Hydroxyl value 200 - 220

Iodine value Not more than 2.0.

Purity **(1)** Clarity of solution—Dissolve 3.0 g of Stearyl Alcohol in 25 mL of ethanol (99.5) by warming: the solution is clear.

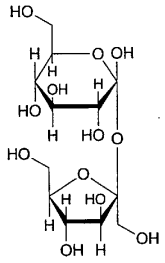
(2) Alkali—To the solution obtained in (1) add 2 drops of phenolphthalein TS: no red color develops.

Residue on ignition Not more than 0.05% (2 g).

Containers and storage Containers—Well-closed containers.

Sucrose

精製白糖



$C_{12}H_{22}O_{11}$: 342.30

β-D-Fructofuranosyl-α-D-glucopyranoside [*57-50-1*]

Sucrose contains no additives.

For Sucrose used for preparation of the large volume infusions, the label states the purpose.

Description Sucrose is a white crystalline powder, or lustrous colorless or white crystals.

It is very soluble in water, and slightly soluble in ethanol (95).

Identification **(1)** To 10 mg each of Sucrose and white soft sugar add diluted methanol (3 in 5) to make 20 mL each, and use these solutions as the sample solution and the standard solution (a), respectively. Separately, to 10 mg each of glucose, lactose monahydrate, fructose and white soft sugar add methanol (3 in 5) to make 20 mL, and use this solution as the standard solution (b). Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 2 μL each of the sample solution and the standard solution (a) and (b) on a plate of silica gel for thin-layer chromatography, and dry the plate completely. Develop the plate with a mixture of 1,2-dichloroethane, acetic acid (100), methanol and water (10:5:3:2) to a distance of about 15 cm, and dry the plate with a hot air. And immediately repeat the development with replaced developing mixture, and dry the plate in the same way. Spray evenly a solution of 0.5 g of thymol in 100 mL of a mixture of ethanol (95) and sulfuric acid (19:1), heat at 130°C for 10 minutes: the principal spot from the sample solution is the same with the principal spot from the standard solution (a) in the *Rf*, color and size, and four spots from the standard solution (b) are apparently distinguishable.

(2) Dissolve 50.0 g of Sucrose in recently boiled and cooled water to make 100 mL, and use this solution as the sample solution. To 1 mL of the sample solution add water to make 100 mL, then to 5 mL of this solution add 0.15 mL of freshly prepared copper (II) sulfate TS and 2 mL of freshly prepared 2 mol/L sodium hydroxide TS: the solution is clear and blue, and not changes on boiling. Then to this solution add 4 mL of dilute hydrochloric acid, boil, and add 4 mL of 2 mol/L sodium hydroxide TS: orange precipitates are immediately produced. 20

Optical rotation $[\alpha]_D^{20}$: +66.3 - +67.0° (26.0 g, water, 100 mL, 100 mm).

Purity **(1)** Clarity and color of solution—The sample solution obtained in the Identification (2) is clear, and has no more color than the following control solution.

Control solution: To exactly 2.4 mL of iron (III) chloride colorimetric stock solution and exactly 0.6 mL of cobalt (II) chloride colorimetric stock solution add 7.0 mL of diluted hydrochloric acid (7 in 250). To 5.0 mL of this solution add 95.0 mL of diluted hydrochloric acid (7 in 250).

(2) Acid or alkali—To 10 mL of the sample solution obtained in the Identification (2) add 0.3 mL of phenolphthalein TS: the solution is colorless, and develops a red color on addition of 0.3 mL of 0.01 mol/L sodium hydroxide VS.

(3) Sulfite—Dissolve 5.0 g of Sucrose in 40 mL of water, add 2.0 mL of dilute sodium hydroxide TS and water to make exactly 50 mL, and use this solution as the sample solution. Separately, dissolve 0.076 g of sodium disulfite in water to make exactly 50 mL, then pipet 5 mL of this solution, add water to make exactly 100 mL. Pipet 3 mL of this solution, add water to make exactly 100 mL, and use this solution as the standard solution. Immediately, pipet 10 mL each of the sample solution and the standard solution, add 1.0 mL of 3 mol/L hydrochloric acid, 2.0 mL of decolorized fuchsin TS and 2.0 mL of formaldehyde solution TS, and allow to stand for 30 minutes. Determine the absorbance at 583 nm of these solutions as directed under the Ultraviolet-visible Spectrophotometry using the control solution obtained by proceeding with 10.0 mL of water in the same manner as above: the absorbance of the sample solution is not larger than that of the standard solution (not more than 15 ppm as SO_2). When the standard solution does not show a red-purple to blue-purple color, result of the test is invalid.

(4) Lead—Put exactly 0.050 g of Sucrose in a polytetrafuruoroethylene decomposition-vessel, add 0.5 mL of nitric acid to dissolve, seal up the vessel, and heat at 150°C for 5 hours. After cooling, add water to make exactly 5 mL, and use this solution as the sample solution. Perform the test with more than 3 parts of the sample solution as directed in the standard addition method under the Atomic Absorption Spectrophotometry (electrothermal type) according to the following conditions. The standard solution is prepared by adding water to a suitable volume of Standard Lead Solution exactly volumed, and perform a blank determination with a solution prepared by adding water to 10.0 mL of nitric acid to make exactly 100 mL, and make any necessary correction (not more than 0.5 ppm).

Operating conditions—

Lamp: A hollow cathode lamp

Wavelengh: 283.3 mm

Temperature for drying: 110°C

Temperature for incineration: 600°C

Temperature for atomization: 2100°C

(5) Invert sugar—Transfer 5 mL of the sample solution obtained in the Identification (2) to a test-tube about 150 mm long and about 16 mm in diameter, add 5 mL of water, 1.0 mL of 1 mol/L sodium hydroxide VS and 1.0 mL of methylene blue TS, mix, and place in a water bath. After exactly 2 minutes, take the tube out of the bath, and examine the solution immediately: the blue color does not disappear completely (0.04%). Ignore any blue color at the air and solution interface.

Conductivity (i) Potassium chloride conductivity calibration standard solution—Dissolve powdered potassium chloride, previously dried at 500 - 600°C for 4 hours, in newly distillated water having less conductivity than 2 $\mu S \cdot cm^{-1}$ to get three kinds of the standard solution containing 0.7455 g, 0.0746 g and 0.0149 g of potassium chloride in 1000.0 g, respectively. The conductivities of these solutions at 20°C are shown in the following table.

Standard solution (g/1000.0 g)	Conductivity ($\mu S \cdot cm^{-1}$)	Resistivity ($\Omega \cdot cm$)
0.7455	1330	752
0.0746	133.0	7519
0.0149	26.0	37594

(ii) Apparatus—Use an appropriate conductivity meter. The conductivity is determined to measure the electrical resistance of the column of liquid between the electrodes of the immersed measuring device (conductivity cell). The apparatus is supplied with alternative current to avoid the effects of electrode polarization. It is usually equipped with a temperature compensation device. The conductivity cell contains of two parallel platinum electrodes coated with platinum black, and both electrodes are generally protected by a glass tube which allows good exchange between the solution and the electrodes. Use a cell giving the cell constant of 0.01 to 1 cm^{-1}.

(iii) Procedure—Use the suitable potassium chloride conductivity calibration standard solution to the measurement. After washing the well with water, rinse 2 to 3 times with the calibration standard solution, fill up the cell with the calibration standard solution, and determine the conductivity of the calibration standard solution kept at 20 ±0.1°C. Repeat the determination, and measure the conductivity of the calibration standard solution, G_{χ_0} (μS), after a stable reading of ± 3% is obtained. The cell constant, J, is calculated by the following:

$$J = \frac{\chi_{KCl}}{G_{\chi_0}}$$

J: Cell constant (cm^{-1})

χ_{KCl}: Conductivity constant of the potassium chloride conductivity calibration standard solution ($\mu S \cdot cm^{-1}$) (20°C)

G_{χ_0}: Conductivity measured (μS)

Dissolve 31.3 g of Sucrose in newly distillated water to make exactly 100 mL, and use this solution as the sample solution. After washing well the cell with water, rinse the cell with the sample solution 2 to 3 times , fill up with the sample solution, and determine the conductivity of the sample solution, G_T (μS), kept at 20 ± 0.1°C, while stirring. Determine the conductivity of the water used for preparation of the sample solution, G_0 (μS), in the same manner as above, and calculate the conductivity, χ_T ($\mu S \cdot cm^{-1}$) and χ_0 ($\mu S \cdot cm^{-1}$), by the following expressions:

$$\chi_T\ (\mu S \cdot cm^{-1}) = JG_T$$
$$\chi_0\ (\mu S \cdot cm^{-1}) = JG_0$$

Determine the corrected conductivity, χ_C, of the sample solution by the following expression: not more than 35 $\mu S \cdot cm^{-1}$.

$$\chi_C\ (\mu S \cdot cm^{-1}) = \chi_T - 0.35\,\chi_0$$

Loss on drying Not more than 0.1% (2 g, 105°C, 3 hours).

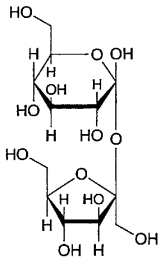
Dextrins For Sucrose used to prepare large volume aqueous infusions, to 2 mL of the sample solution obtained in the Identification (2) add 8 mL of water, 0.05 mL of dilute hydrochloric acid and 0.05 mL of iodine TS: the solution remains yellow.

Bacterial endotoxins Less than 0.25 EU/mg, for Sucrose exclusively to be used to prepare Injections for intravenous infusion of larger volume.

Containers and storage Containers—Well-closed containers.

White Soft Sugar

白糖



$C_{12}H_{22}O_{11}$: 342.30

β-D-Fructofuranosyl-α-D-glucopyranoside [*57-50-1*]

Description White Soft Sugar is colorless or white crystals or crystalline powder. It is odorless and has a sweet taste.

It is very soluble in water, very slightly soluble in ethanol (95), and practically insoluble in diethyl ether.

A solution of White Soft Sugar (1 in 10) is neutral.

Identification **(1)** When 1 g of White Soft Sugar is ignited, it melts and swells, and decomposes, emitting an odor of caramel, to bulky charcoal.

(2) To 0.1 g of White Soft Sugar add 2 mL of dilute sulfuric acid, boil, add 4 mL of sodium hydroxide TS and 3 mL of Fehling's TS, and heat to boiling: a red to dark red precipitate is produced.

Optical rotation $[\alpha]_D^{20}$: +65.0 - +67.0° (after drying, 13 g, water, 50 mL, 100 mm).

Purity **(1)** Clarity and color of solution—Dissolve 100 g of White Soft Sugar in 100 mL of water, take 50 mL of this solution in a Nessler tube, and view transversely the Nessler tube against a white background: the solution is colorless or only slightly yellow and has no blue color. Fill the solution in