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Dextrin

DEFINITION

Dextrin is starch, or partially hydrolyzed starch, modified by heating in a dry state, with or without acids, alkalies, or pH control agents. During heating, moisture may be added.

IDENTIFICATION

• **A.**

Sample: 1 g

Analysis:

Suspend the *Sample* in 20 mL of water, and add a few drops of iodine TS.

Acceptance criteria: A blue to reddish-brown color results.

• **B.** Dextrin is very soluble in boiling water, forming a mucilaginous solution (difference from starch).

ASSAY

• **Reducing Sugars (Dextrose Equivalent)**

Sample: A quantity of Dextrin equivalent to 2.0 g on the dried basis

Analysis: To the *Sample* add 100 mL of water, shake for 30 min, dilute with water to 200 mL, accurately measured, and filter. To 10.0 mL of alkaline cupric tartrate TS add 20.0 mL of the filtrate, mix, and heat on a hot plate adjusted to bring the solution to a boil in 3 min. Boil for 2 min, and cool quickly. Add 5 mL of potassium iodide solution (3 in 10) and 10 mL of 2 N sulfuric acid, mix, and titrate immediately with 0.1 N sodium thiosulfate VS, using starch TS, added toward the end of the titration, as an indicator.

Repeat the procedure beginning with “To 10.0 mL of alkaline cupric tartrate TS” using, in place of the filtrate, 20.0 mL of a solution (1 in 1000) of anhydrous dextrose, accurately prepared. Perform a blank titration.

Compare $(V_B - V_U)$ and $(V_B - V_S)$.

$$\text{Result 1} = (V_B - V_U)$$

$$\text{Result 2} = (V_B - V_S)$$

V_B = volume of 0.1 N sodium thiosulfate consumed in the titrations of the blank

V_U = volume of 0.1 N sodium thiosulfate consumed in the titrations of the Dextrin

V_S = volume of 0.1 N sodium thiosulfate consumed in the titrations of the dextrose

Acceptance criteria: $(V_B - V_U)$ is NMT $(V_B - V_S)$, corresponding to NMT 10%, calculated as dextrose ($C_6H_{12}O_6$).

IMPURITIES

• **Residue on Ignition ⟨281⟩:** NMT 0.5%

• **Chloride and Sulfate,** *Chloride* ⟨221⟩

Sample: 3.0 g

Control: 2.8 mL of 0.020 N hydrochloric acid in 75 mL of water

Analysis: Dissolve the *Sample* in 75 mL of boiling water. Cool, dilute with water to 75 mL, and filter if necessary. To 25 mL of this solution and the *Control*, add 2 mL of nitric acid and 1 mL of silver nitrate TS.

Acceptance criteria: Any turbidity produced is NMT that of the *Control*, corresponding to NMT 0.2% of chloride.

• **Limit of Protein**

Sample: 10 g

Analysis: Proceed as directed in *Nitrogen Determination* ⟨461⟩, using the *Sample* instead of 1 g, 60 mL of sulfuric acid instead of 20 mL, and multiplying the percentage of nitrogen found by 6.25.

Acceptance criteria: NMT 1.0%

SPECIFIC TESTS

- **Acidity**

Sample: 10.0 g

Analysis: Add the *Sample* to 100 mL of 70% alcohol, previously neutralized to phenolphthalein. Shake for 1 h, filter, and titrate 50 mL of the filtrate with 0.10 N sodium hydroxide.

Acceptance criteria: NMT 3.0 mL

- **Botanic Characteristics**

Microscopic: Granules are similar in appearance to the starch from which the Dextrin has been prepared, except that when prepared from corn starch, many of the granules show concentric striations, and when prepared from potato starch, concentric striations are not clearly visible; the hilum is frequently bicleft; and a small proportion of the granules are distorted.

- **Loss on Drying** ⟨731⟩**:** Dry a sample at a pressure not exceeding 100 mm of mercury at 120° for 4 h: it loses NMT 13.0% of its weight.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers.

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

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

Chromatographic Database Information: Chromatographic Database

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