

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 distilled water having less conductivity than $2 \mu\text{S}\cdot\text{cm}^{-1}$ 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 ($\mu\text{S}\cdot\text{cm}^{-1}$) | Resistivity ($\Omega\cdot\text{cm}$) |
|-----------------------------------|--|---|
| 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 $20 \pm 0.1^\circ\text{C}$. Repeat the determination, and measure the conductivity of the calibration standard solution, G_{x_0} (μS), after a stable reading of $\pm 3\%$ is obtained. The cell constant, J , is calculated by the following:

$$J = \frac{\chi_{\text{KCl}}}{G_{x_0}}$$

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

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

G_{x_0} : Conductivity measured (μS)

Dissolve 31.3 g of Sucrose in newly distilled 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 $20 \pm 0.1^\circ\text{C}$, 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 cal-

culate the conductivity, χ_T ($\mu\text{S}\cdot\text{cm}^{-1}$) and χ_0 ($\mu\text{S}\cdot\text{cm}^{-1}$), by the following expressions:

$$\begin{aligned}\chi_T (\mu\text{S}\cdot\text{cm}^{-1}) &= JG_T \\ \chi_0 (\mu\text{S}\cdot\text{cm}^{-1}) &= JG_0\end{aligned}$$

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

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

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

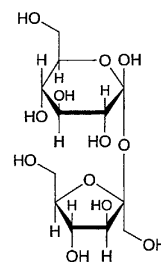
Dextrins For Sucrose used to prepare large volume aqueous infusions, to 2 mL of the sample solution obtained in the Identification (2) add 8 mL of water, 0.05 mL of dilute hydrochloric acid and 0.05 mL of iodine TS: the solution remains yellow.

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



$\text{C}_{12}\text{H}_{22}\text{O}_{11}$: 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

the Nessler tube, stopper, and allow to stand for 2 days: no precipitate is produced.

(2) Chloride—To 10.0 g of White Soft Sugar add water to make 100 mL, and use this solution as the sample solution. To 20 mL of the sample solution add 6 mL of dilute nitric acid and water to make 50 mL. Perform the test using this solution as the test solution. Prepare the control solution with 0.30 mL of 0.01 mol/L hydrochloric acid VS (not more than 0.005%).

(3) Sulfate—To 40 mL of the sample solution obtained in (2) add 1 mL of dilute hydrochloric acid and water to make 50 mL. Perform the test using this solution as the test solution. Prepare the control solution with 0.50 mL of 0.005 mol/L sulfuric acid VS (not more than 0.006%).

(4) Calcium—To 10 mL of the sample solution obtained in (2) add 1 mL of ammonium oxalate TS: this solution shows immediately no change.

(5) Heavy metals—Proceed with 5.0 g of White Soft Sugar according to Method 1, and perform the test. Prepare the control solution with 2.5 mL of Standard Lead Solution (not more than 5 ppm).

(6) Arsenic—Prepare the test solution with 1.0 g of White Soft Sugar according to Method 1, and perform the test using Apparatus B (not more than 2 ppm).

(7) Invert sugar—Dissolve 5.0 g of White Soft Sugar in water to make 100 mL, filter if necessary, and use this solution as the sample solution. Separately place 100 mL of alkaline copper (II) sulfate solution in a 300-mL beaker, cover the beaker with a watch glass, and boil. Immediately add 50.0 mL of the sample solution, boil the mixture exactly for 5 minutes, add at once 50 mL of freshly boiled and cooled water, dip it in a water bath of a temperature below 10°C for 5 minutes, and collect the precipitate in a tared glass filter (G4). Wash the residue on the filter with water until the last washing is neutral, then wash with 10 mL of ethanol (95), add 10 mL of diethyl ether, and dry at 105°C for 30 minutes: the mass of the residual precipitate is not more than 0.120 g.

Loss on drying Not more than 1.30% (15 g, 105°C, 2 hours).

Residue on ignition Not more than 0.10% (2 g).

Containers and storage Containers—Well-closed containers.

Sulfur and Camphor Lotion

イオウ・カンフルローション

Method of preparation

| | |
|---|-----------------------|
| Sulfur | 60 g |
| <i>d</i> -Camphor or <i>dl</i> -Camphor | 5 g |
| Hydroxypropylcellulose | 4 g |
| Calcium Hydroxide | 1 g |
| Ethanol | 4 mL |
| Water or Purified Water | a sufficient quantity |
| To make 1000 mL | |

Dissolve Hydroxypropylcellulose in 200 mL of Water or Purified Water. Add this solution in small portions to the triturate of Sulfur with the Ethanol solution of *d*-Camphor

or *dl*-Camphor, and triturate again the mixture. Separately, dissolve Calcium Hydroxide in 500 mL of Water or Purified Water, stopper tightly, shake, and allow to stand. Add 300 mL of this supernatant liquid to the above mixture, then add Water or Purified Water to make 1000 mL, and shake thoroughly.

Description Sulfur and Camphor Lotion is a light yellow suspension.

A part of the components separates out on standing.

Identification (1) To 5 mL of well shaken Sulfur and Camphor Lotion add 25 mL of water, and centrifuge [use this supernatant liquid for test (3)]. To 0.02 g of the precipitate add 2 mL of pyridine and 0.2 mL of sodium hydrogen carbonate TS, and boil: a blue color develops (sulfur).

(2) To 10 mL of well shaken Sulfur and Camphor Lotion add 5 mL of diethyl ether, and mix. Separate the diethyl ether layer, and filter through a pledget of cotton. Wash the cotton with a small portion of diethyl ether, combine the washings with the filtrate, and distil cautiously on a water bath to remove the diethyl ether. Dissolve the residue in 1 mL of methanol, add 1 mL of 2,4-dinitrophenylhydrazine TS, and heat for about 2 minutes on a water bath. Cool, dilute with water to make about 5 mL, and allow to stand. Filter the produced precipitate through a glass filter (G4), and wash the residue on the filter with water until the last washing is colorless. Dissolve the residue in 10 mL of ethanol (95), add 5 mL of sodium hydroxide TS, and allow to stand for 2 minutes: a red color develops (*d*-camphor or *dl*-camphor).

(3) The supernatant liquid obtained in (1) responds to the Qualitative Tests (2) and (3) for calcium salt.

Containers and storage Containers—Tight containers.

Sulfur, Salicylic Acid and Thianthol Ointment

イオウ・サリチル酸・チアントール軟膏

Method of preparation

| | |
|---|-----------------------|
| Sulfur | 100 g |
| Salicylic Acid, finely powdered | 30 g |
| Thianthol | 100 mL |
| Zinc Oxide, very finely powdered | 100 g |
| Simple Ointment or a suitable ointment base | a sufficient quantity |
| To make 1000 g | |

Prepare as directed under Ointments, with above ingredients.

Description Sulfur, Salicylic Acid and Thianthol Ointment is light yellow in color.

Identification (1) Stir well 0.5 g of Sulfur, Salicylic Acid and Thianthol Ointment with 10 mL of water while heating, cool, and filter. To 1 mL of the filtrate add 5 mL of iron (III) nitrate TS: a purple color is produced (salicylic acid).

(2) Shake 1 g of Sulfur, Salicylic Acid and Thianthol Ointment with 20 mL of diethyl ether, remove the super-