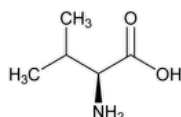


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Valine



$C_5H_{11}NO_2$ 117.15

L-Valine CAS RN®: 72-18-4; UNII: HG18B9YRS7.

DEFINITION

Valine contains NLT 98.5% and NMT 101.5% of L-valine ($C_5H_{11}NO_2$), calculated on the dried basis.

IDENTIFICATION

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

ASSAY

PROCEDURE

Sample: 110 mg of Valine

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 *Titrant*. Perform the blank determination.

Calculate the percentage of valine ($C_5H_{11}NO_2$) in the portion of Valine 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, 117.2 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: 0.50 mL of 0.020 N hydrochloric acid

Sample: 0.73 g of Valine

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 Valine

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-Valine RS](#) and [USP L-Phenylalanine RS](#) in 0.1 N hydrochloric acid

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

Sample solution: 10 mg/mL of Valine in 2 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: 80 mg/mL in 6 N hydrochloric acid

Acceptance criteria: +26.6° to +28.8°

- **pH (791).**

Sample solution: 50 mg/mL

Acceptance criteria: 5.5–7.0

- **LOSS ON DRYING (731).**

Analysis: Dry at 105° for 3 h.

Acceptance criteria: NMT 0.3%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers.

- **USP REFERENCE STANDARDS (11).**

[USP L-Phenylalanine RS](#)

[USP L-Valine RS](#)

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

Topic/Question	Contact	Expert Committee
VALINE	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](#)