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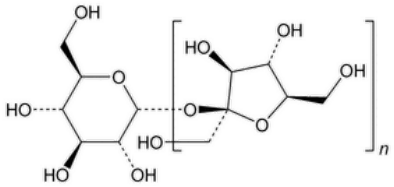
Inulin



$C_6H_{11}O_5(C_6H_{10}O_5)_nOH$

Inulin.

Inulin

CAS RN®: 9005-80-5; UNII: JOS53KRJ01.

» Inulin is a polysaccharide which, on hydrolysis, yields mainly fructose. It contains not less than 94.0 percent and not more than 102.0 percent of $C_6H_{11}O_5(C_6H_{10}O_5)_nOH$, calculated on the dried basis.

Packaging and storage—Preserve in well-closed containers. Store at 25°, excursions permitted between 15° and 30°.

USP Reference standards ⟨11⟩—

USP Dextrose RS
USP Fructose RS

Completeness of solution—Dissolve 10 g in 20 mL of boiling water in a 200-mL volumetric flask, add 150 mL of water, allow to cool, dilute with water to volume, and mix: the solution is clear.

Specific rotation ⟨781S⟩: between −32.0° and −40.0°.

Test solution: 100 mg per mL, in 0.012 N ammonium hydroxide.

Microbial enumeration tests ⟨61⟩ and **Tests for specified microorganisms ⟨62⟩**—It meets the requirements of the tests for absence of *Salmonella* species and *Escherichia coli* and for absence of *Staphylococcus aureus* and *Pseudomonas aeruginosa;* the total aerobic microbial count is less than 1000 per g.

Loss on drying ⟨731⟩: not more than 10.0% after it has been dried at 105° for 2 hours, 2 g of the finely ground powder being used for the test.

Residue on ignition ⟨281⟩—Multiply the percentage of *Calcium* found by 3.4. The residue on ignition does not exceed this percentage by more than 0.05%.

pH, Chloride, Iron, and Reducing sugars—Dissolve 10.0 g in 20 mL of boiling water in a 100-mL volumetric flask, allow to cool, dilute with water to volume, and mix. Use the solution for the following tests.

pH ⟨791⟩—The pH of the solution is between 4.5 and 7.0.

Chloride ⟨221⟩—A 10-mL portion of the solution shows no more chloride than corresponds to 0.20 mL of 0.020 N hydrochloric acid (0.014%).

Iron—To 10 mL of the solution add 0.5 mL of hydrochloric acid and 3 drops of potassium ferrocyanide TS: the solution does not become blue within 1 minute.

Reducing sugars—To 2 mL of the solution add 5 mL of alkaline cupric tartrate TS: no reduction occurs at room temperature, and only slight reduction occurs after 1 minute of boiling.

Calcium—Heat 10.0 g in 100 mL of water to dissolve. Cool to room temperature, add 15 mL of 1 N sodium hydroxide and 300 mg of hydroxy naphthol blue, and titrate with 0.05 M edetate disodium VS to a blue endpoint. Not more than 5.0 mL is required: not more than 0.10% calcium is found.

Sulfate ⟨221⟩—A 1.0 g portion shows no more sulfate than corresponds to 0.5 mL of 0.020 N sulfuric acid (0.05%).

[Note—Inulin should be dissolved in 30 to 40 mL of water with gentle warming, prior to dilution to final volume.]

Free fructose—

Blue tetrazolium solution—Dissolve 50 mg of blue tetrazolium in 10 mL of alcohol, and mix.

Tetramethylammonium hydroxide solution—Prepare a mixture of 1 volume of tetramethylammonium hydroxide TS and 9 volumes of alcohol.

Standard stock solution—Prepare an aqueous solution having a known concentration of about 250 µg of USP Fructose RS per mL. Store at about 4°.

Standard preparation—On the day of use, quantitatively dilute a portion of the *Standard stock solution* with alcohol to obtain a solution having a known concentration of about 2.5 µg per mL. Store at about 4°.

Test preparation—Transfer about 2.5 g of Inulin, accurately weighed, to a 100-mL volumetric flask, add about 75 mL of water, heat on a steam bath until solution is complete, cool to room temperature, dilute with water to volume, and mix. Pipet 1 mL into a 100-mL volumetric flask, dilute with alcohol to volume, and mix. If the solution is turbid, pass through fine-porosity filter paper.

Procedure—Pipet 10 mL of the *Test preparation* and 10 mL of the *Standard preparation* into separate glass-stoppered centrifuge tubes. Into each of the tubes, and into a similar tube containing 10.0 mL of alcohol to provide the blank, pipet 1 mL of *Blue tetrazolium solution,* and mix. Then into each tube pipet 1 mL of *Tetramethylammonium hydroxide solution,* mix, and allow to stand in the dark for 60 minutes. Without delay, concomitantly determine the absorbances of the solutions from the *Test preparation* and the *Standard preparation* at 530 nm, with a suitable spectrophotometer, against the blank. Calculate the percentage, *F,* of free fructose in the Inulin taken by the formula:

$$F = (C/W)(A_U/A_S)$$

in which *C* is the concentration, in µg per mL, of USP Fructose RS in the *Standard preparation; W* is the quantity, in g, of Inulin taken; and A_U and A_S are the absorbances of the solutions from the *Test preparation* and the *Standard preparation,* respectively. The limit is 2.0%, calculated on the dried basis.

Content of combined glucose—

Standard stock solution—Transfer about 50 mg of USP Dextrose RS, accurately weighed, to a 100-mL volumetric flask, dissolve in a solution of benzoic acid (1.7 in 1000), dilute with the same solution to volume, and mix. Allow to stand at room temperature for not less than 3 hours before using. This solution is stable for 1 month at about 4°.

Standard preparation—Pipet 7 mL of *Standard stock solution* into a 100-mL volumetric flask, dilute with water to volume, mix, and use at once.

Assay preparation—Transfer about 0.5 g of Inulin, accurately weighed, to a 100-mL volumetric flask, add 5.0 mL of water, dissolve by heating on a steam bath, cool to room temperature, add 0.5 mL of 8 N hydrochloric acid, and mix. Place the flask in a boiling water bath for 5 minutes, cool, dilute with water to volume, and mix. Pipet 2 mL of this solution into a 10-mL volumetric flask, dilute with water to volume, and mix. [NOTE—This solution is used also for preparing the *Assay preparation* in the *Assay for inulin.*]

Procedure—Pipet 3-mL portions of glucose oxidase–chromogen TS into 3 separate test tubes, and bring to a temperature of 37 ± 0.5° in a water bath. Pipet 2 mL of *Standard preparation* into one of the tubes, pipet 2 mL of *Assay preparation* into another, and pipet 2 mL of water into the third tube to provide the blank. Maintain at 37 ± 0.5° for an additional 10 minutes, then remove the tubes, and allow them to cool. Determine the absorbances of the solutions from the *Assay preparation* and the *Standard preparation* at about 505 nm, with a suitable spectrophotometer, using the reagent blank as a reference. Calculate the percentage of combined glucose, *G*, in the Inulin taken by the formula:

$$G = 50(C/W)(A_U/A_S)$$

in which *C* is the concentration, in mg per mL, of USP Dextrose RS in the *Standard preparation; W* is the amount, in g, of Inulin taken; and A_U and A_S are the absorbances of the solutions from the *Assay preparation* and the *Standard preparation,* respectively. Not less than 2.0% and not more than 5.0%, calculated on the dried basis, is found.

Assay for inulin—

Thiobarbituric acid solution—Dissolve 250 mg of thiobarbituric acid in 100 mL of 8 N hydrochloric acid, and mix. This solution is stable for 2 weeks at a temperature of about 4°.

Standard stock solution—Quantitatively dissolve an accurately weighed quantity of USP Fructose RS in an aqueous solution of benzoic acid (1.7 in 1000) to obtain a solution having a known concentration of about 1 mg of USP Fructose RS per mL. [NOTE—This solution is stable for 1 month at about 4°.]

Standard preparation—Quantitatively dilute the *Standard stock solution* with water to one-fiftieth of its concentration. Use immediately.

Assay preparation—Pipet 4 mL of the *Assay preparation* from the *Content of combined glucose* into a 200-mL volumetric flask, add water to volume, and mix.

Procedure—Pipet 1-mL portions of the *Standard preparation* and the *Assay preparation* into separate glass-stoppered tubes. Pipet 1 mL of water into a third tube to provide the blank. Pipet 5-mL portions of *Thiobarbituric acid solution* into each tube, and mix. Place all of the tubes simultaneously in a water bath maintained at a temperature of about 83°, and allow them to stay immersed for 5 minutes, accurately timed. Remove the tubes simultaneously, and allow them to cool in a dark place for 30 minutes. Determine the absorbances of the solutions from the *Assay preparation* and the *Standard preparation* at about 435 nm, with a suitable spectrophotometer, using the reagent blank as a reference. Calculate the percentage of $C_6H_{11}O_5(C_6H_{10}O_5)_nOH$ in the Inulin taken by the formula:

$$0.900[2.5(C/W)(A_U/A_S) - F] + G$$

in which 0.900 is the ratio of the formula weight of an anhydrofructose unit of inulin to that of fructose; *C* is the concentration, in µg per mL, of USP Fructose RS in the *Standard preparation; W* is the quantity, in g, of Inulin weighed for the *Content of combined glucose; A_U* and A_S are the

absorbances of the solutions from the *Assay preparation* and the *Standard preparation,* respectively; *F* is the percentage of free fructose; and *G* is the percentage of combined glucose.

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

Topic/Question	Contact	Expert Committee
INULIN	Maria Monagas Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements

Chromatographic Database Information: Chromatographic Database

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