

## BRIEFING

**Cellulose Acetate**, *NF 20* page 2528 and page 4677 of *PF 23(5)* [Sept.–Oct. 1997]. The United States Pharmacopeia is the coordinating pharmacopeia for the international harmonization of compendial standards for this article. The revisions presented in this proposal, which represents the **Adoption Stage 6** draft, reflect the Committee of Revision's results in this harmonization effort and have been accepted by the members of the Pharmacopeial Discussion Group. Proposed changes from the current *NF* monograph include the following:

1. **Definition**— This section is clarified with the indication that the acetyl group limits are to be calculated on the dried basis.
2. **Packaging and storage**— No change.
3. **Labeling**— Requirements are added that the immediate container label indicate nominal or targeted acetyl content value.
4. **USP Reference standards**— No change.
5. **Identification**— No change.
6. **Loss on drying**— No change.
7. **Residue on ignition**— No change.
8. **Heavy metals**— No change.
9. **Free acid**— The requirement that the material be previously dried is deleted.
10. **Organic volatile impurities**— No change.
11. **Content of acetyl**— The requirement that the material be previously dried is deleted.

(EMC: J. Lane ) RTS—37006-6

### **Change to read:**

#### ■ Cellulose Acetate

Cellulose acetate.

Cellulose, diacetate [9035-69-2].

Cellulose, triacetate [9012-09-3].

» Cellulose Acetate is partially or completely acetylated cellulose. It contains not less than 29.0 percent and not more than 44.8 percent, by weight, of acetyl (C<sub>2</sub>H<sub>3</sub>O) groups, calculated on the dried basis. Its acetyl content is not less than 90.0 percent and not more than 110.0 percent of that indicated on the label.

**Packaging and storage**— Preserve in tight containers.

**Labeling**— The label states the nominal percentage content of acetyl.

*USP Reference standards* á11ñ— *USP Cellulose Acetate RS*.

**Identification**— Prepare a 1 in 10 solution of Cellulose Acetate, previously dried, in dioxane. Spread 1 drop of the 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 hour, and reassemble the dried plates: the infrared absorption spectrum exhibits maxima only at the same wavelengths as that of a similar preparation of *USP Cellulose Acetate RS*, treated in the same manner.

*Loss on drying* á731ñ— Dry it at 105° for 3 hours: it loses not more than 5.0% of its weight.

*Residue on ignition* á281ñ: not more than 0.1%.

*Heavy metals, Method II* á231ñ: 0.001%.

**Free acid**— Transfer about 5 g, accurately weighed, 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 hours. Filter through paper, and wash the flask and the filter with water, adding these washings to the filtrate. Add phenolphthalein TS, and titrate the combined filtrate and washings with 0.01 N sodium hydroxide VS. Calculate the percentage of free acid in the portion of Cellulose Acetate taken by the formula:

$$0.06005A/W,$$

in which *A* is the volume, in mL, of 0.01 N sodium hydroxide consumed; and *W* is the weight, in g, of the Cellulose Acetate taken, calculated on the dried basis. Not more than 0.1%, calculated as acetic acid, is found.

*Organic volatile impurities, Method IV 467*: meets the requirements.

#### Content of acetyl—

FOR CELLULOSE ACETATE LABELED TO CONTAIN NOT MORE THAN 42.0% OF ACETYL GROUPS— Transfer about 2 g, accurately weighed, to a 500-mL flask. Add 100 mL of acetone and 5 mL to 10 mL of water to the flask, insert the stopper into the flask, and stir with a magnetic stirrer until solution is complete. Add 30 mL, accurately measured, of 1.0 N sodium hydroxide VS 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 minutes. Add 100 mL of water that has been preheated to 80°, washing down the sides of the flask, stir for 2 minutes and cool to room temperature. Titrate the excess sodium hydroxide solution with 1.0 N sulfuric acid VS to a phenolphthalein endpoint. Treat a blank in the same manner. Calculate the percentage of acetyl in the portion of Cellulose Acetate taken by the formula:

$$4.305(B - A)/W,$$

in which *B* and *A* are the volumes, in mL, of 1.0 N sulfuric acid consumed by the blank and the Cellulose Acetate, respectively; and *W* is the weight, in g, of Cellulose Acetate taken, calculated on the dried basis.

FOR CELLULOSE ACETATE LABELED TO CONTAIN MORE THAN 42.0% OF ACETYL GROUPS— Transfer about 2 g, accurately weighed, to a 500-mL conical flask. Add 30.0 mL of dimethylsulfoxide and 100 mL of acetone, and stir for 16 hours 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 minutes. Allow to stand without stirring for 60 minutes. Resume stirring, and add 100 mL of water that has been preheated to 80°, washing down the sides of the flask. Stir for 2 minutes, and cool to room temperature. Add 4 to 5 drops of phenolphthalein TS, and titrate the excess sodium hydroxide solution with 0.5 N hydrochloric acid VS. Add an accurately measured excess of about 0.5 mL of 0.5 N hydrochloric acid VS. Stir for 5 minutes. Allow to stand for 30 minutes. Titrate with 0.5 N sodium hydroxide VS 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 by the formula:

$$4.305n/W,$$

in which *n* is the corrected value of the net number of milliequivalents of sodium hydroxide consumed; and *W* is the weight, in g, of Cellulose Acetate taken, calculated on the dried basis.■<sub>1</sub>

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