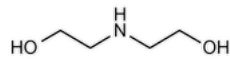


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Diethanolamine



$C_4H_{11}NO_2$ 105.14
Ethanol, 2,2'-iminobis-;
2,2'-Iminodiethanol CAS RN®: 111-42-2.

DEFINITION

Diethanolamine is a mixture of ethanolamines, consisting largely of diethanolamine. It contains NLT 98.5% and NMT 101.0% of ethanolamines, calculated on the anhydrous basis as $NH(C_2H_4OH)_2$.

IDENTIFICATION

Change to read:

• A. ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197F](#)▲ (CN 1-MAY-2020)

ASSAY

PROCEDURE

Sample: 2 g
Blank: 50 mL of water
Titrimetric system
(See [Titrimetry \(541\)](#).)
Mode: Direct titration
Titrant: 0.5 N hydrochloric acid VS
Endpoint detection: Visual

Analysis: To the *Sample* add 50 mL of water and bromocresol green TS. Titrate with the *Titrant*. Perform a blank determination. Calculate the percentage of diethanolamine, expressed as $NH(C_2H_4OH)_2$, in the *Sample* taken:

$$\text{Result} = \{[(V_s - V_b) \times N \times F] / W\} \times 100$$

V_s = *Titrant* volume consumed by the *Sample* (mL)
 V_b = *Titrant* volume consumed by the *Blank* (mL)
 N = actual normality of the *Titrant* (mEq/mL)
 F = equivalency factor, 105.14 (mg/mEq)
 W = *Sample* weight (mg)

Acceptance criteria: 98.5%–101.0% on the anhydrous basis

IMPURITIES

LIMIT OF TRIETHANOLAMINE

Mixed indicator: 1.5 mg/mL of methyl orange and 0.8 mg/mL of xylene cyanole FF in water
Sample: 20 g
Blank: 100 mL of methanol and 6–8 drops of *Mixed indicator*
Titrimetric system
(See [Titrimetry \(541\)](#).)
Mode: Direct titration
Titrant: 0.5 N alcoholic sulfuric acid VS
Endpoint detection: Visual

Analysis: Place 100 mL of methanol and 6–8 drops of *Mixed indicator* in a 500-mL glass-stoppered conical flask, and neutralize with 0.1 N alcoholic sulfuric acid or 0.1 N alcoholic potassium hydroxide. The neutral solution is amber when viewed by transmitted light and is red-

brown when viewed by reflected light. Add the *Sample*. Cautiously add 75 mL of acetic anhydride, and swirl to effect complete solution. Cool to room temperature, if necessary, and allow to stand at room temperature for 30 min. Titrate with the *Titrant*. Perform a blank determination.

Calculate the percentage of triethanolamine in the *Sample* taken:

$$\text{Result} = \{[(V_s - V_b) \times N \times F]/W\} \times 100$$

V_s = *Titrant* volume consumed by the *Sample* (mL)

V_b = *Titrant* volume consumed by the *Blank* (mL)

N = actual normality of the *Titrant* (mEq/mL)

F = equivalency factor, 149.2 mg/mEq

W = *Sample* weight (mg)

Acceptance criteria: NMT 1.0% by weight

SPECIFIC TESTS

• [REFRACTIVE INDEX \(831\)](#): 1.473–1.476 at 30°

• [WATER DETERMINATION, Method I \(921\)](#)

Sample: 20 g

Solvent: A mixture of methanol and glacial acetic acid (40:25)

Acceptance criteria: NMT 0.15%

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers.

• [USP REFERENCE STANDARDS \(11\)](#)

[USP Diethanolamine RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
DIETHANOLAMINE	Documentary Standards Support	SE2020 Simple Excipients

Chromatographic Database Information: [Chromatographic Database](#)

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