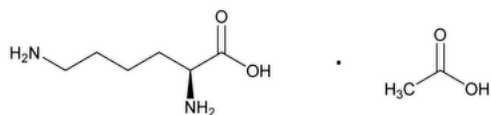


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Lysine Acetate



$C_6H_{14}N_2O_2 \cdot C_2H_4O_2$ 206.24

L-Lysine monoacetate CAS RN®: 57282-49-2; UNII: TTL6G7LIWZ.

DEFINITION

Lysine Acetate contains NLT 98.0% and NMT 102.0% of L-lysine acetate ($C_6H_{14}N_2O_2 \cdot C_2H_4O_2$), calculated on the dried basis.

IDENTIFICATION

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

ASSAY

• PROCEDURE

Sample: 100 mg of Lysine Acetate

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 lysine acetate ($C_6H_{14}N_2O_2 \cdot C_2H_4O_2$) 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, 103.1 mg/mEq

W = *Sample* weight (mg)

Acceptance criteria: 98.0%–102.0% 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 Lysine Acetate

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 Lysine Acetate

Acceptance criteria: NMT 0.03%

Change to read:

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

Change to read:

• **RELATED COMPOUNDS**

Standard solution: 0.05 mg/mL of [USP L-Lysine Acetate RS](#) in water

[NOTE—This solution has a concentration equivalent to 0.5% of that of the *Sample solution*.]

Sample solution: 10 mg/mL of Lysine Acetate in water

System suitability solution: 0.4 mg/mL each of [USP L-Lysine Acetate RS](#) and [USP Arginine Hydrochloride RS](#)

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: Isopropyl alcohol and ammonium hydroxide (7:3)

Spray reagent: ▲2 mg/mL▲ (ERR 1-Jun-2023) 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*

Dry the plate between 100° and 105° until the ammonia completely disappears. 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: 100 mg/mL in water

Acceptance criteria: +8.4° to +9.9°

- **LOSS ON DRYING (731):** Dry a sample at 80° for 3 h: it loses NMT 0.2% of its weight.

ADDITIONAL REQUIREMENTS

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

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

[USP Arginine Hydrochloride RS](#)

[USP L-Lysine Acetate RS](#)

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

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

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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