

Printed on: Mon Dec 01 2025, 15:28:37 pm

Printed by: Ita Aryani

Status: Currently Official on 01-Dec-2025

Official Date: Official as of 01-Jun-2023

Document Type: USP Monographs

DocId: GUID-AD006E64-D158-4467-8C93-CA8828ED7C7B_5_en-US

DOI: https://doi.org/10.31003/USPNF_M5840_05_01

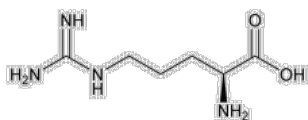
DOI Ref: 2uiy3

Printed from: https://online.uspnf.com/uspnf/document/1_GUID-AD006E64-D158-4467-8C93-CA8828ED7C7B_5_en-US

© 2025 USPC

Do not distribute

Arginine



$C_6H_{14}N_4O_2$ 174.20

L-Arginine CAS RN®: 74-79-3.

DEFINITION

Arginine contains NLT 98.5% and NMT 101.5% of $C_6H_{14}N_4O_2$, as L-arginine, calculated on the dried basis.

IDENTIFICATION

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

ASSAY

• PROCEDURE

Sample: 80 mg of Arginine

Titrimetric system

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

Mode: Direct titration

Titrant: 0.1 N perchloric acid VS

Endpoint detection: Potentiometric

Blank: 3 mL of formic acid and 50 mL of glacial acetic acid

Analysis: Dissolve the *Sample* in a mixture of 3 mL of formic acid and 50 mL of glacial acetic acid, and titrate with Titrant. Calculate the percentage of $C_6H_{14}N_4O_2$ in the portion 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: 87.10 mg/mEq

W = weight of *Sample* (mg)

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

IMPURITIES

INORGANIC IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.3%
- [CHLORIDE AND SULFATE, Chloride\(221\)](#): A 1.0-g portion shows no more chloride than corresponds to 0.70 mL of 0.020 N hydrochloric acid (0.05%).
- [CHLORIDE AND SULFATE, Sulfate\(221\)](#): A 1.0-g portion shows no more sulfate than corresponds to 0.30 mL of 0.020 N sulfuric acid (0.03%).

Change to read:

- [IRON \(241\), Procedures, Procedure 1](#) ▲ (CN 1-JUN-2023) : NMT 30 ppm

ORGANIC IMPURITIES

• PROCEDURE

Adsorbent: 0.25-mm layer of chromatographic silica gel mixture

Standard solution: 0.05 mg/mL of [USP L-Arginine RS](#) in 0.1 N hydrochloric acid. [NOTE—This solution has a concentration equivalent to 0.5% of that of the *Sample solution*.]

Sample solution: 10 mg/mL of Arginine in 2 N hydrochloric acid

System suitability solution: 0.4 mg/mL each of [USP L-Arginine RS](#) and [USP L-Lysine Hydrochloride RS](#) in 0.1 N hydrochloric acid

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

Application volume: 5 µL

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

Analysis

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

Proceed as directed under [Chromatography \(621\)](#), [Thin-Layer Chromatography](#). 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 chromatogram obtained from the *System suitability solution* exhibits two clearly separated spots.

Acceptance criteria

Individual impurities: Any secondary spot from the *Sample solution* is not larger or more intense than the principal spot from the *Standard solution*, NMT 0.5%

Total impurities: NMT 2.0%

SPECIFIC TESTS

- **OPTICAL ROTATION, *Specific Rotation*(781S):** +26.3° to +27.7°

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

- **LOSS ON DRYING (731):** Dry a sample at 105° for 3 h: it loses NMT 0.5% of its weight.

ADDITIONAL REQUIREMENTS

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

- **USP REFERENCE STANDARDS (11)**

[USP L-Arginine 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	Fatkhulla K Tadjimukhamedov Associate Scientific Liaison	NBDS2025 Non-botanical Dietary Supplements
REFERENCE STANDARDS SUPPORT	RS Technical Services RSTECH@usp.org	NBDS2025 Non-botanical Dietary Supplements

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. PF 44(5)

Current DocID: GUID-AD006E64-D158-4467-8C93-CA8828ED7C7B_5_en-US

DOI: https://doi.org/10.31003/USPNF_M5840_05_01

DOI ref: [2uiy3](#)