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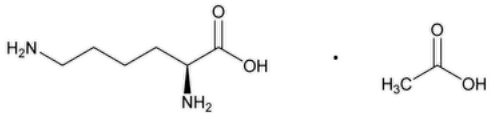
Lysine Acetate



$C_6H_{14}N_2O_2 \cdot C_2H_4O_2$ 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:
Pharmacopeial Forum: Volume No. Information currently unavailable

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