**Assay**—Proceed as directed in the *Assay under Aprotinin.*

### Arginine

**DEFINITION**

Arginine contains NLT 98.5% and NMT 101.5% of C\(_6\)H\(_{14}\)N\(_4\)O\(_2\), as L-arginine, calculated on the dried basis.

**IDENTIFICATION**

- **Infrared Absorption (197K)**

**ASSAY**

- **Procedure**
  
  **Sample:** 80 mg of Arginine
  
  **Titrimetric system**
  
  (See Titrimetry (541).)
  
  **Mode:** Direct titration
  
  **Titrant:** 0.1 N per chloric 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\(_6\)H\(_{14}\)N\(_4\)O\(_2\) in the portion taken:

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

- **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%).
  
  - Iron (241): NMT 30 ppm
  
  - Heavy Metals, Method I (231): NMT 15 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:** Isopropl 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

### Arginine Hydrochloride

**DEFINITION**

Arginine Hydrochloride contains NLT 98.5% and NMT 101.5% of arginine hydrochloride (C\(_6\)H\(_{14}\)N\(_4\)O\(_2\)· HCl), calculated on the dried basis.

**IDENTIFICATION**

- **A. Infrared Absorption (197K)**

**ASSAY**

- **Procedure**
  
  **Sample:** 100 mg of Arginine Hydrochloride
  
  **Titrimetric system**
  
  (See Titrimetry (541).)
  
  **Mode:** Direct titration
  
  **Titrant:** 0.1 N per chloric acid VS
  
  **Endpoint detection:** Potentiometric
  
  **Blank:** 50 mL of glacial acetic acid and 3 mL of 98% formic acid. Add 6 mL of mer curic acetate TS.
  
  **Analysis:** Dissolve the Sample in 3 mL of 98% formic acid and 50 mL of glacial acetic acid. Add 6 mL of mer curic acetate TS and titrate with the Titrant. Calculate the percentage of arginine hydrochloride (C\(_6\)H\(_{14}\)N\(_4\)O\(_2\)· HCl) in the Sample taken:

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

- **Acceptance criteria:**
  
  - **Organic Impurities**
    
    - **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:** Isopropl alcohol and ammonium hydroxide (7:3)