

Analysis

Samples: *Standard solution* and *Sample solution*

Record the chromatograms for a run time NLT 3 times the retention time of the acesulfame potassium peak, and measure the area responses of the peaks.

Acceptance criteria: The response of any peak at a retention time other than that of acesulfame potassium from the *Sample solution* does not exceed the response of the acesulfame potassium peak from the *Standard solution* (0.002%).

SPECIFIC TESTS• **ACIDITY OR ALKALINITY**

Sample solution: 4.0 g in 20 mL of carbon dioxide-free water

Analysis: Add 0.1 mL of bromothymol blue TS. If the solution is yellow, titrate with 0.01 N sodium hydroxide to produce a blue color. If the solution is blue, titrate with 0.01 N hydrochloric acid to produce a yellow color.

Acceptance criteria: NMT 0.2 mL of 0.01 N sodium hydroxide or NMT 0.2 mL of 0.01 N hydrochloric acid is required.

- **LOSS ON DRYING (731):** Dry a sample at 105° for 3 h: it loses NMT 1.0% of its weight.

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in a well-closed container, and protect from light. Store at room temperature.
- **USP REFERENCE STANDARDS (11)**
USP Acesulfame Potassium RS

Acetic Acid

Acetic acid;
Acetic acid [64-19-7].

DEFINITION

Acetic Acid is a solution containing NLT 36.0% and NMT 37.0%, by weight, of C₂H₄O₂.

IDENTIFICATION

- **A. IDENTIFICATION TESTS—GENERAL, Acetate (191):** Meets the requirements

ASSAY• **PROCEDURE**

Analysis: Place 6 mL in a tared, glass-stoppered flask, and weigh. Add 40 mL of water, then add phenolphthalein TS. Titrate with 1 N sodium hydroxide VS. Each mL of 1 N sodium hydroxide is equivalent to 60.05 mg of C₂H₄O₂.

Acceptance criteria: 36.0%–37.0%

IMPURITIES• **NONVOLATILE RESIDUE**

Analysis: Evaporate 20 mL in a tared porcelain dish on a steam bath, and dry at 105° for 1 h.

Acceptance criteria: The weight of the residue does not exceed 1.0 mg (0.005%).

• **CHLORIDE**

Sample solution: Acetic acid (1 in 10) in water

Analysis: To 10 mL of the *Sample solution* add 5 drops of silver nitrate TS.

Acceptance criteria: No opalescence is produced.

• **SULFATE**

Sample solution: Acetic acid (1 in 10) in water

Analysis: To 10 mL of the *Sample solution* add 5 drops of barium chloride TS.

Acceptance criteria: No turbidity is produced.

Delete the following:• **HEAVY METALS (231)**

Sample solution: To the residue obtained in the test for *Nonvolatile Residue* add 8 mL of 0.1 N hydrochloric acid, warm gently until completely dissolved, and dilute with water to 100 mL. Use 10 mL of this solution.

Acceptance criteria: NMT 10 ppm (Official 1-Jan-2018)

• **READILY OXIDIZABLE SUBSTANCES**

Analysis: Dilute 4.0 mL in a glass-stoppered vessel with 20 mL of water, and add 0.30 mL of 0.10 N potassium permanganate.

Acceptance criteria: The pink color is not changed to brown at once, and the liquid does not become entirely brown or free from a pink tint in less than 30 s.

ADDITIONAL REQUIREMENTS

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

Diluted Acetic Acid**DEFINITION**

Diluted Acetic Acid is a solution containing, in each 100 mL, NLT 5.7 g and NMT 6.3 g of acetic acid (C₂H₄O₂).

Prepare Diluted Acetic Acid as follows (see *Pharmaceutical Compounding—Nonsterile Preparations (795)*).

| | |
|-----------------------------------------------|---------|
| Acetic Acid | 158 mL |
| Purified Water, a sufficient quantity to make | 1000 mL |

Mix the ingredients.

IDENTIFICATION

- **A. IDENTIFICATION TESTS—GENERAL, Acetate (191):** Meets the requirements

ASSAY• **PROCEDURE**

Sample: 25 mL

Analysis: To the *Sample* add 15 mL of carbon dioxide-free water. Add phenolphthalein TS, and titrate with 1 N sodium hydroxide VS. Each mL of 1 N sodium hydroxide is equivalent to 60.05 mg of acetic acid (C₂H₄O₂).

Acceptance criteria: 5.7–6.3 g of acetic acid per 100 mL of Diluted Acetic Acid

IMPURITIES**Delete the following:**• **HEAVY METALS, Method I (231)**

Test preparation: Evaporate 5 mL in a porcelain dish on a steam bath to dryness. Warm the residue with 2 mL of 1 N acetic acid, and dilute with water to 50 mL. Dilute 20 mL of this solution with water to 25 mL.

Acceptance criteria: NMT 10 ppm (Official 1-Jan-2018)

• **LIMIT OF CHLORIDE**

Sample solution: A solution of Diluted Acetic Acid in water (6 in 10)

Analysis: Add 5 drops of silver nitrate TS to 10 mL of the *Sample solution*.

Acceptance criteria: No opalescence is found.

• **LIMIT OF SULFATE**

Sample solution: A solution of Diluted Acetic Acid in water (6 in 10)