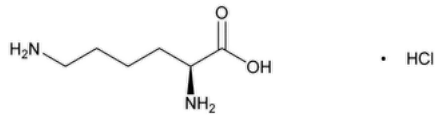


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# Lysine Hydrochloride



L-Lysine hydrochloride CAS RN®: 657-27-2; UNII: JNJ23Q2COM.

### DEFINITION

Lysine Hydrochloride contains NLT 98.5% and NMT 101.5% of L-lysine hydrochloride ( $\text{C}_6\text{H}_{14}\text{N}_2\text{O}_2 \cdot \text{HCl}$ ), calculated on the dried basis.

### IDENTIFICATION

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

### ASSAY

#### PROCEDURE

**Sample:** 90 mg of Lysine Hydrochloride

**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. Add 10 mL of mercuric acetate TS, and titrate with the *Titrant*. Perform the *Blank* determination.

Calculate the percentage of lysine hydrochloride ( $\text{C}_6\text{H}_{14}\text{N}_2\text{O}_2 \cdot \text{HCl}$ ) 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, 91.33 mg/mEq

$W$  = *Sample* weight (mg)

**Acceptance criteria:** 98.5%–101.5% on the dried basis

### OTHER COMPONENTS

#### CONTENT OF CHLORIDE

**Sample:** 350 mg of Lysine Hydrochloride

**Blank:** 140 mL of water

#### Titrimetric system

(See [Titrimetry \(541\)](#).)

**Mode:** Direct titration

**Titrant:** 0.1 N silver nitrate VS

**Endpoint detection:** Visual

**Analysis:** Transfer the *Sample* to a porcelain casserole, and add 140 mL of water and 1 mL of dichlorofluorescein TS. Titrate with the *Titrant* until the silver chloride flocculates and the mixture acquires a faint pink color. Perform the *Blank* determination.

Calculate the percentage of chloride (Cl) 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, 35.45 mg/mEq

$W$  = *Sample* weight (mg)

**Acceptance criteria:** 19.0%–19.6%

#### IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

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

**Standard solution:** 0.10 mL of 0.020 N sulfuric acid

**Sample:** 0.33 g of Lysine Hydrochloride

**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 Hydrochloride 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 Hydrochloride in water

**System suitability solution:** 0.4 mg/mL each of [USP L-Lysine Hydrochloride 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  $\mu$ L

**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:** 80 mg/mL in 6 N hydrochloric acid

**Acceptance criteria:** +20.4° to +21.4°

• [LOSS ON DRYING \(731\)](#): Dry a sample at 105° for 3 h: it loses NMT 0.4% of its weight.

#### ADDITIONAL REQUIREMENTS

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

• [USP REFERENCE STANDARDS \(11\)](#)

[USP Arginine Hydrochloride RS](#)

[USP L-Lysine Hydrochloride RS](#)

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

| Topic/Question       | Contact                                                                     | Expert Committee                           |
|----------------------|-----------------------------------------------------------------------------|--------------------------------------------|
| LYSINE HYDROCHLORIDE | <a href="#">Fatkhulla K Tadjimukhamedov</a><br>Associate Scientific Liaison | NBDS2020 Non-botanical Dietary Supplements |

**Chromatographic Database Information:** [Chromatographic Database](#)

**Most Recently Appeared In:**

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