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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 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.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
ACETIC ACID IRRIGATION	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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