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## Aspirin Delayed-Release Tablets

### DEFINITION

Aspirin Delayed-Release Tablets contain NLT 95.0% and NMT 105.0% of the labeled amount of aspirin ( $C_9H_8O_4$ ).

### IDENTIFICATION

- **A.** The retention time of the aspirin peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

**Change to read:**

- **B.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), *Infrared Spectroscopy: 197K* ▲ (CN 1-MAY-2020)

**Sample:** Shake a quantity of finely powdered Tablets, equivalent to about 500 mg of aspirin, with 10 mL of alcohol for several minutes.

Centrifuge the mixture. Pour off the clear supernatant, and evaporate it to dryness. Dry the residue under vacuum at 60° for 1 h.

**Acceptance criteria:** Meet the requirements

### ASSAY

#### 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:** 4.0-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 of 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:** 95.0%–105.0%

### PERFORMANCE TESTS

- [DISSOLUTION \(711\)](#), *Procedure, Apparatus 1 and Apparatus 2, Delayed-Release Dosage Forms, Method B Procedure*

**Apparatus 1:** 100 rpm

**Times**

**Acid stage:** 2 h**Buffer stage:** 90 min**Diluent:** 0.1 N hydrochloric acid and 0.20 M tribasic sodium phosphate (3:1). Adjust, if necessary, with 2 N hydrochloric acid or 2 N sodium hydroxide to a pH of  $6.8 \pm 0.05$ .**Standard solution:** [USP Aspirin RS](#) of a known concentration in 0.1 N hydrochloric acid (for analyzing the *Acid stage*) and in *Diluent* (for analyzing the *Buffer stage*)**Sample solution:** Pass a portion of the solution under test through a suitable filter, diluted, if necessary, with 0.1 N hydrochloric acid (for analyzing the *Acid stage*) and with *Diluent* (for analyzing the *Buffer stage*).**Instrumental conditions****Mode:** UV**Analytical wavelengths****Acid stage:** 280 nm**Buffer stage:** 265 nm**Analysis****Samples:** *Standard solution* and *Sample solution*Determine the percentage of the labeled amount of aspirin ( $C_9H_8O_4$ ) dissolved by determining UV absorbances at the isosbestic point of aspirin and salicylic acid (about 280 nm in the *Acid stage*, and about 265 nm in the *Buffer stage*).**Tolerances****Acid stage:** NMT 10% (Q) of the labeled amount of aspirin ( $C_9H_8O_4$ ) is dissolved.**Buffer stage:** NLT 75% (Q) of the labeled amount of aspirin ( $C_9H_8O_4$ ) is dissolved.

- **UNIFORMITY OF DOSAGE UNITS (905):** Meet the requirements

**IMPURITIES**

- **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***Standard solution:** 0.015 mg/mL of [USP Salicylic Acid RS](#) in *Diluent***Sample solution:** Use the *Sample stock solution* from the Assay.**System suitability****Samples:** *System suitability solution* 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***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 3.0%**ADDITIONAL REQUIREMENTS**

- **PACKAGING AND STORAGE:** Preserve in tight containers.

- **USP REFERENCE STANDARDS (11).**

[USP Aspirin RS](#)[USP Salicylic Acid RS](#)Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
ASPIRIN DELAYED-RELEASE TABLETS	<a href="#">Documentary Standards Support</a>	SM22020 Small Molecules 2

Topic/Question	Contact	Expert Committee
REFERENCE STANDARD SUPPORT	RS Technical Services <a href="mailto:RSTECH@usp.org">RSTECH@usp.org</a>	SM22020 Small Molecules 2

Chromatographic Database Information: [Chromatographic Database](#)

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