Aspirin Effervescent Tablets for Oral Solution

**DEFINITION**

Aspirin Effervescent Tablets for Oral Solution contain Aspirin and an effervescent mixture of a suitable organic acid and an alkali metal bicarbonate and/or carbonate. Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of aspirin (C9H8O4).

**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.
- B. Sample: 1/2 Tablet
  Analysis: Add the Sample to 50 mL of water in a flask, and immediately stopper with a stopper fitted with tubing so that the evolved gas passes through calcium hydroxide TS.
  Acceptance criteria: A white precipitate forms.

**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 a pH of 3.4.
  Diluent: Acetonitrile and formic acid (99:1)
  Standard solution: 0.5 mg/mL of USP Aspirin RS in Diluent
  Sample stock solution: Nominally 5 mg/mL of aspirin prepared as follows. 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 10 min, and centrifuge.
  Sample solution: Nominally 0.5 mg/mL of aspirin in Diluent from Sample stock solution.
  Chromatographic system (See Chromatography (621), System Suitability.)
  Mode: LC
  Detector: UV 280 nm
  Column: 4-mm × 30-cm; packing L1
  Flow rate: 2 mL/min
  Injection volume: 10 μL

**Change to read:**

- Suitable requirements: NLT 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 Tablets taken:
  \[
  \text{Result} = \left( \frac{r_0}{r_s} \right) \times \left( \frac{C_s}{C_0} \right) \times 100
  \]
  \( r_0 \) = 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)
  \( C_0 \) = nominal concentration of aspirin in the Sample solution (mg/mL)

**Acceptance criteria:** NMT 8.0%

**SPECIFIC TESTS**

- Acid-Neutralizing Capacity (301): NLT 5.0 mEq of acid is consumed by 1 Tablet.

**ADDITIONAL REQUIREMENTS**

- Packaging and Storage: Preserve in tight containers.
- USP Reference Standards (11)
  USP Aspirin RS
  USP Salicylic Acid RS

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