Between each measurement, aspirate the *Blank solution*, and ascertain that the reading returns to zero. Plot the absorbances of the *Standard solutions* and the *Sample solution* versus the added quantity of nickel. Extrapolate the line joining the points on the graph until it meets the concentration axis. The distance between this point and the intersection of the axes represents the concentration of nickel in the *Sample solution*.

Acceptance criteria: NMT 1 ppm, calculated on the anhydrous basis

Organic Impurities

- **PROCEDURE: REDUCING SUGARS**

Sample: An amount of Maltitol Solution equivalent to 3.3 g on the anhydrous basis

Analysis: To the *Sample* add 3 mL of water, 20.0 mL of cupric citrate TS, and a few glass beads. Heat so that boiling begins after 4 min, and maintain boiling for 3 min. Cool rapidly, and add 40 mL of diluted acetic acid, 60 mL of water, and 20.0 mL of 0.05 N iodine VS. With continuous shaking, add 25 mL of a mixture of 6 mL of hydrochloric acid and 94 mL of water. When the precipitate has dissolved, titrate the excess of iodine with 0.05 N sodium thiosulfate VS using 2 mL of starch TS, added toward the end of the titration, as an indicator.

[NOTE—The amount determined in this test is not included in the calculated amount under *Other Impurities*.]

Acceptance criteria: NLT 12.8 mL of 0.05 N sodium thiosulfate VS is required, corresponding to NMT 0.3% of reducing sugars, on the anhydrous basis, as glucose.

SPECIFIC TESTS

- **MICROBIAL ENUMERATION TESTS** ⟨**61**⟩ and **TESTS FOR SPECIFIC MICROORGANISMS** ⟨**62**⟩**:** The total aerobic microbial count using the *Plate Method* is NMT 1000 cfu/mL, and the total combined molds and yeasts count is NMT 100 cfu/mL.
- **pH** ⟨**791**⟩**:** 5.0–7.5, in a 14% (w/w) solution of Maltitol Solution in carbon dioxide-free water
- **WATER DETERMINATION,** *Method I* ⟨**921**⟩**:** NMT 31.5%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers. No storage requirements are specified.
- **USP REFERENCE STANDARDS** ⟨**11**⟩

USP Diethylene Glycol RS
USP Ethylene Glycol RS
USP Maltitol RS
USP Sorbitol RS

Maltodextrin

DEFINITION

Maltodextrin is a nonsweet, nutritive saccharide mixture of polymers that consists of D-glucose units, with a Dextrose Equivalent less than 20. It is prepared by the partial hydrolysis of a food grade starch with suitable acids and/or enzymes. It may be physically modified to improve its physical and functional characteristics.

ASSAY

- **DEXTROSE EQUIVALENT**

Standard solution: 10 mg/mL of USP Dextrose RS

Sample solution: Transfer 5 g of Maltodextrin with the aid of hot water to a 100-mL volumetric flask, cool, add water to volume, and mix.

Analysis: Transfer 25.0-mL portions of alkaline cupric tartrate TS to each of two boiling flasks. Bring the contents of one flask to boiling within 2 min while titrating with the *Standard solution* to within 0.5 mL of the anticipated endpoint. Boil gently for 2 min. Continue to boil gently, add 2 drops of methylene blue solution (1 in 100), and complete the titration within 1 min by adding the *Standard solution* dropwise or in small increments until the blue color disappears, determined by viewing against a white background in daylight or under equivalent illumination. If more than 0.5 mL of the titrant was required after the addition of the indicator, repeat the titration, adding the necessary volume of titrant before adding the indicator. Bring the contents of the second flask to boiling, and similarly titrate with the *Sample solution*.

Calculate the Dextrose Equivalent, on the dried basis, in the portion of Maltodextrin taken:

$$\text{Result} = [100/(1 - 0.01 \times A)] \times (C_S/C_U) \times (V_S/V_U)$$

A = percentage *Loss on Drying* of the Maltodextrin taken
C_S = concentration of USP Dextrose RS in the *Standard solution* (mg/mL)
C_U = concentration of Maltodextrin in the *Sample solution* (mg/mL)
V_S = titrated volume of the *Standard solution* (mL)
V_U = titrated volume of the *Sample solution* (mL)

Acceptance criteria: Less than 20

[NOTE—This is a limit test. For Maltodextrins with lower reducing values, other procedures may give other results.]

IMPURITIES

- **RESIDUE ON IGNITION** ⟨**281**⟩**:** NMT 0.5%
- **HEAVY METALS,** *Method II* ⟨**231**⟩**:** NMT 5 ppm
- **LIMIT OF PROTEIN**

Sample: 10 g

Analysis: Transfer the *Sample* to an 800-mL Kjeldahl flask, and add 10 g of anhydrous potassium sulfate or sodium sulfate, 300 mg of copper selenite or mercuric oxide, and 60 mL of sulfuric acid. Gently heat the mixture, keeping the flask inclined at about a 45° angle, and after frothing has ceased, boil briskly until the solution has remained clear for about 1 h. Cool, and very cautiously add about 50 mL of water while swirling to dissipate the resulting heat. Add an additional 150–250 mL of water, mix, and cool again. Cautiously pour 75 mL (or enough to make the mixture strongly alkaline) of sodium hydroxide solution (2 in 5) down the inside of the flask so that it forms a layer under the acid solution, and then add a few pieces of granular zinc. Immediately connect the flask to a distillation apparatus consisting of a Kjeldahl connecting bulb and a condenser, the delivery tube of which extends well beneath the surface of an accurately measured excess of 0.1 N sulfuric acid contained in a 500-mL flask. Gently rotate the contents of the Kjeldahl flask to mix, and distill until all ammonia has passed into the absorbing acid solution (about 250 mL of distillate). To the receiving flask add 0.25 mL of methyl red–methylene blue TS, and titrate the excess acid with 0.1 N sodium hydroxide. Perform a blank determination, substituting pure sucrose or dextrose for the test specimen, and make any necessary correction. Each mL of 0.1 N sulfuric acid consumed is equivalent to 1.401 mg of nitrogen (N).

Calculate the percentage of N in the specimen taken, and then calculate the percentage of protein by multiplying the percentage of N by 6.25.

Acceptance criteria: NMT 0.1%

- **LIMIT OF SULFUR DIOXIDE**

Hydrogen peroxide solution: Dilute 30% hydrogen peroxide with water to obtain a 3% solution. Just before use, add 3 drops of methyl red TS, and neutralize to a yellow endpoint with 0.01 N sodium hydroxide. Do not exceed the endpoint.

Nitrogen: Use high-purity nitrogen, with a flow regulator that will maintain a flow of 200 ± 10 mL/min. Guard against the presence of oxygen by passing the nitrogen through a scrubber, such as alkaline pyrogallol, prepared as follows. Add 4.5 g of pyrogallol to a gas-washing bottle, purge the bottle with nitrogen for 3 min, and add a solution containing 85 mL of water and 65 g of potassium hydroxide, while maintaining an atmosphere of nitrogen in the bottle.

Apparatus: The apparatus (see *Figure 1*) is designed to effect the selective transfer of sulfur dioxide from the specimen in boiling aqueous hydrochloric acid to the *Hydrogen peroxide solution*. The backpressure is limited to the unavoidable pressure due to the height of the *Hydrogen peroxide solution* above the tip of the bubbler, *F*. Keeping the backpressure as low as possible reduces the likelihood that sulfur dioxide will be lost through leaks. Preboil vinyl and silicone tubing. Apply a thin film of stopcock grease to the sealing surfaces of all of the joints except the joint between the separatory funnel and the flask, and clamp the joints to ensure tightness. The separatory funnel, *B*, has a capacity of 100 mL or greater. The inlet adapter, *A*, with a hose connector provides a means of applying headpressure over the solution. [NOTE—A pressure-equalizing dropping funnel is not recommended because condensate, which may contain sulfur dioxide, is deposited in the funnel and the side arm.]

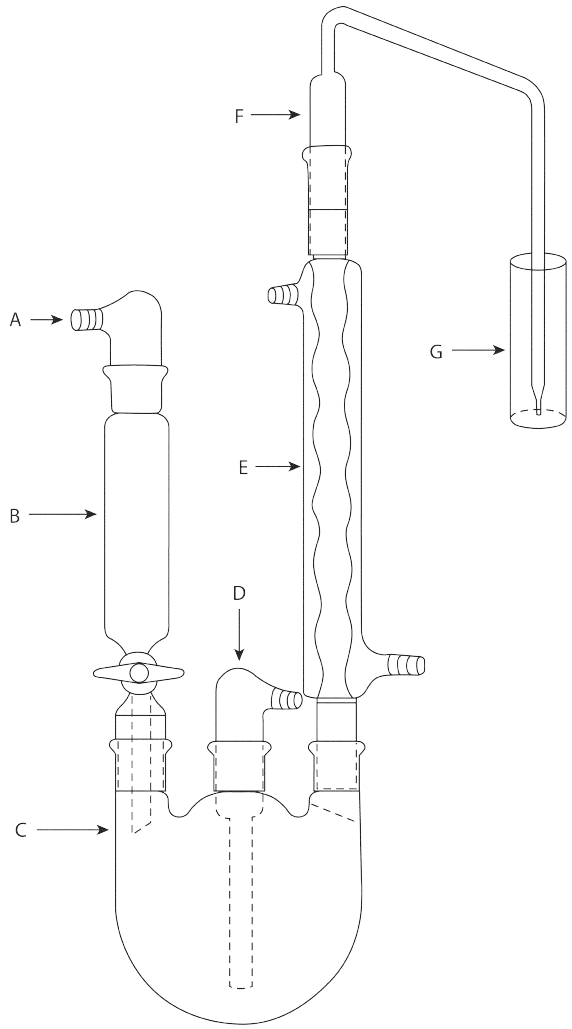


Figure 1. Apparatus for the Sulfur Dioxide Test.

The round-bottomed flask, *C*, is a 1000-mL flask with three 24/40 tapered joints. The gas inlet tube, *D*, is long enough to permit introduction of the nitrogen within 2.5 cm of the bottom of the flask. The Allihn condenser, *E*, has a jacket length of 300 mm. The bubbler, *F*, is fabricated from glass according to the dimensions given in *Figure 2*. The *Hydrogen peroxide solution* is contained in a vessel, *G*, having an inside diameter of about 2.5 cm and a depth of about 18 cm. Circulate coolant, such as a mixture of water and methanol (4:1) maintained at 5°, to chill the condenser.

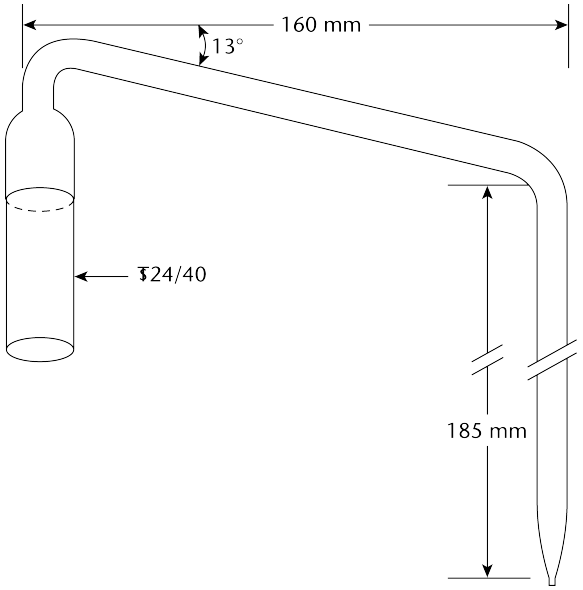


Figure 2. Bubbler (*F*) for the Sulfur Dioxide Apparatus.

Analysis: Position the *Apparatus* in a heating mantle controlled by a power-regulating device. Add 400 mL of water to the flask. Close the stopcock of the separatory funnel, and add 90 mL of 4 N hydrochloric acid to the separatory funnel. Begin the flow of *Nitrogen* at a rate of 200 ± 10 mL/min. Start the condenser coolant flow. Add 30 mL of the *Hydrogen peroxide solution* to vessel G. After 15 min, remove the separatory funnel, and transfer a mixture of 50.0 g of Maltodextrin and 100 mL of alcohol solution (5 in 100). Apply stopcock grease to the outer joint of the separatory funnel, return the separatory funnel to the tapered joint flask, and concomitantly resume the nitrogen flow. Apply headpressure above the hydrochloric acid solution in the separatory funnel with a rubber bulb equipped with a valve. Open the stopcock of the separatory funnel to permit the hydrochloric acid solution to flow into the flask. Continue to maintain sufficient pressure above the hydrochloric acid solution to force it into the flask. [NOTE—The stopcock may be temporarily closed, if necessary, to pump up the pressure.]

To guard against escape of sulfur dioxide (SO_2) into the separatory funnel, close the stopcock before the last few mL of hydrochloric acid drain out. Apply power to the heating mantle sufficient to cause about 85 drops of reflux/min. After refluxing for 1.75 h, remove vessel G, add 3 drops of methyl red TS, and titrate the contents with 0.01 N sodium hydroxide VS, using a 10-mL buret with an overflow tube and a hose connection to a carbon dioxide–absorbing tube, to a yellow endpoint that persists for at least 20 s. Perform a blank determination, and make any necessary correction (see *Titrimetry* ⟨541⟩).

Calculate the quantity, in µg/g, of SO_2 in the portion of Maltodextrin taken:

$$\text{Result} = 1000 \times F \times V \times N/W$$

F = milliequivalent weight of sulfur dioxide, 32.03
V = titrant volume consumed (mL)
N = actual normality of the titrant
W = weight of Maltodextrin taken (g)

Acceptance criteria: NMT 40 µg/g (ppm)

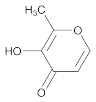
SPECIFIC TESTS

- **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*.
- **pH ⟨791⟩:** 4.0–7.0, in a 0.2-g/mL solution in carbon dioxide-free water.

• **Loss on Drying** ⟨**731**⟩**:** Dry a sample at 105° for 2 h in a forced-air oven: it loses NMT 6.0% of its weight.

ADDITIONAL REQUIREMENTS
• **Packaging and Storage:** Preserve in tight containers, or in well-closed containers, at a temperature not exceeding 30° and a relative humidity not exceeding 50%.
• **USP Reference Standards** ⟨**11**⟩
USP Dextrose RS

Maltol



$C_6H_6O_3$ 126.11
3-Hydroxy-2-methyl-4-pyrone [118-71-8].

DEFINITION
Maltol contains NLT 99.0% of maltol ($C_6H_6O_3$), calculated on the anhydrous basis.

IDENTIFICATION
• **A. Infrared Absorption** ⟨**197K**⟩
• **B. Ultraviolet Absorption** ⟨**197U**⟩
Sample solution: 0.01 mg/mL in 0.1 N hydrochloric acid
Blank: 0.1 N hydrochloric acid

ASSAY
• **Procedure**
Standard solution: 0.01 mg/mL of USP Maltol RS in 0.1 N hydrochloric acid
Sample solution: 0.01 mg/mL of Maltol in 0.1 N hydrochloric acid
Instrumental conditions
Mode: UV
Analytical wavelength: Maximum at about 274 nm
Blank: 0.1 N hydrochloric acid
Analysis
Samples: *Standard solution* and *Sample solution*
Calculate the percentage of maltol ($C_6H_6O_3$) in the portion of Maltol taken:

$$\text{Result} = (A_U/A_S) \times (C_S/C_U) \times 100$$

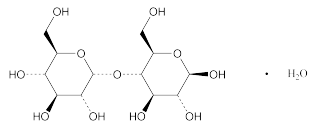
A_U = absorbance of the *Sample solution*
A_S = absorbance of the *Standard solution*
C_S = concentration of USP Maltol RS in the *Standard solution* (mg/mL)
C_U = concentration of the *Sample solution* (mg/mL)
Acceptance criteria: NLT 99.0% on the anhydrous basis

IMPURITIES
• **Residue on Ignition** ⟨**281**⟩**:** NMT 0.2%, determined on 1.0 g
• **Lead** ⟨**251**⟩**:** NMT 10 ppm
• **Heavy Metals,** *Method II* ⟨**231**⟩**:** NMT 20 ppm

SPECIFIC TESTS
• **Melting Range or Temperature,** *Class Ia* ⟨**741**⟩**:** 160°–164°
• **Water Determination,** *Method I* ⟨**921**⟩**:** NMT 0.5%

ADDITIONAL REQUIREMENTS
• **Packaging and Storage:** Preserve in tight containers, protected from light. No storage requirements are specified.
• **USP Reference Standards** ⟨**11**⟩
USP Maltol RS

Maltose



$C_{12}H_{22}O_{11} \cdot H_2O$ 360.31
and $C_{12}H_{22}O_{11}$ 342.30
4-*O*-α-D-Glucopyranosyl-β-D-glucopyranose.

» Maltose is a sugar. It contains one molecule of water of hydration or is anhydrous. It contains not less than 92.0 percent of maltose, calculated on the anhydrous basis. The amounts of other sugars, if detected, are not included in the requirements or the calculated amount under *Other Impurities.*

Packaging and storage—Preserve in well-closed containers. No storage requirements specified.

USP Reference standards ⟨11⟩**—**
USP Maltose Monohydrate RS

Identification—

A: Add 2 to 3 drops of a solution of Maltose (1 in 20) to 5 mL of hot alkaline cupric tartrate TS. A red precipitate is formed.

B: The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation,* as obtained in the *Assay.*

pH ⟨791⟩**—**Prepare a 1 in 10 solution in carbon dioxide-free water. For the anhydrous form, it is between 3.7 and 4.7; and for the monohydrate form, it is between 4.0 and 5.5.

Water, *Method I* ⟨921⟩**—**The anhydrous form contains not more than 1.5%. The monohydrate form contains not less than 4.5% and not more than 6.5%.

Residue on ignition ⟨281⟩**:** not more than 0.05%, determined on a 2-g portion, accurately weighed.

Heavy metals, *Method I* ⟨231⟩**:** not more than 5 µg per g.

Dextrin, starch, and sulfite—Dissolve 1.0 g of Maltose in 10 mL of water, and add 1 drop of iodine TS: a yellow color develops. Then add 1 drop of starch TS to this portion: a blue color develops.

Assay—

Mobile phase—Use degassed water.

Resolution solution—Dissolve accurately weighed quantities of maltotriose, maltose, and glucose in water to obtain a solution having concentrations of about 10 mg of each per g.

Standard preparation—Dissolve an accurately weighed quantity of USP Maltose Monohydrate RS in water to obtain a solution having a concentration of about 10 mg per g. Calculate the exact concentration on the anhydrous basis.

Assay preparation—Dissolve about 0.10 g of Maltose, accurately weighed, in water, and dilute with water to about 10 g. Accurately record the final solution weight, and mix thoroughly.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatographic system is equipped with a refractive index detector maintained at a constant temperature of about 40°, and a 7.8-mm × 30-cm column that contains packing L58 (see *Chromatography* ⟨621⟩). The column temperature is maintained at about 80°, controlled to within ±2°. Chromatograph the *Resolution solution,* and record the peak responses as directed for *Procedure.* Adjust the flow rate to about 0.35 mL per