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Cellacefate

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

Cellulose, acetate, 1,2-benzenedicarboxylate;

Cellulose acetate phthalate

CAS RN®: 9004-38-0.

DEFINITION

Cellacefate is a reaction product of phthalic anhydride and a partial acetate ester of cellulose. It contains NLT 21.5% and NMT 26.0% of acetyl (C_2H_3O) groups and NLT 30.0% and NMT 36.0% of phthalyl (*o*-carboxybenzoyl) ($C_8H_5O_3$) groups, calculated on the anhydrous, acid-free basis.

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197K.**▲ (CN 1-May-2020) Do not dry specimens.

ASSAY

• **Phthalyl Content**

Sample solution: Transfer 1 g to a conical flask, dissolve in 50 mL of a mixture of alcohol and acetone (3:2), and add phenolphthalein TS.

Analysis: Titrate the *Sample solution* with 0.1 N sodium hydroxide VS. Perform a blank determination, and make any necessary correction (see *Titrimetry ⟨541⟩*).

Calculate the percentage of phthalyl on the acid-free basis:

$$\text{Result} = \{[(1.491 \times A/W) - (1.795 \times B)]/(100 - B)\} \times 100$$

A = volume of 0.1 N sodium hydroxide consumed, corrected for the blank (mL)

W = weight of Cellacefate taken, calculated on the anhydrous basis (g)

B = percentage of acid found in the test for *Limit of Free Acid*

Acceptance criteria: 30.0%–36.0% of phthalyl ($C_8H_5O_3$) on the anhydrous, acid-free basis

• **Content of Acetyl**

Sample solution: Transfer 100 mg to a glass-stoppered flask, and add 25.0 mL of 0.1 N sodium hydroxide VS. Connect the flask to a reflux condenser, and reflux for 30 min. Cool, and add phenolphthalein TS.

Analysis: Titrate the *Sample solution* with 0.1 N hydrochloric acid VS. Perform a blank determination (see *Titrimetry ⟨541⟩*).

Calculate the free and combined acids as acetyl:

$$\text{Result} = 0.4305 \times (A/W)$$

A = volume of 0.1 N sodium hydroxide consumed, corrected for the blank (mL)

W = weight of Cellacefate taken, calculated on the anhydrous basis (g)

Calculate the percentage of acetyl on the acid-free basis:

$$\text{Result} = 100 \times [P - (0.5182 \times B)]/(100 - B) - (0.5772 \times C)$$

P = free and combined acids, as acetyl

B = percentage of acid found in the test for *Limit of Free Acid*

C = percentage of phthalyl found in the test for *Phthalyl Content*

Acceptance criteria: 21.5%–26.0% of acetyl (C_2H_3O) on the anhydrous, acid-free basis

IMPURITIES

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

- **Limit of Free Acid**

Sample solution: Transfer 3.0 g to a glass-stoppered flask, add 100 mL of dilute methanol (1 in 2), insert the stopper in the flask, and shake for 2 h. Filter, and wash the flask and the filter with two 10-mL portions of the methanol solution, adding the washings to the filtrate.

Analysis: Titrate the combined filtrate and washings from the *Sample solution* with 0.1 N sodium hydroxide VS to a phenolphthalein endpoint. Perform a blank determination on 120 mL of the dilute methanol (1 in 2) (see *Titrimetry ⟨541⟩*).

Calculate the percentage of free acid, B:

$$\text{Result} = 0.8306 \times A/W$$

A = volume of 0.1 N sodium hydroxide consumed, corrected for the blank (mL)

W = weight of Cellacefate taken, calculated on the anhydrous basis (g)

Acceptance criteria: NMT 3.0%, calculated as phthalic acid

SPECIFIC TESTS

- **Water Determination, *Method I*⟨921⟩**

Sample: 0.5 g

Analysis: Dissolve the *Sample* in a mixture of dehydrated alcohol and methylene chloride (3:2) instead of methanol as the solvent.

Acceptance criteria: NMT 5.0%

- **Viscosity—Capillary Methods ⟨911⟩**

Sample: 15 g, calculated on the anhydrous basis

Analysis: Dissolve the *Sample* in 85 g of a mixture of 249 parts of anhydrous acetone and 1 part of water, by weight.

Acceptance criteria: The apparent viscosity (see *Viscosity—Capillary Methods ⟨911⟩, Method I*) is between 45 and 90 centipoises, determined at 25 ± 0.2°.

ADDITIONAL REQUIREMENTS

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

- **USP Reference Standards ⟨11⟩**

USP Cellacefate RS

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

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

Chromatographic Database Information: Chromatographic Database

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