

the quantity, in mg, of acetazolamide ($C_4H_6N_4O_3S_2$) in the portion of Tablets taken by the formula:

$$1000C(R_U / R_S)$$

in which C is the concentration, in mg per mL, of USP Acetazolamide RS in the *Standard preparation*; and R_U and R_S are the peak response ratios of the analyte peak to the internal standard peak obtained from the *Assay preparation* and the *Standard preparation*, respectively.

Glacial Acetic Acid



$C_2H_4O_2$ 60.05
Acetic acid [64-19-7].

DEFINITION

Glacial Acetic Acid contains NLT 99.5% and NMT 100.5%, by weight, of $C_2H_4O_2$.

IDENTIFICATION

- **IDENTIFICATION TESTS—GENERAL, Acetate (191):** Meets the requirements
Sample solution (for lanthanum nitrate test): Glacial Acetic Acid and water (1:100)

ASSAY

- **PROCEDURE**
Sample solution: Measure 2 mL of Glacial Acetic Acid into a glass-stoppered flask, previously tared while containing about 20 mL of water, and weigh again to obtain the weight of the substance under assay.
Analysis: Add 20 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 $C_2H_4O_2$.
Acceptance criteria: 99.5%–100.5%

IMPURITIES

Inorganic Impurities

- **LIMIT OF NONVOLATILE RESIDUE:** Evaporate 20 mL in a tared dish, and dry at 105° for 1 h: the weight of the residue does not exceed 1.0 mg.
- **HEAVY METALS (231):** NMT 5 ppm
Sample solution: To the residue obtained in the test for *Limit of Nonvolatile Residue* add 8 mL of 0.1 N hydrochloric acid, warm gently until solution is complete, dilute with water to 100 mL, and use 20 mL.
- **CHLORIDE AND SULFATE, Chloride (221)**
Sample solution: Dilute 1.0 mL with 20 mL of water.
Analysis: Add 5 drops of silver nitrate TS.
Acceptance criteria: No opalescence is produced.
- **CHLORIDE AND SULFATE, Sulfate (221)**
Sample solution: Dilute 1.0 mL with 10 mL of water.
Analysis: Add 1 mL of barium chloride TS.
Acceptance criteria: No turbidity is produced.

Organic Impurities

- **PROCEDURE: READILY OXIDIZABLE SUBSTANCES**
Sample solution: Dilute 2.0 mL in a glass-stoppered vessel with 10 mL of water.
Analysis: Add 0.10 mL of 0.10 N potassium permanganate.
Acceptance criteria: The pink color is not changed to brown within 2 h.

SPECIFIC TESTS

- **CONGEALING TEMPERATURE (651):** NLT 15.6°

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers, and store at room temperature.

Acetic Acid Irrigation

DEFINITION

Acetic Acid Irrigation is a sterile solution of Glacial Acetic Acid in Water for Injection. It contains, in each 100 mL, NLT 237.5 mg and NMT 262.5 mg of $C_2H_4O_2$.

IDENTIFICATION

- **A. IDENTIFICATION TESTS—GENERAL, Acetate (191)**
Sample: 100 mL of Acetic Acid Irrigation
Analysis: Evaporate the *Sample* to about 10 mL.
Acceptance criteria: The resulting solution meets the requirements.

ASSAY

- **PROCEDURE**
Sample: 50 mL of Acetic Acid Irrigation
Analysis: Pipet the *Sample* into a 150-mL conical flask, add 2 drops of phenolphthalein TS, and titrate with 0.1 N sodium hydroxide VS. Each mL of 0.1 N sodium hydroxide is equivalent to 6.005 mg of acetic acid ($C_2H_4O_2$).
Acceptance criteria: 237.5–262.5 mg of $C_2H_4O_2$ in each 100 mL of Acetic Acid Irrigation

SPECIFIC TESTS

- **PH (791):** 2.8–3.4
- **BACTERIAL ENDOTOXINS TEST (85):** It contains NMT 0.5 USP Endotoxin Unit/mL.
- **OTHER REQUIREMENTS:** It meets the requirements under *Injections (1)*, except that the container in which it is packaged may be designed to empty rapidly and may exceed 1000 mL in capacity.

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in single-dose containers, preferably of Type I or Type II glass, and store at controlled room temperature. It may be packaged in suitable plastic containers.
- **USP REFERENCE STANDARDS (11)**
USP Endotoxin RS

Acetic Acid Otic Solution

DEFINITION

Acetic Acid Otic Solution is a solution of Glacial Acetic Acid in a suitable nonaqueous solvent. It contains NLT 85.0% and NMT 130.0% of the labeled amount of $C_2H_4O_2$.

IDENTIFICATION

- **A.**
Sample solution: Dilute 5 mL of Acetic Acid Otic Solution with 10 mL of water.
Analysis: Adjust the *Sample solution* with 1 N sodium hydroxide to a pH of 7. Add ferric chloride TS.
Acceptance criteria: A deep red color is produced, and it is destroyed by the addition of hydrochloric acid.
- **B.**
Analysis: Warm it with sulfuric acid and alcohol.
Acceptance criteria: Ethyl acetate, recognizable by its characteristic odor, is evolved.

ASSAY

- **PROCEDURE**
Sample: A quantity of Acetic Acid Otic Solution containing 100 mg of glacial acetic acid
Analysis: Transfer the *Sample* to a 250-mL conical flask, and add 5 mL of saturated sodium chloride solution, 40 mL of water, and 3 drops of phenolphthalein TS. Titrate with 0.1 N sodium hydroxide VS to a faint pink endpoint. Each mL of 0.1 N sodium hydroxide is equivalent to 6.005 mg of acetic acid ($C_2H_4O_2$).