Aspirin Tablets

**DEFINITION**
Aspirin Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of aspirin (C9H8O4). Tablets of larger than 81-mg size contain no sweeteners or other flavors. [NOTE—Tablets that are enteric-coated meet the requirements for Aspirin Delayed-Release Tablets.]

**IDENTIFICATION**

Change to read:

- A. The retention time of the aspirin peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay. [IRA 1-Jan-2017]
- B. INFRARED ABSORPTION (197K)
  Sample: Shake a quantity of finely powdered Tablets, equivalent to about 500 mg of aspirin, with 10 mL of alcohol for several min. Centrifuge the mixture. Pour off the clear supernatant, and evaporate it to dryness. Dry the residue under vacuum at 60°C for 1 h.

Acceptance criteria: Meet the requirements

**ASSAY**

Change to read:

- **PROCEDURE**
  Mobile phase: 2 g/L of sodium 1-heptanesulfonate in a mixture of acetonitrile and water (15:85). Adjust with glacial acetic acid to pH 3.4.
  Diluent: Acetonitrile and formic acid (99:1)
  Standard solution: 0.5 mg/mL of USP Aspirin RS in Diluent
  Sample stock solution: Nominal 5 mg/mL of aspirin prepared as follows. [IRA 1-Jan-2017]
  Transfer a quantity, equivalent to about 100 mg of aspirin from NLT 20 finely powdered Tablets, to a suitable container. Add 20.0 mL of Diluent and 10 glass beads. Shake vigorously for about 10 min, and centrifuge.
  Sample solution: Nominal 0.5 mg/mL of aspirin in Diluent from Sample stock solution. [IRA 1-Jan-2017]

Chromatographic system
(See Chromatography (621), System Suitability.)
Mode: LC
Detector: UV 280 nm
Column: 4.6-mm × 30-cm; packing L1
Flow rate: 2 mL/min
Injection volume: 10 µL
System suitability
Sample: Standard solution
Suitability requirements
Tailing factor: NMT 2.0
Relative standard deviation: NMT 2.0%

Analysis
Samples: Standard solution and Sample solution
Calculate the percentage of the labeled amount of aspirin (C9H8O4) in the portion of Tablets taken:

\[ \text{Result} = \left( \frac{r_u}{r_S} \right) \times \left( \frac{C_S}{C_u} \right) \times 100 \]

- \( r_u \) = peak response of aspirin from the Sample solution
- \( r_S \) = peak response of aspirin from the Standard solution
- \( C_S \) = concentration of USP Aspirin RS in the Standard solution (mg/mL)

Acceptance criteria: 90.0%–110.0%

**PERFORMANCE TESTS**

- **Dissolution (711)**
  Medium: 0.05 M acetate buffer, prepared by mixing 2.99 g of sodium acetate trihydrate and 1.66 mL of glacial acetic acid with water to obtain a total of 1000 mL of solution with a pH of 4.50 ± 0.05; 500 mL
  Apparatus 1: 50 rpm
  Time: 30 min
  Standard solution: A known concentration of USP Aspirin RS in Medium. Prepare the Standard solution at the time of use. [NOTE—A quantity of alcohol not to exceed 1% of the total volume of the Standard solution may be used to dissolve the Reference Standard prior to dilution with Medium.]
  Sample solution: Pass a portion of the solution under test through a suitable filter, and dilute with Medium, if necessary.

Instrumental conditions
Mode: UV
Analytical wavelength: 265 nm
Analysis
Samples: Standard solution and Sample solution
Determine the percentage of the labeled amount of aspirin (C9H8O4) dissolved from UV absorbances at the isobestic point of aspirin and salicylic acid at about 265 nm.

Tolerances:
NLT 80% (Q) of the labeled amount of aspirin (C9H8O4) is dissolved.

- **Uniformity of dosage units (905)**: Meet the requirements

**IMPURITIES**

Change to read:

- **Limit of free salicylic acid**
  Mobile phase, Diluent, and Chromatographic system: Proceed as directed in the Assay.
  Standard suitability solution: 0.015 mg/mL of USP Salicylic Acid RS and 0.05 mg/mL of USP Aspirin RS in Diluent [IRA 1-Jan-2017]
  Standard solution: 0.015 mg/mL of USP Salicylic Acid RS in Diluent [IRA 1-Jan-2017]
  Sample solution: Use the Sample stock solution prepared as directed in the Assay.

System suitability
Samples: System suitability solution [IRA 1-Jan-2017] and Standard solution
[NOTE—The relative retention times for salicylic acid and aspirin are about 0.7 and 1.0, respectively.]
Suitability requirements
Resolution: NLT 2.0 between salicylic acid and aspirin, System suitability solution [IRA 1-Jan-2017]
Relative standard deviation: NMT 4.0%, Standard solution

Analysis
Samples: Standard solution and Sample solution
Calculate the percentage of salicylic acid (C7H6O3) in the portion of Tablets taken:

\[ \text{Result} = \left( \frac{r_S}{r_u} \right) \times \left( \frac{C_u}{C_S} \right) \times 100 \]

- \( r_u \) = peak response of salicylic acid from the Sample solution
- \( r_S \) = peak response of salicylic acid from the Standard solution

©2016 The United States Pharmacopeial Convention All Rights Reserved.

C171021-M6290-CHM62015, Rev. 0 20161118
Aspirin

\[ C_s = \text{concentration of USP Salicylic Acid RS in the Standard solution (mg/mL)} \]
\[ C_d = \text{nominal concentration of aspirin in the Sample solution (mg/mL)} \]

Acceptance criteria: NMT 0.3%; for coated Tablets: NMT 3.0%

ADDITIONAL REQUIREMENTS

- Packaging and Storage: Preserve in tight containers. Preserve flavored or sweetened Tablets of 81-mg size or smaller in containers holding NMT 36 Tablets each.

- USP Reference Standards (11)
  - USP Aspirin RS
  - USP Salicylic Acid RS