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Arginine Tablets

DEFINITION

Arginine Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of arginine or arginine hydrochloride in an amount equivalent to arginine ($C_6H_{14}N_4O_2$).

IDENTIFICATION

• **A. Thin-Layer Chromatographic Identification Test ⟨201⟩**

Standard solution: 1.5 mg/mL of USP L-Arginine RS or USP Arginine Hydrochloride RS in water

Sample solution: Weigh and finely powder NLT 20 Tablets, mix, and transfer a portion of the powder, equivalent to about 150 mg of arginine, to a 100-mL volumetric flask, add 80 mL of water, sonicate for 15 min, dilute with water to volume, mix, and filter.

Application volume: 5 µL

Developing solvent system: Isopropyl alcohol and ammonium hydroxide (7:3)

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

Analysis: Proceed as directed for *Chromatography ⟨621⟩, Thin-Layer Chromatography.* Dry the plate at 100°–105° until the ammonia disappears completely. Spray with the *Spray reagent*, and heat at 100°–105° for about 15 min. Examine the plate under white light.

Acceptance criteria: The principal spot from the *Sample solution* corresponds in appearance and R_F value to that from the *Standard solution*.

• **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in *Strength*.

STRENGTH

• **Procedure**

Buffer: 6.9 mg/mL of monobasic sodium phosphate in water. Adjust with phosphoric acid to a pH of 3.5.

Solution A: 0.5 mg/mL of 1-octanesulfonic acid sodium salt in *Buffer*

Mobile phase: *Solution A* and acetonitrile (95:5)

Standard solution: 1.5 mg/mL of USP L-Arginine RS or USP Arginine Hydrochloride RS in *Buffer*

Sample solution: Weigh and finely powder NLT 20 Tablets, mix, and transfer a portion of the powder, equivalent to about 150 mg of arginine, to a 100-mL volumetric flask, add 80 mL of *Buffer*, sonicate for 15 min, dilute with *Buffer* to volume, mix, and filter.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability.*)

Mode: LC

Detector: UV 215 nm

Column: 4.6-mm × 25-cm; packing L7

Flow rate: 0.8 mL/min

Injection size: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 1500 theoretical plates

Relative standard deviation: NMT 2.0% from the arginine peak, in repeated injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of arginine in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of the *Standard solution* (mg/mL)

C_U = nominal concentration of Arginine in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0% of the labeled amount of arginine ($C_6H_{14}N_4O_2$)

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PERFORMANCE TESTS

- **Disintegration and Dissolution of Dietary Supplements ⟨2040⟩:** Meet the requirements for *Dissolution*

  Medium: 0.1 N hydrochloric acid; 900 mL

  Apparatus 2: 100 rpm

  Time: 60 min

  Standard solution: Proceed as directed in the *Procedure* for *Strength*.

  Sample solution: Sample per *Disintegration and Dissolution of Dietary Supplements ⟨2040⟩*. Dilute with *Medium* to a concentration similar to that of the *Standard solution*.

  Analysis: Determine the amounts of arginine dissolved in the *Procedure* for *Strength*, making any necessary modifications.

  Tolerances: NLT 75% of the labeled amount of arginine ($C_6H_{14}N_4O_2$) is dissolved.

- **Weight Variation of Dietary Supplements ⟨2091⟩:** Meet the requirements

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight, light-resistant containers.
- **Labeling:** The label states the form of arginine that is used and the equivalent amount of arginine.
- **USP Reference Standards ⟨11⟩**

  USP L-Arginine RS

  USP Arginine Hydrochloride RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
ARGININE 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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