Status: Currently Official on 15-Feb-2025
Official Date: Official as of 01-Jun-2023
Document Type: Dietary Supplement Monographs
DocId: GUID-E6CE8CF3-82BA-4BA8-A072-4EAE7CA53877_5_en-US
DOI: https://doi.org/10.31003/USPNF_M7102_05_01
DOI Ref: hik4v

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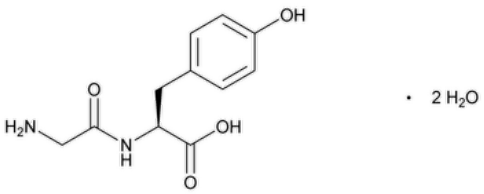
Glycyl-L-tyrosine



$C_{11}H_{14}N_2O_4 \cdot 2H_2O$ 274.27

L-2-Aminoacetamide-3-(parahydroxyphenyl) propionic acide dihydrate;

Glycyl-L-tyrosine dihydrate CAS RN®: 658-79-7.

DEFINITION

Glycyl-L-tyrosine contains NLT 98.0% and NMT 101.5% of glycyl-L-tyrosine ($C_{11}H_{14}N_2O_4$), calculated on the anhydrous and solvent-free basis, and excluding glycine and tyrosine.

IDENTIFICATION

• **A. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197A**

• **B.** It meets the requirements for *Optical Rotation, Specific Rotation ⟨781S⟩* in *Specific Tests*.

ASSAY

• **Procedure**

Sample: 300 mg

Blank: Mix 5 mL of formic acid with 50 mL of glacial acetic acid.

Titrimetric system

(See *Titrimetry ⟨541⟩*.)

Mode: Direct titration

Titrant: 0.1 N perchloric acid VS

Endpoint detection: Potentiometric

Analysis: Dissolve the *Sample* in 5 mL of formic acid, add 50 mL of glacial acetic acid, and titrate with the *Titrant*. Perform the *Blank* determination, and make any necessary correction.

Calculate the percentage of glycyl-L-tyrosine ($C_{11}H_{14}N_2O_4$) in the *Sample* taken:

$$\text{Result}_1 = [(V_S - V_B) \times N \times (F/W)] \times 100$$

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, 238.2 mg/mEq

W = *Sample* weight (mg)

Calculate the percentage of glycyl-L-tyrosine ($C_{11}H_{14}N_2O_4$) in the *Sample* taken, excluding glycine and tyrosine:

$$\text{Result}_2 = [(\text{Result}_1 - a - b)]/[(100 - Gly - Tyr)] \times 100$$

$$a = Gly \times (M_{r1}/M_{r2})$$

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$$b = Tyr \times (M_{r1}/M_{r3})$$

Gly = percentage of glycine from the *Related Compounds* test

Tyr = percentage of tyrosine from the *Related Compounds* test

M_{r1} = molecular weight of glycyl-L-tyrosine, 238.2

M_{r2} = molecular weight of glycine, 75.1

M_{r3} = molecular weight of tyrosine, 181.2

Acceptance criteria: 98.0%–101.5% on the anhydrous and solvent-free basis, and excluding glycine and tyrosine

IMPURITIES

- **Residue on Ignition** ⟨281⟩**:** NMT 0.1%
- **Chloride and Sulfate,** *Chloride*⟨221⟩

  Sample: 0.89 g

  Standard solution: 0.50 mL of 0.010 N hydrochloric acid

  Acceptance criteria: NMT 200 µg/g
- **Chloride and Sulfate,** *Sulfate*⟨221⟩

  Sample: 0.96 g

  Standard solution: 0.20 mL of 0.010 N sulfuric acid

  Acceptance criteria: NMT 200 µg/g

Change to read:

- ▲**Iron** ⟨241⟩, *Procedures, Procedure 1*▲ (CN 1-Jun-2023) **:** NMT 10 µg/g
- **Residual Solvents** ⟨467⟩

  Acceptance criteria

  Ethanol: NMT 0.5%

  [Note—For the *Acceptance criteria* for any other residual solvents, see *Residual Solvents* ⟨467⟩.]
- **Limit of Ammonium**

  Standard stock solution: Dissolve 1.486 g of ammonium chloride in 500.0 mL of water.

  Standard calibration solutions: Transfer 0.01, 0.1, 1.0, and 10.0 mL of *Standard stock solution* into separate 100-mL volumetric flasks, and dilute with water to volume. The final concentrations are 0.1, 1, 10, and 100 µg/mL of ammonium ions (NH_4^+), respectively.

  Sample solution: Transfer 1.0 g of Glycyl-L-tyrosine to a 150-mL beaker containing a plastic-coated stirring bar, add 100.0 mL of water, and stir until dissolved.

  Electrode system: Use a gas-sensing, ammonia-specific indicating electrode with internal reference connected to a pH meter capable of measuring potentials with a minimum reproducibility of ±0.1 mV (see *pH* ⟨791⟩). Condition the electrode according to the manufacturer's instructions.

  Analysis

  Standard response line: Transfer 100 mL of water into a 150-mL beaker containing a plastic-coated stirring bar, insert the electrode into the water, stir, and measure the potential. Add 1 mL of 10 N sodium hydroxide solution, stir, and measure the potential after stabilization (about 3 min). The potential difference must be below 20 mV. Transfer 100.0 mL of each of *Standard calibration solutions* (0.1, 1, 10, 100 µg/mL of ammonium ions) into separate 150-mL beakers, and add 1 mL of 10 N sodium hydroxide. Insert the electrode into each solution, stir, and measure the potential after stabilization (about 3 min). Plot a curve (four calibration points) of the potential (mV) as function of ammonium ion concentrations (µg/mL).

  Sample: *Sample solution*

  Rinse the electrode, insert it into the *Sample solution*, add 1 mL of 10 N sodium hydroxide, and stir. Check the pH, which must be above 11; if not, adjust with 10 N sodium hydroxide. After 3 min, measure the potential, and determine the corresponding ammonium ion concentration from the calibration curve.

  Calculate the content of ammonium in the portion of the *Sample* taken:

$$\text{Result} = (V \times C)/W$$

V = volume of the *Sample solution* (mL)

C = concentration of ammonium ions in the *Sample solution* determined from the *Standard response line* (µg/mL)

W = weight of Glycyl-L-tyrosine taken to prepare the *Sample solution* (g)

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