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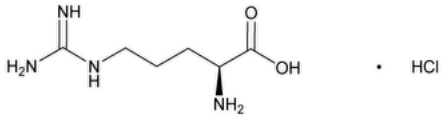
Arginine Hydrochloride



$C_6H_{14}N_4O_2 \cdot HCl$ 210.66

L-Arginine monohydrochloride;

L-(+)-Arginine monohydrochloride CAS RN®: 1119-34-2; UNII: F7LTH1E20Y.

DEFINITION

Arginine Hydrochloride contains NLT 98.5% and NMT 101.5% of arginine hydrochloride ($C_6H_{14}N_4O_2 \cdot HCl$), calculated on the dried basis.

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197K**▲ (CN 1-May-2020)

ASSAY

• **Procedure**

Sample: 100 mg of Arginine Hydrochloride

Titrimetric system

(See *Titrimetry ⟨541⟩*.)

Mode: Direct titration

Titrant: 0.1 N perchloric acid VS

Endpoint detection: Potentiometric

Blank: 50 mL of glacial acetic acid and 3 mL of 98% formic acid. Add 6 mL of mercuric acetate TS.

Analysis: Dissolve the *Sample* in 3 mL of 98% formic acid and 50 mL of glacial acetic acid. Add 6 mL of mercuric acetate TS and titrate with the *Titrant*.

Calculate the percentage of arginine hydrochloride ($C_6H_{14}N_4O_2 \cdot HCl$) in the *Sample* taken:

$$\text{Result} = [(V - B) \times N \times F \times 100]/W$$

V = *Sample* titrant volume (mL)

B = *Blank* titrant volume (mL)

N = titrant normality (mEq/mL)

F = equivalency factor, 105.3 mg/mEq

W = weight of *Sample* (mg)

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

IMPURITIES

• **Residue on Ignition ⟨281⟩:** NMT 0.1%

• **Chloride and Sulfate, *Sulfate*⟨221⟩:** A 1.6-g portion shows no more sulfate than corresponds to 0.50 mL of 0.020 N sulfuric acid (0.03%).

• **Chromatographic Purity**

System suitability solution: 0.4 mg/mL each of USP Arginine Hydrochloride RS and USP L-Lysine Hydrochloride RS in water

Standard solution: 0.05 mg/mL of USP Arginine Hydrochloride RS in water. [Note—This solution has a concentration equivalent to about 0.5% of that of the *Sample solution*.]

Sample solution: 10 mg/mL of Arginine Hydrochloride in water

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 (70:30)

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

Analysis

Samples: *System suitability solution*, *Standard solution*, and *Sample solution*

Proceed as directed in the chapter. Dry the plate between 100° and 105° until the ammonia disappears completely. Spray with *Spray reagent*, and heat between 100° and 105° for about 15 min. Examine the plate under white light. The *System suitability solution* exhibits two clearly separated spots.

Acceptance criteria: Any secondary spot from the *Sample solution* is not larger or more intense than the principal spot from the *Standard solution*.

Individual impurities: NMT 0.5%

Total impurities: NMT 2.0%

SPECIFIC TESTS

- **Optical Rotation, *Specific Rotation*⟨781S⟩:** +21.4° to +23.6° (*t* = 20°)

Sample solution: 80 mg/mL in 6 N hydrochloric acid

- **Loss on Drying ⟨731⟩:** Dry a sample at 105° for 2 h: it loses NMT 0.2% of its weight.
- **Chloride Content**

Sample: 350 mg of Arginine Hydrochloride

Titrimetric system

(See *Titrimetry* ⟨541⟩.)

Mode: Direct titration

Titrant: 0.1 N silver nitrate VS

Endpoint detection: Colorimetric

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

Calculate the percentage of chloride (Cl) in the *Sample* taken:

$$\text{Result} = (V \times N \times F \times 100)/W$$

V = *Sample* titrant volume (mL)

N = titrant normality (mEq/mL)

F = equivalency factor, 35.45 mg/mEq

W = weight of *Sample* (mg)

Acceptance criteria: 16.5%–17.1%

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
ARGININE HYDROCHLORIDE	Fatkhulla K Tadjimukhamedov Associate Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements

Chromatographic Database Information: Chromatographic Database

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