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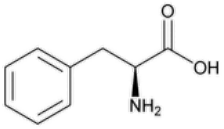
Phenylalanine



$C_9H_{11}NO_2$ 165.19

L-Phenylalanine CAS RN®: 63-91-2; UNII: 47E5O17Y3R.

DEFINITION

Phenylalanine contains NLT 98.5% and NMT 101.5% of L-phenylalanine ($C_9H_{11}NO_2$), calculated on the dried basis.

IDENTIFICATION

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

ASSAY

- **Procedure**

Sample: 160 mg of Phenylalanine

Blank: Mix 3 mL of formic acid and 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 3 mL of formic acid and 50 mL of glacial acetic acid. Titrate with the *Titrant*. Perform the *Blank* determination.

Calculate the percentage of phenylalanine ($C_9H_{11}NO_2$) 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, 165.2 mg/mEq

W = *Sample* weight (mg)

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

IMPURITIES

- **Residue on Ignition ⟨281⟩:** NMT 0.4%
- **Chloride and Sulfate, *Chloride*⟨221⟩**

Standard solution: 0.50 mL of 0.020 N hydrochloric acid

Sample: 0.73 g of Phenylalanine

Acceptance criteria: NMT 0.05%

- **Chloride and Sulfate, *Sulfate*⟨221⟩**

Standard solution: 0.10 mL of 0.020 N sulfuric acid

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Sample: 0.33 g of Phenylalanine

Acceptance criteria: NMT 0.03%

Change to read:

- ▲**Iron** ⟨241⟩, *Procedures, Procedure 1*▲ (CN 1-Jun-2023) **:** NMT 30 ppm
- **Related Compounds**

Diluent: Glacial acetic acid and water (1:1)

Standard solution: 0.05 mg/mL of USP L-Phenylalanine RS in *Diluent*. [Note—This solution has a concentration equivalent to 0.5% of that of the *Sample solution*.]

System suitability solution: 0.4 mg/mL each of USP L-Phenylalanine RS and USP L-Tyrosine RS in *Diluent*

Sample solution: 10 mg/mL of Phenylalanine in *Diluent*

Chromatographic system

(See *Chromatography* ⟨621⟩, *Thin-Layer Chromatography*.)

Mode: TLC

Adsorbent: 0.25-mm layer of chromatographic silica gel mixture

Application volume: 5 µL

Developing solvent system: Butyl alcohol, glacial acetic acid, and water (3:1:1)

Spray reagent: 2 mg/mL of ninhydrin in a mixture of butyl alcohol and 2 N acetic acid (95:5)

System suitability

Suitability requirements: The chromatogram of the *System suitability solution* exhibits two clearly separated spots.

Analysis

Samples: *Standard solution*, *System suitability solution*, and *Sample solution*

After air-drying the plate, spray with *Spray reagent*, and heat between 100° and 105° for 15 min. Examine the plate under white light.

Acceptance criteria: Any secondary spot of the *Sample solution* is not larger or more intense than the principal spot of the *Standard solution*.

Individual impurities: NMT 0.5%

Total impurities: NMT 2.0%

SPECIFIC TESTS

- **Optical Rotation**, *Specific Rotation*⟨781S⟩

Sample solution: 20 mg/mL in water

Acceptance criteria: −32.7° to −34.7°

- **pH** ⟨791⟩

Sample solution: 10 mg/mL solution

Acceptance criteria: 5.4–6.0

- **Loss on Drying** ⟨731⟩**:** Dry a sample at 105° for 3 h: it loses NMT 0.3% of its weight.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers.
- **USP Reference Standards** ⟨11⟩

USP L-Phenylalanine RS

USP L-Tyrosine RS

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

Topic/Question	Contact	Expert Committee
PHENYLALANINE	Fatkhulla K Tadjimukhamedov Associate Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	NBDS2020 Non-botanical Dietary Supplements

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