Cellulose Acetate

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Manufacturers, regulatory authorities, health authorities, researchers, and other stakeholders are invited to provide their feedback and comments on this draft proposal. Manufacturers are also invited to submit samples of their products to the IPC to ensure that the proposed monograph adequately controls the quality of the product(s) they manufacture. Comments and samples received after the last date will not be considered by the IPC before finalizing the monograph.

Please send any comments you may have on this draft document to lab.ipc@gov.in, with a copy to Dr. Gaurav Pratap Singh (email: gpsingh.ipc@gov.in) before the last date for comments.

Document History and Schedule for the Adoption Process

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Further follow-up action as required.	

Cellulose Acetate

Cellulose diacetate; Cellulose triacetate.

Cellulose Acetate partially or completely acetylated cellulose.

Cellulose Acetate contains not less than 29.0 per cent and not more than 44.8 per cent by weight, of acetyl groups C_2H_3O, calculated on the dried basis and not less than 90.0 per cent and not more than 110.0 per cent of that indicated on the label.

Category. Pharmaceutical aid.

Description. A fine, white powder or free-flowing pellets, available in a range of viscosities and acetyl contents.

Identification

Dissolve 0.2 g of the previously dried substance in 10 ml of *acetone* (mono- and diester) or in *methylene chloride* (di-and triester). 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.

Determine by infrared absorption spectrophotometry (2.4.6). Compare the spectrum with that obtained with *cellulose acetate IPRS* or with the reference spectrum of cellulose acetate.

Tests

Limit of Free acid. Not more than 0.1 per cent, calculated as acetic acid,

Weigh and transfer 5 g of substance under examination to a 250-ml volumetric 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 freshly boiled, cooled water, adding the washings to the filtrate. Add *phenolphthalein solution* and titrate with *0.01 M sodium hydroxide.*

Calculate the percentage of free acid in the portion of cellulose acetate by using following expression;

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

where,

V = Volume of *0.01 M sodium hydroxide* consumed (ml).
W = Weight of cellulose acetate taken, calculated on the dried basis (g).

Microbial contamination (2.2.9). Total aerobic microbial count not more than 1000 cfu per g, total combined molds and yeast count not more than 100 cfu per g, 1g is free from *Escherichia coli* and *Salmonella Species.*

Heavy metals (2.3.13). 1.0 g complies with limit test for heavy metals, Method B (20 ppm).

Sulphated ash (2.3.18). Not more than 0.1 per cent.

Loss on drying (2.4.19). Not more than 5.0 per cent, determined on 1.0 g by drying in an oven at 105° for 3 hours.

Assay. *Content of Acetyl—*

For cellulose acetate labeled to contain not more than 42.0 per cent of acetyl group. [Not less than 29.0 per cent and not more than 44.8 per cent by weight of acetyl, C_2H_3O groups, on the dried basis]

Weigh and transfer 2.0 g of substance under examination to a 500-ml volumetric flask, add 100 ml *acetone* and 5 ml to 10 ml of *water*. Insert the stopper into the flask and stir with a magnetic stirrer until solution is complete. Add

30.0 ml of *1 M sodium hydroxide*, 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 and titrate with *1 M sulphuric acid* using *phenolphthalein* as indicator. Carry out a blank titration.

Calculate the percentage of acetyl in the portion of cellulose acetate by using following expression;

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

where,

V_B = Volume of *1 M sulphuric acid* consumed by the blank (ml)
V_S = Volume of *1 M sulphuric acid* consumed by cellulose acetate (ml)
W = weight of Cellulose acetate taken, calculated on the dried basis (g)

For cellulose acetate labeled to contain not less than 42.0 per cent of acetyl group. [Not less than 29.0 per cent and not more than 44.8 per cent by weight of acetyl, C_2H_3O groups on the dried basis]

Weigh and transfer 2.0 g of substance under examination to a 500-ml volumetric flask. Add 30.0 ml of *dimethyl sulphoxide* and 100 ml of *acetone*, and stir for 16 horus with the aid of a magnetic stirrer. Add 30 ml of *1 M sodium hydroxide* 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 and titrate excess sodium hydroxide solution with *0.5 M hydrochloric acid* using 5 drops of *phenolphthalein solution* as indicator. Add an excess of 0.5 ml of *1 M sodium hydroxide*. Stir for 5 minutes. Allow to stand for 30 minutes. Titrate with *0.5 M hydrochloric acid* to a persistent pink end point, 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 by using following expression;

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

where,

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).

Storage. Store protected from moisture.

Labelling. The labeling states the nominal percentage content of acetyl.