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

**Acceptance criteria:** 95.0%–105.0%

**PERFORMANCE TESTS**

• **DISSOLUTION** ⟨*711*⟩

**Test 1:** If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 1*.

**Medium:** 0.1 N hydrochloric acid; 900 mL

**Apparatus 2:** 60 rpm

**Times:** 1 and 4 h

**Standard solution:** A known concentration of USP Aspirin RS in *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:** 280 nm

**Analysis**

**Samples:** *Standard solution* and *Sample solution*

Determine the percentage of the labeled amount of aspirin ($C_9H_8O_4$) dissolved from UV absorbances at the isosbestic point at about 280 nm.

**Tolerances:** See *Table 1*.

**Table 1**

| Time (h) | Amount Dissolved (%) |
|---|---|
| 1 | 20–55 |
| 4 | NLT 80 |

The percentages of the labeled amount of aspirin ($C_9H_8O_4$) dissolved at the times specified conform to *Dissolution* ⟨*711*⟩, *Acceptance Table 2*.

**Test 2:** If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 2*.

**Medium:** Water; 1000 mL

**Apparatus 2:** 30 rpm

**Times:** 1, 2, 4, and 8 h

**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 5% of the total volume of the *Standard solution* may be used to dissolve the USP Reference Standard prior to dilution with *Medium*.]

**Sample solutions:** 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 solutions*

Determine the percentage of the labeled amount of aspirin ($C_9H_8O_4$) dissolved from UV absorbances at the isosbestic point at about 265 nm.

**Tolerances:** See *Table 2*.

**Table 2**

| Time (h) | Amount Dissolved (%) |
|---|---|
| 1 | 15–40 |
| 2 | 25–60 |
| 4 | 35–75 |
| 8 | NLT 70 |

The percentages of the labeled amount of aspirin ($C_9H_8O_4$) dissolved at the times specified conform to *Dissolution* ⟨*711*⟩, *Acceptance Table 2*.

• **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* prepared as directed in 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.

• **LABELING:** The labeling indicates the *Dissolution* test with which the product complies.

• **USP REFERENCE STANDARDS** ⟨*11*⟩

USP Aspirin RS

USP Salicylic Acid RS

## Aspirin, Alumina, and Magnesia Tablets

**DEFINITION**

Aspirin, Alumina, and Magnesia Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of aspirin ($C_9H_8O_4$), the equivalent of NLT 90.0% and NMT 110.0% of the labeled amount of aluminum hydroxide [$Al(OH)_3$], and NLT 90.0% and NMT 110.0% of the labeled amount of magnesium hydroxide [$Mg(OH)_2$].

**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* for *Aspirin*.

• **B. IDENTIFICATION TESTS—GENERAL** ⟨*191*⟩, *Magnesium*

**Sample solution:** To a 0.7-g portion of finely powdered Tablets, add 20 mL of 3 N hydrochloric acid and 5 drops of methyl red TS, heat to boiling, and add 6 N ammonium hydroxide until the color of the solution changes to deep yellow. Continue boiling for 2 min, and filter. Use the filtrate for analysis and use the precipitate in *Identification C*.