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 ($C_9H_8O_4$).

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.**

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.• (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 10 min, and centrifuge.

Sample solution: •Nominally 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-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 ($C_9H_8O_4$) in the portion Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

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)

C_U = nominal concentration of aspirin in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **SOLUTION TIME:** NMT 5 min for 2 Tablets completely dissolved in 180 mL of water at 17.5 ± 2.5°.

• **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*.

•**System suitability solution:** 0.015 mg/mL of USP Salicylic Acid RS and 0.5 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 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 ($C_7H_6O_3$) in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of salicylic acid from the *Sample solution*

r_S = peak response of salicylic acid from the *Standard solution*

C_S = concentration of USP Salicylic Acid RS in the *Standard solution* (mg/mL)

C_U = 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