242067_4_en-US
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