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Cellulose Acetate

Portions of this monograph that are national *USP* text, and are not part of the harmonized text, are marked with symbols (♦) to specify this fact.

Cellulose acetate;
Cellulose, diacetate CAS RN®: 9035-69-2.
Cellulose, triacetate
CAS RN®: 9012-09-3.

DEFINITION

Cellulose Acetate is partially or completely acetylated cellulose. It contains NLT 29.0% and NMT 44.8%, by weight, of acetyl (C_2H_3O) groups, calculated on the dried basis. Its acetyl content is NLT 90.0% and NMT 110.0% of that indicated on the label.

IDENTIFICATION

• **A. Infrared Absorption**

Sample solution: Prepare a 20 mg/mL solution of Cellulose Acetate, previously dried, in acetone (mono- and diester) or in methylene chloride (di- and triester).

Analysis: Spread 1 drop of the *Sample solution* on a sodium chloride plate, place a second sodium chloride plate over it, and spread the specimen between the plates. Separate the plates, heat them both at 105° for 1 h, and reassemble the dried plates.

Acceptance criteria: The IR absorption spectrum exhibits maxima only at the same wavelengths as those of a similar preparation of USP Cellulose Acetate RS, treated in the same manner.

ASSAY

• **Content of Acetyl**

For Cellulose Acetate labeled to contain NMT 42.0% of acetyl groups

Sample: 2 g of Cellulose Acetate

Titrimetric system

(See *Titrimetry* ⟨541⟩.)

Mode: Residual titration

Titrant: 1.0 N sodium hydroxide VS

Back-titrant: 1.0 N sulfuric acid VS

Endpoint detection: Visual

Analysis: Transfer the *Sample* to a 500-mL flask. Add 100 mL of acetone and 5–10 mL of water to the flask, insert the stopper into the flask, and stir with a magnetic stirrer until solution is complete. Pipet 30 mL of *Titrant* to the solution, with constant stirring. A finely divided precipitate of regenerated cellulose, free from lumps, is obtained. Insert the stopper into the flask, and stir with a magnetic stirrer for 30 min. Add 100 mL of water that has been preheated to 80°, washing down the sides of the flask. Stir for 2 min, and cool to room temperature. Titrate the excess sodium hydroxide solution with *Back-titrant* to a phenolphthalein endpoint. Treat a blank in the same manner.

Calculate the percentage of acetyl in the portion of Cellulose Acetate taken:

$$\text{Result} = (V_B - V_S)/W \times 4.305$$

V_B = *Back-titrant* volume consumed by the blank (mL)

V_S = *Back-titrant* volume consumed by Cellulose Acetate (mL)

W = weight of Cellulose Acetate taken, calculated on the dried basis (g)

Acceptance criteria: 29.0%–44.8% by weight of acetyl (C_2H_3O) groups on the dried basis

For Cellulose Acetate labeled to contain more than 42.0% of acetyl groups

Sample: 2 g of Cellulose Acetate

Titrimetric system

(See *Titrimetry ⟨541⟩*.)

Mode: Residual titration

Titrant: 0.5 N hydrochloric acid VS

Back-titrant: 0.5 N sodium hydroxide VS

Endpoint detection: Visual

Analysis: Transfer the *Sample* to a 500-mL conical flask. Add 30.0 mL of dimethyl sulfoxide and 100 mL of acetone, and stir for 16 h with the aid of a magnetic stirrer. Pipet 30 mL of 1 N sodium hydroxide VS slowly into the flask, with constant stirring. Insert the stopper into the flask, and stir for 6 min. Allow to stand without stirring for 60 min. Resume stirring, and add 100 mL of water that has been preheated to 80°, washing down the sides of the flask. Stir for 2 min, and cool to room temperature. Add 4–5 drops of phenolphthalein TS, and titrate the excess sodium hydroxide solution with *Titrant*. Add an excess of 0.5 mL of *Titrant*. Stir for 5 min. Allow to stand for 30 min. Titrate with *Back-titrant* to a persistent pink endpoint, using a magnetic stirrer for agitation. Calculate the net number of milliequivalents of sodium hydroxide consumed, and correct this value by use of the average of two blank determinations run concomitantly through the entire procedure.

Calculate the percentage of acetyl in the portion of Cellulose Acetate taken:

$$\text{Result} = (n/W) \times 4.305$$

n = corrected value of the net number of milliequivalents of sodium hydroxide consumed

W = weight of Cellulose Acetate taken, calculated on the dried basis (g)

Acceptance criteria: 29.0%–44.8% by weight of acetyl (C_2H_3O) groups on the dried basis

IMPURITIES

• **Residue on Ignition ⟨281⟩:** NMT 0.1%

• **Limit of Free Acid**

Sample: 5 g

Titrimetric system

(See *Titrimetry ⟨541⟩*.)

Mode: Direct titration

Titrant: 0.01 N sodium hydroxide VS

Endpoint detection: Visual

Analysis: Transfer the *Sample* to a 250-mL flask. Add 150 mL of freshly boiled, cooled water. Insert the stopper into the flask, swirl the suspension gently, and allow it to stand for 3 h. Filter through paper, and wash the flask and the filter with freshly boiled, cooled water, adding the washings to the filtrate. Add phenolphthalein TS, and titrate the combined filtrate and washings with the *Titrant*.

Calculate the percentage of free acid in the portion of Cellulose Acetate taken:

$$\text{Result} = (V/W) \times 0.06005$$

V = *Titrant* volume consumed (mL)

W = weight of Cellulose Acetate taken, calculated on the dried basis (g)

Acceptance criteria: NMT 0.1%, calculated as acetic acid

SPECIFIC TESTS

• **Loss on Drying ⟨731⟩**

Analysis: Dry at 105° for 3 h.

Acceptance criteria: NMT 5.0%

• **Microbial Enumeration Tests ⟨61⟩** and **Tests for Specified Microorganisms ⟨62⟩:** The total aerobic microbial count is NMT 10^3 cfu/g, and the total combined molds and yeasts count is NMT 10^2 cfu/g. It meets the requirements of the tests for absence of *Escherichia coli* and *Salmonella* species.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers.

• **Labeling:** The labeling states the nominal percentage content of acetyl.

• **USP Reference Standards ⟨11⟩**

USP Cellulose Acetate RS

Topic/Question	Contact	Expert Committee
CELLULOSE ACETATE	Documentary Standards Support	CE2020 Complex Excipients

Chromatographic Database Information: Chromatographic Database

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