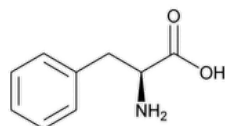


Status: Currently Official on 16-Feb-2025
 Official Date: Official as of 01-Jun-2023
 Document Type: USP Monographs
 DocId: GUID-E235A273-8CE7-4A24-AF89-9D2D3E265024_5_en-US
 DOI: https://doi.org/10.31003/USPNF_M64020_05_01
 DOI Ref: t0o0j

© 2025 USPC
 Do not distribute

Phenylalanine



$C_9H_{11}NO_2$ 165.19

L-Phenylalanine CAS RN[®]: 63-91-2; UNII: 47E5017Y3R.

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

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](#)

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

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. Information currently unavailable

2/16/25, 11:03 AM

USP-NF Phenylalanine

Current DocID: GUID-E235A273-8CE7-4A24-AF89-9D2D3E265024_5_en-US

DOI: https://doi.org/10.31003/USPNF_M64020_05_01

DOI ref: [t0o0j](#)

OFFICIAL