Status: Currently Official on 13-Feb-2025
Official Date: Official as of 01-Jan-2018
Document Type: NF Monographs
DocId: GUID-465A06DD-75C4-4943-B5BB-636A7B6703B2_3_en-US
DOI: https://doi.org/10.31003/USPNF_M430_03_01
DOI Ref: sqk77

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 ($C_2H_4O_2$).

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 ($C_2H_4O_2$).

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

IMPURITIES

• **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)

Analysis: Add 5 drops of barium chloride TS to 10 mL of the *Sample solution*.

Acceptance criteria: No turbidity is produced.

• **Limit of Nonvolatile Residue**

Sample: 20 mL

Analysis: Evaporate the *Sample* in a tared porcelain dish on a steam bath, and dry it at 105° for 1 h.

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

SPECIFIC TESTS

• **Readily Oxidizable Substances**

Sample: 20 mL in a glass-stoppered flask

Analysis: Add 0.30 mL of 0.10 N potassium permanganate to the *Sample*.

Acceptance criteria: The pink color is not changed to brown immediately, 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.

Topic/Question	Contact	Expert Committee
DILUTED ACETIC ACID	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 27(4)

Current DocID: GUID-465A06DD-75C4-4943-B5BB-636A7B6703B2_3_en-US
Previous DocID: GUID-465A06DD-75C4-4943-B5BB-636A7B6703B2_1_en-US
DOI: https://doi.org/10.31003/USPNF_M430_03_01
DOI ref: sqk77