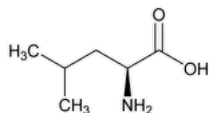


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Leucine



$C_6H_{13}NO_2$ 131.17

L-Leucine CAS RN®: 61-90-5; UNII: GMW67QNF9C.

DEFINITION

Leucine contains NLT 98.5% and NMT 101.5% of L-leucine ($C_6H_{13}NO_2$), calculated on the dried basis.

IDENTIFICATION

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

ASSAY

• PROCEDURE

Sample: 130 mg of Leucine

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 leucine ($C_6H_{13}NO_2$) in the portion of the *Sample* taken:

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

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

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

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

F = equivalency factor, 131.2 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 \(221\)](#), [Chloride](#)**

Standard solution: 0.50 mL of 0.020 N hydrochloric acid

Sample: 0.73 g of Leucine

Acceptance criteria: NMT 0.05%

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

Standard solution: 0.10 mL of 0.020 N sulfuric acid

Sample: 0.33 g of Leucine

Acceptance criteria: NMT 0.03%

Change to read:

- **[IRON \(241\)](#), [Procedures, Procedure 1](#)** (CN 1-JUN-2023) : NMT 30 ppm

- **RELATED COMPOUNDS**

System suitability solution: 0.4 mg/mL each of [USP L-Leucine RS](#) and [USP L-Valine RS](#) in 0.1 N hydrochloric acid

Standard solution: 0.05 mg/mL of [USP L-Leucine RS](#) in 0.1 N hydrochloric acid. [NOTE—This solution has a concentration equivalent to 0.5% of that of the *Sample solution*.]

Sample solution: 10 mg/mL of Leucine in 0.1 N hydrochloric acid

Chromatographic system
(See [Chromatography \(621\)](#), [General Procedures](#), [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
Sample: *System suitability solution*
Suitability requirements: The chromatogram of the *System suitability solution* exhibits two clearly separated spots.

Analysis
Samples: *System suitability solution*, *Standard 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 \(781S\)](#), [Procedures](#), [Specific Rotation](#)
Sample solution: 40 mg/mL in 6 N hydrochloric acid
Acceptance criteria: +14.9° to +17.3°
- [pH \(791\)](#)
Sample solution: 10 mg/mL in water
Acceptance criteria: 5.5–7.0
- [LOSS ON DRYING \(731\)](#)
Analysis: Dry at 105° for 3 h.
Acceptance criteria: NMT 0.2%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers.
- [USP REFERENCE STANDARDS \(11\)](#)
[USP L-Leucine RS](#)
[USP L-Valine RS](#)

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

Topic/Question	Contact	Expert Committee
LEUCINE	Fatkhulla K Tadjimukhamedov Associate Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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