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Lysine Hydrochloride Tablets

DEFINITION

Lysine Hydrochloride Tablets contain NLT 90.0% and NMT 120.0% of the labeled amount of $C_6H_{14}N_2O_2 \cdot HCl$, as L-lysine hydrochloride.

IDENTIFICATION

• A. THIN-LAYER CHROMATOGRAPHIC IDENTIFICATION TEST

Standard solution: 0.4 mg/mL of [USP L-Lysine Hydrochloride RS](#) in water

Sample solution: A filtered solution in water, equivalent to 0.4 mg/mL of lysine hydrochloride from powdered Tablets

Chromatographic system

(See [Chromatography \(621\)](#), [Thin-Layer Chromatography](#).)

Mode: TLC

Adsorbent: 0.25-mm layer of chromatographic silica gel

Application volume: 10 μ L

Developing solvent system: Isopropyl alcohol and ammonium hydroxide (70:30)

Spray reagent: 2 mg/mL of ninhydrin in a mixture of butyl alcohol and 2 N acetic acid (95:5)

Analysis

Samples: *Standard solution* and *Sample solution*

Develop the plate, and dry at 100°–105° until the ammonia disappears completely. Spray with *Spray reagent*, and heat at 100°–105° for 15 min. Examine the plate under white light.

Acceptance criteria: The R_f value of the principal spot from the *Sample solution* corresponds to that from the *Standard solution*.

STRENGTH

• PROCEDURE

Sample: A portion of the powder from NLT 20 finely powdered Tablets, equivalent to 75 mg of lysine hydrochloride

Blank: Proceed as directed in the *Analysis* without the *Sample*.

Titrimetric system

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

Mode: Direct titration

Titrant: 0.1 N perchloric acid VS

Endpoint detection: Potentiometric or visual

Analysis: Dissolve the *Sample* in 5 mL of mercuric acetate TS with gentle heating. Cool, then add 50 mL of glacial acetic acid. Add 3 drops of crystal violet TS when needed. Titrate with *Titrant*. Perform the *Blank* determination.

Calculate the percentage of the labeled amount of L-lysine hydrochloride ($C_6H_{14}N_2O_2 \cdot HCl$) in the portion of *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 = nominal amount of L-lysine hydrochloride in the *Sample* taken (mg)

Acceptance criteria: 90.0–120.0%

PERFORMANCE TESTS

- [DISINTEGRATION AND DISSOLUTION \(2040\)](#): Meet the requirements for *Disintegration*
Time: 20 min
- [WEIGHT VARIATION OF DIETARY SUPPLEMENTS \(2091\)](#): Meet the requirements

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers, and store at controlled room temperature.
- [USP REFERENCE STANDARDS \(11\)](#)
[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 TABLETS	Natalia Davydova 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](#)

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