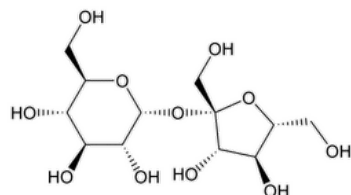


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# Sucrose

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$C_{12}H_{22}O_{11}$  342.30  
 α-D-Glucopyranoside, β-D-fructofuranosyl-;  
 Sucrose CAS RN®: 57-50-1.

## DEFINITION

Sucrose is a sugar obtained from *Saccharum officinarum* Linné (Fam. Gramineae), *Beta vulgaris* Linné (Fam. Chenopodiaceae), and other sources. It contains no added substances.

## IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197K

## IMPURITIES

**Change to read:**

- **SULFITE**

[NOTE—Prepare solutions immediately before use using freshly prepared distilled water or the diluents specified in the test kit.]

**Sample solution:** 400 mg/mL of Sucrose in freshly prepared distilled water

**Sulfite standard solution (80 ppm  $SO_2$ ):** 0.1575 mg/mL of anhydrous sodium sulfite in freshly prepared distilled water

**Reference solution:** Dissolve 4.0 g of Sucrose in freshly prepared distilled water, add 0.5 mL of *Sulfite standard solution (80 ppm  $SO_2$ )*, and dilute with freshly prepared distilled water to 10.0 mL.

**Blank:** Freshly prepared distilled water

**Analysis:** Determine the sulfite content by a suitable enzymatic method based on the following reactions. Sulfite is oxidized by sulfite oxidase to sulfate and hydrogen peroxide, which in turn is reduced by nicotinamide–adenine dinucleotide–peroxidase in the presence of reduced nicotinamide–adenine dinucleotide (NADH). The amount of NADH oxidized is proportional to the amount of sulfite. Separately introduce 2.0 mL each of the *Sample solution*, *Reference solution*, and *Blank* in 10-mm cuvettes, and add the reagents as described in the kit instructions.<sup>1</sup> Measure the absorbance at the maximum at about 340 nm before and at the end of the reaction time, and subtract the value obtained with the *Blank*.

**Acceptance criteria:** The absorbance difference of the *Sample solution* is NMT half the absorbance difference of the *Reference solution*.

## SPECIFIC TESTS

- **APPEARANCE OF SOLUTION**

**Sample solution:** 500 mg/mL of Sucrose in water. [NOTE—Set a portion of this solution aside for the tests for *Dextrins* and *Reducing Sugars*.]

**Hydrazine sulfate solution:** 10 mg/mL of hydrazine sulfate in water. Allow to stand for 4–6 h.

**Hexamethylenetetramine solution:** In a 100-mL ground glass-stoppered flask dissolve 2.5 g of hexamethylenetetramine in 25.0 mL of water.

**Primary opalescent suspension:** To the *Hexamethylenetetramine solution* in the flask add 25.0 mL of *Hydrazine sulfate solution*. Mix, and allow to stand for 24 h. This suspension is stable for 2 months, provided it is stored in a glass container free from surface defects. The

suspension must not adhere to the glass and must be well mixed before use.

**Standard of opalescence:** *Primary opalescent suspension* in water (3 in 200). This suspension is freshly prepared and may be stored for up to 24 h.

**Reference suspension I:** *Standard of opalescence* and water (5:95)

**Acceptance criteria:** The clarity of the *Sample solution* is the same as that of water or its opalescence is not more pronounced than that of *Reference suspension I*.

• **CONDUCTIVITY**

**Sample solution:** 313 mg/mL of Sucrose in freshly boiled and cooled water

**Apparatus:** Use a conductivity meter or resistivity meter that measures the resistance of the column of liquid between the electrodes of the immersed measuring device. The apparatus is supplied with alternating current to avoid the effects of electrode polarization. It is equipped with a temperature compensation device or a precision thermometer.

**Calibration:** Choose a conductivity cell that is appropriate for the conductivity of the solution to be examined. The higher the expected conductivity, the higher the cell constant that must be chosen so that the value measured,  $R$ , is as large as possible for the apparatus used. Commonly used conductivity cells have cell constants on the order of  $0.1 \text{ cm}^{-1}$ ,  $1 \text{ cm}^{-1}$ , and  $10 \text{ cm}^{-1}$ . Use a standard solution of potassium chloride that is appropriate for the measurement. Rinse the cell several times with water that has been previously boiled and cooled to room temperature and at least twice with the potassium chloride solution used for the determination of the cell constant of the conductivity cell. Measure the resistance of the conductivity cell using the potassium chloride solution at  $20 \pm 0.1^\circ$ .

The constant,  $C$  (in  $\text{cm}^{-1}$ ), of the conductivity cell is given by the expression:

$$C = R_{KCl} \times K_{KCl}$$

$R_{KCl}$  = measured resistance (M $\Omega$ )

$K_{KCl}$  = conductivity of the standard solution of potassium chloride used ( $\mu\text{S} \cdot \text{cm}^{-1}$ )

The measured constant,  $C$ , of the conductivity cell must be within 5% of the given value.

**Analysis**

**Sample:** *Sample solution*

Measure the conductivity of the *Sample solution* ( $C_1$ ), while gently stirring with a magnetic stirrer, and that of the water used for preparing the *Sample solution* ( $C_2$ ). The readings must be stable within 1% over a period of 30 s.

Calculate the conductivity of the *Sample solution* from the expression:

$$\text{Result} = C_1 - (0.35 \times C_2)$$

$C_1$  = conductivity of the *Sample solution*

$C_2$  = water used for preparing the *Sample solution*

**Acceptance criteria:** NMT  $35 \mu\text{S} \cdot \text{cm}^{-1}$  at  $20^\circ$

• **OPTICAL ROTATION (781S), *Specific Rotation***

**Sample solution:** 260 mg/mL

**Acceptance criteria:**  $+66.3^\circ$  to  $+67.0^\circ$  at  $20^\circ$

• **\*COLOR VALUE**

**Sample solution:** Dissolve 50.0 g in 50.0 mL of water. Mix, filter (diameter of pores,  $0.45 \mu\text{m}$ ), and degas.

**Analysis:** Measure the absorbance at 420 nm, using a cell of at least 4 cm (a cell length of 10 cm or more is preferred).

Calculate the *Color Value* using the expression:

$$\text{Result} = (A \times 1000)/(b \times c)$$

$A$  = absorbance measured at 420 nm

$b$  = cell path length (cm)

$c$  = concentration of the solution (g/mL), calculated from the refractive index of the solution. Use [Table 1](#), and interpolate the values if necessary.

**Suitability requirements**

**Repeatability:** The absolute difference between two results is NMT 3.

Table 1

$n_D^{20}$	c (g/mL)
1.4138	0.570
1.4159	0.585
1.4179	0.600
1.4200	0.615
1.4221	0.630
1.4243	0.645
1.4264	0.661

**Acceptance criteria:** NMT 45 if labeled as parenteral grade; NMT 75 for nonparenteral grade.

• **DEXTRINS**

[NOTE—If intended for use in the preparation of large-volume infusions, it complies with the test for *Dextrins*.]

**Sample solution:** Prepare as directed in the test for *Appearance of Solution*.

**Analysis:** To 2 mL of the *Sample solution* add 8 mL of water, 0.05 mL of dilute hydrochloric acid (73 g/L of HCl), and 0.05 mL of 0.05 M iodine.

**Acceptance criteria:** The solution remains yellow.

• **REDUCING SUGARS**

**Sample solution:** Prepare as directed in the test for *Appearance of Solution*.

**Analysis:** To 5 mL of the *Sample solution* in a test tube, about 150-mm long and 16-mm in diameter, add 5 mL of water, 1.0 mL of 1 M sodium hydroxide, and 1.0 mL of a 1-g/L solution of methylene blue. Mix, and place in a water bath. After exactly 2 min, take the tube out of the bath, and examine the solution immediately.

**Acceptance criteria:** The blue color does not disappear completely, ignoring any blue color at the air/solution interface.

• **LOSS ON DRYING (731)**

**Sample:** 2.000 g

**Analysis:** Dry the *Sample* at 105° for 3 h.

**Acceptance criteria:** NMT 0.1%

• **BACTERIAL ENDOTOXINS TEST (85):** Less than 0.25 IU/mg

[NOTE—If intended for use in the preparation of large-volume infusions, it complies with the test for *Bacterial Endotoxins*.]

**ADDITIONAL REQUIREMENTS**

• **PACKAGING AND STORAGE:** Preserve in well-closed containers.

• **LABELING:** The label states, where applicable, that the substance is suitable for use in the manufacture of large-volume parenteral dosage forms.

• **USP REFERENCE STANDARDS (11)**

USP Sucrose RS

1 ▲ Test kit for sulfite determination may be ordered from the following suppliers: Megazyme Ltd. (Product code K-ETSULPH); R-Biopharm (Enzytec) (Article No. E6275); Nzytech (Catalogue No. AK00071) and BioSenTec (Product reference 040-E). ▲ (ERR 1-Apr-2024)

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