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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 ($C_2H_4O_2$).
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.

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
ACETIC ACID OTIC SOLUTION	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: [Chromatographic Database](#)

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