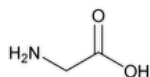


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Glycine

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$C_2H_5NO_2$ 75.07

Glycine CAS RN®: 56-40-6.

DEFINITION

Glycine contains NLT 98.5% and NMT 101.5% of glycine ($C_2H_5NO_2$), calculated on the dried basis.

IDENTIFICATION

- **A. [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#):** 197M

ASSAY

• PROCEDURE

Sample: 150 mg of Glycine

Blank: 100 mL of [glacial acetic acid](#)

Titrimetric system

(See [Titrimetry \(541\)](#).)

Mode: Direct titration

Titrant: [0.1 N perchloric acid VS](#)

Endpoint detection: Visual

Analysis: Dissolve the *Sample* in 100 mL of [glacial acetic acid](#), and add 1 drop of [crystal violet TS](#). Titrate with the *Titrant* to a green endpoint. Perform the *Blank* determination.

Calculate the percentage of glycine ($C_2H_5NO_2$) 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, 75.07 mg/mEq

W = *Sample* weight (mg)

Acceptance criteria: 98.5%–101.5% on the dried basis

IMPURITIES

- **[RESIDUE ON IGNITION \(281\)](#):** NMT 0.1%

- **[CHLORIDE AND SULFATE \(221\)](#), [Chloride](#)**

Standard solution: 0.10 mL of 0.020 N [hydrochloric acid](#)

Sample: 1 g of Glycine

Acceptance criteria: NMT 0.007%

- **[CHLORIDE AND SULFATE \(221\)](#), [Sulfate](#)**

Standard solution: 0.20 mL of 0.020 N [sulfuric acid](#)

Sample: 3 g of Glycine

Acceptance criteria: NMT 0.0065%

• **HYDROLYZABLE SUBSTANCES**

Sample solution: 100 mg/mL of Glycine

Analysis: Boil 10 mL of the *Sample solution* for 1 min, and set aside for 2 h.

Acceptance criteria: The solution appears as clear and as mobile as 10 mL of the same solution that has not been boiled.

Change to read:

• **RELATED COMPOUNDS**

Solution A: Transfer 2.16 g of [octanesulfonic acid sodium salt](#) to a 1000-mL volumetric flask, add 900 mL of HPLC grade [water](#) and 2.0 mL of [perchloric acid](#), and mix to dissolve. Adjust with 5 N [sodium hydroxide](#) solution to a pH of 2.2. Dilute with HPLC grade [water](#) to volume.

Pass the solution through a membrane filter of 0.2-µm pore size.

Solution B: [Acetonitrile](#)

Mobile phase: Gradient elution. See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	100	0
7	100	0
13	90	10
18	90	10
35	100	0
45	100	0

Standard solution: A mixture of 0.005 mg/mL each of [USP Glycine RS](#), [USP Diglycine RS](#), [USP Triglycine RS](#), and glycine anhydride,¹ and 0.0025 mg/mL of monochloroacetic acid² in HPLC grade [water](#). [NOTE—Monochloroacetic acid may be omitted from the *Standard solution* if the article being tested does not contain this substance.]

Sample solution: Transfer 125 mg of Glycine into a 25-mL volumetric flask, dissolve in and dilute with HPLC grade [water](#) to volume.

Blank: HPLC grade [water](#)

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 200 nm

Column: 4.6-mm × 15-cm; 3-µm packing L1

Column temperature: 25°

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Samples: *Standard solution* and *Blank*

[NOTE—See [Table 2](#) for the relative retention times.]

Suitability requirements

Interference peaks: Compare the chromatogram obtained from the *Standard solution* with that obtained from the *Blank*. Any peak area from the *Blank* that overlaps or co-elutes with the amino acid peak from the *Standard solution* is NMT 2.0% of that amino acid peak area.

Resolution: NLT 2.0 between the diglycine and triglycine peaks, *Standard solution*

Relative standard deviation: NMT 5.0% each for the specified peaks, *Standard solution*

Analysis

Samples: *Standard solution*, *Sample solution*, and *Blank*