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# Aspirin Boluses

## DEFINITION

Aspirin Boluses contain NLT 90.0% and NMT 110.0% of the labeled amount of aspirin ( $C_9H_8O_4$ ).

## IDENTIFICATION

### A. PROCEDURE

**Analysis:** Crush 1 Bolus. Boil a portion of the powder, equivalent to 300 mg of aspirin, with 50 mL of [water](#). Cool and add a drop of [ferric chloride TS](#).

**Acceptance criteria:** A violet-red color is produced.

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

## 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:** 0.4 mg/mL of [USP Aspirin RS](#) and 0.01 mg/mL of [USP Salicylic Acid RS](#) in *Diluent*

**Sample stock solution:** Nominally 4 mg/mL of aspirin prepared as follows. Finely powder NLT 10 Boluses. Transfer a portion of the powder to an appropriate volumetric flask and dilute with *Diluent* to volume. Stir the solution by mechanical means for 15 min.

**Sample solution:** Nominally 0.4 mg/mL of aspirin from *Sample stock solution* in *Diluent*. Pass a portion of this solution through a filter of 0.5- $\mu$ m or finer pore size. Use the filtrate.

### Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

**Mode:** LC

**Detector:** UV 254 nm

**Column:** 4.6-mm  $\times$  25-cm; 5- $\mu$ m packing [L1](#)

**Flow rate:** 1 mL/min

**Injection volume:** 20  $\mu$ L

### System suitability

**Sample:** *Standard solution*

[NOTE—The relative retention times for salicylic acid and aspirin are 0.6 and 1.0, respectively.]

### Suitability requirements

**Resolution:** NLT 2.0 between salicylic acid and aspirin

**Relative standard deviation:** NMT 2.0% for aspirin

### Analysis

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

Calculate the percentage of the labeled amount of aspirin ( $C_9H_8O_4$ ) in the portion of Boluses 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

### DISSOLUTION (711)

**Medium:** 0.5 M phosphate buffer (see [Reagents, Indicators, and Solutions—Buffer Solutions](#)), pH 7.4; 900 mL

**Apparatus 2:** 75 rpm

**Time:** 45 min

**Diluent:** [Acetonitrile](#) and [formic acid](#) (99:1)

**Standard solution:** [USP Aspirin RS](#) in *Diluent* at a suitable concentration. [NOTE—Prepare the solution at the time of use.]

**Sample solution:** Pass a portion of the solution under test through a suitable filter. Dilute with *Diluent*, if necessary.

#### Instrumental conditions

**Mode:** UV-Vis

**Analytical wavelength:** The isosbestic point of aspirin and salicylic acid at  $265 \pm 2$  nm

#### Analysis

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

Calculate the percentage of the labeled amount of aspirin ( $C_9H_8O_4$ ) dissolved:

$$\text{Result} = (A_U/A_S) \times C_S \times V \times D \times (1/L) \times 100$$

$A_U$  = absorbance of the *Sample solution*

$A_S$  = absorbance of the *Standard solution*

$C_S$  = concentration of the *Standard solution* (mg/mL)

$V$  = volume of *Medium*, 900 mL

$D$  = dilution factor of the *Sample solution*, if necessary

$L$  = label claim (mg/Bolus)

**Tolerances:** NLT 80% ( $Q$ ) of the labeled amount of aspirin ( $C_9H_8O_4$ ) is dissolved.

- [UNIFORMITY OF DOSAGE UNITS \(905\)](#): Meet the requirements

#### IMPURITIES

- **LIMIT OF SALICYLIC ACID**

**Mobile phase, Diluent, Sample solution, Chromatographic system, and System suitability:** Proceed as directed in the Assay.

**Salicylic acid standard solution:** 0.01 mg/mL of [USP Salicylic Acid RS](#) in *Diluent*

#### Analysis

**Samples:** *Sample solution* and *Salicylic acid standard solution*

Calculate the actual concentration ( $C$ ), in mg/mL, of aspirin ( $C_9H_8O_4$ ) in the *Sample solution* taken:

$$\text{Result} = C_U \times (F/100)$$

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

$F$  = percentage of the labeled amount of aspirin ( $C_9H_8O_4$ ) in the portion of Boluses taken, as determined in the Assay

Calculate the percentage of salicylic acid ( $C_7H_6O_3$ ) in the portion of Boluses taken:

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

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

$r_S$  = peak response of salicylic acid from the *Salicylic acid standard solution*

$C_S$  = concentration of [USP Salicylic Acid RS](#) in the *Salicylic acid standard solution* (mg/mL)

$C$  = actual concentration of aspirin in the *Sample solution*

**Acceptance criteria:** NMT 0.3%

#### ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers.
- **LABELING:** Label Boluses to indicate that they are for veterinary use only.
- [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         |
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