

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 (C₂H₄O₂).
 Acceptance criteria: 237.5–262.5 mg of C₂H₄O₂ 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 and Implanted Drug Products (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.

Delete the following:

- **USP REFERENCE STANDARDS (11)**
 USP Endotoxin RS
 (CN 1-May-2018)

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 C₂H₄O₂.

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 (C₂H₄O₂).

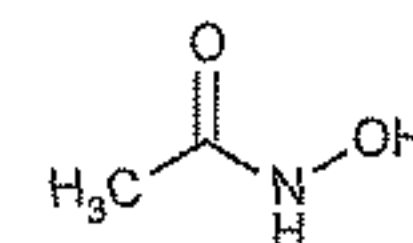
Acceptance criteria: 85.0%–130.0%

SPECIFIC TESTS

- **PH (791)**
 Sample solution: Acetic Acid Otic Solution and water (1:1)
 Acceptance criteria: 2.0–4.0

ADDITIONAL REQUIREMENTS

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

Acetohydroxamic Acid

C₂H₅NO₂ 75.07
N-Acetyl hydroxyacetamide;
 Acetohydroxamic acid [546-88-3].

DEFINITION

Acetohydroxamic Acid, dried over phosphorus pentoxide for 16 h, contains NLT 98.0% and NMT 101.0% of acetohydroxamic acid (C₂H₅NO₂).

IDENTIFICATION

- **A. INFRARED ABSORPTION (197K)**
- **B.**
 Sample solution: 20 mg/mL in water
 Analysis: To 10 mL of the *Sample solution* add 2 drops of potassium permanganate TS.
 Acceptance criteria: The pink color of the permanganate disappears.

ASSAY

- **PROCEDURE**
 Ferric chloride solution: 20 mg/mL of ferric chloride in 0.1 N hydrochloric acid
 Standard solution: 500 µg/mL of USP Acetohydroxamic Acid RS in 0.1 N hydrochloric acid
 Sample solution: 500 µg/mL of Acetohydroxamic Acid, previously dried, in 0.1 N hydrochloric acid
 Blank: 0.1 N hydrochloric acid
 Analysis
 Samples: *Standard solutions*, *Sample solution*, and *Blank*
 Transfer 10.0 mL each of the *Standard solution*, *Sample solution*, and *Blank* to separate 100-mL volumetric flasks. To each flask add 50 mL of 0.1 N hydrochloric acid and 10.0 mL of *Ferric chloride solution*, and dilute with 0.1 N hydrochloric acid to volume. Without delay, concomitantly determine the absorbances of the solutions at the wavelength of maximum absorbance at about 502 nm using the *Blank* to set the instrument.
 Calculate the percentage of acetohydroxamic acid (C₂H₅NO₂) in the portion of Acetohydroxamic Acid taken:

$$\text{Result} = (A_U/A_S) \times (C_S/C_U) \times 100$$

- A_U = absorbance of the *Sample solution*
 A_S = absorbance of the *Standard solution*
 C_S = concentration of USP Acetohydroxamic Acid RS in the *Standard solution* (µg/mL)
 C_U = concentration of Acetohydroxamic Acid in the *Sample solution* (µg/mL)
 Acceptance criteria: 98.0%–101.0% on the previously dried basis