**Isoleucine**

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In accordance with the Rules and Procedures of the 2015-2020 Council of Experts, the Non-Botanical Dietary Supplements Expert Committee has revised the Isoleucine monograph. The purpose for the revision is to remove the currently postponed HPLC procedure for the *Related compounds* test in this monograph. The omission of this procedure would not affect the Isoleucine monograph because it has never been implemented. The TLC is still the official procedure for the *Related compounds* test. It will be replaced by a new, improved HPLC procedure in the future revision of the monograph.

The Isoleucine Revision Bulletin supersedes the revision of the Isoleucine monograph published in *First Supplement to USP 40–NF 35*, which was scheduled to become official August 1, 2017. The Revision Bulletin will be incorporated in the *First Supplement to USP 41–NF 36*.

Should you have any questions, please contact Huy Dinh, Senior Scientific Liaison (301–816–8594 or htd@usp.org).
Isoleucine

\[ \text{C}_6\text{H}_{13}\text{NO}_2 \] 131.17
L-Isoleucine [73-32-5].

**DEFINITION**
Isoleucine contains NLT 98.5% and NMT 101.5% of L-isoleucine (\( \text{C}_6\text{H}_{13}\text{NO}_2 \)), calculated on the dried basis.

**IDENTIFICATION**
- **A. INFRARED ABSORPTION (197K)**

**ASSAY**
- **procedure**
  Sample: 130 mg of Isoleucine
  Blank: Mix 3 mL of formic acid and 50 mL of glacial acetic acid.
  **Titrometric system**
  (See Titrimetry (541).)
  **Mode:** Direct titration
  Titrant: 0.1 N perchloric acid VS
  **Analysis:** Dissolve the Sample in 3 mL of formic acid and 50 mL of glacial acetic acid. Titrate with the Titrant. Perform the blank determination.
  Calculate the percentage of L-isoleucine (\( \text{C}_6\text{H}_{13}\text{NO}_2 \)) in the Sample taken:
  \[
  \text{Result} = \left( \frac{(V_f - V_b) \times N_a \times F}{W} \right) \times 100
  \]
  \( V_f \) = Titrant volume consumed by the Sample (mL)
  \( V_b \) = Titrant volume consumed by the Blank (mL)
  \( N_a \) = actual normality of the Titrant (mEq/mL)
  \( F \) = equivalency factor, 131.2 mg/mEq
  \( W \) = Sample weight (mg)
  **Acceptance criteria:** 98.5%–101.5% on the dried basis

**IMPURITIES**
- **Residue on Ignition (281):** NMT 0.3%
- **Chloride and Sulfate (221), Chloride**
  Standard solution: 0.50 mL of 0.020 N hydrochloric acid
  Sample: 0.73 g of Isoleucine
  **Acceptance criteria:** NMT 0.05%
- **Chloride and Sulfate (221), Sulfate**
  Standard solution: 0.10 mL of 0.020 N sulfuric acid
  Sample: 0.33 g of Isoleucine
  **Acceptance criteria:** NMT 0.03%
- **Iron (241):** NMT 30 ppm

Delete the following:
- **Heavy Metals, Method I (231):** NMT 15 ppm
  (Official 1-Jan-2018)

Change to read:

- **USP Reference Standards (11)**
  - USP L-Isoleucine RS
    (RB 1-Aug-2017)
  - USP L-Valine RS
    (RB 1-Aug-2016)

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