retention time as the internal standard peak in the chromato-gram of *Assay preparation A,* calculate the ratio, *r:*

$$r = S_{cb} / S_i$$

in which S_{cb} is the area of the cetyl alcohol peak; and S_i is the area of the peak with the same retention time as the internal standard, respectively, in the chromatogram of *Assay preparation B.* If *r* is less than 300, calculate the corrected area, $S_{a(corr)}$, of the peak corresponding to the internal standard in the chromatogram of the *Assay preparation A:*

$$S_{a(corr)} = S_{ha} - (S_i \times S_{ca} / S_{cb})$$

in which S_{ha} and S_{ca} are the areas of the internal standard peak and the cetyl alcohol peak, respectively, in the chromatogram of *Assay preparation A.*

Inject about 1 μL of each of *Assay preparations C* and *D* into the chromatograph, record the chromatograms, and measure the areas for the major peaks. Carry out the correction for inter-ference in the same manner as for *Assay preparation A,* and calculate the corrected area, $S_{c(corr)}$, of the peak corresponding to the internal standard in the chromatogram of *Assay preparation C.*

Procedure—Inject equal volumes of the *Resolution solution* and *Assay preparations C* and *D* into the chromatograph, record the chromatograms, and measure the areas for the major peaks. The substances are eluted in the following order: cetyl alcohol, 1-heptadecanol (internal standard), and stearyl alcohol. Identify the cetyl alcohol and stearyl alcohol peaks in the chromato-grams of the *Assay preparations* by comparison with the *Resolu-tion solution.* Calculate the percentage of sodium cetyl sulfate in the portion of Sodium Cetostearyl Sulfate taken by the formula:

$$100A_c \times 1.421 \times W_{ch} /(S_{c(corr)} \times W_c)$$

in which A_c is the area of the cetyl alcohol peak in the chromat-ogram of *Assay preparation C;* W_{ch} is the weight of the internal standard, in mg, added in the preparation of *Assay preparation C;* and W_c is the weight, in mg, of Sodium Cetostearyl Sulfate taken to prepare *Assay preparation C,* calculated on the anhy-drous basis.

Calculate the percentage of sodium stearyl sulfate in the por-tion of Sodium Cetostearyl Sulfate taken by the formula:

$$100\ B_c \times 1.377 \times W_{ch} /(S_{c(corr)} \times W_c)$$

in which B_c is the area of the stearyl alcohol peak in the chro-matogram of *Assay preparation C;* and the other terms are as defined above.

Sodium Chloride—*see Sodium Chloride General Monographs*

Sodium Chloride Injection, Bacteriostatic —*see Bacteriostatic Sodium Chloride Injection General Monographs*

Sodium Citrate—*see Sodium Citrate General Monographs*

Sodium Dehydroacetate

$C_8H_7NaO_4$ 190.13
2*H*-Pyran-2,4(3*H*)-dione, 3-acetyl-6-methyl-, monosodium salt [4418-26-2].

DEFINITION
Sodium Dehydroacetate contains NLT 98.0% and NMT 100.5% of sodium dehydroacetate ($C_8H_7NaO_4$), calculated on the an-hydrous basis.

IDENTIFICATION
- **A. MELTING RANGE OR TEMPERATURE ⟨741⟩**
 Sample solution: 150 mg/mL
 Analysis: To 10 mL of the *Sample solution* add 5 mL of 3 N hydrochloric acid, collect the crystals by filtration with suc-tion, wash with 10 mL of water, and dry at 80° for 4 h. Determine the melting point as directed in the chapter.
 Acceptance criteria: 109°–111°
- **B. IDENTIFICATION TESTS—GENERAL,** *Sodium* ⟨191⟩
 Sample solution: 1 in 20
 Acceptance criteria: Meets the requirements

ASSAY
- **PROCEDURE**
 Sample: 500 mg
 Blank: 25 mL of glacial acetic acid containing *p*-naphthol-benzein TS, which has been previously neutralized to a blue color
 Titrimetric system
 (See *Titrimetry* ⟨541⟩.)
 Mode: Direct titration
 Titrant: 0.1 N perchloric acid VS
 Endpoint detection: Visual
 Analysis: Transfer the *Sample* to a 125-mL conical flask, and dissolve it in 25 mL of glacial acetic acid containing *p*-naph-tholbenzein TS, which has been previously neutralized to a blue color. Titrate with 0.1 N perchloric acid VS to the origi-nal blue color. Perform a blank determination.
 Calculate the percentage of dehydroacetate ($C_8H_7NaO_4$) in the *Sample* taken:

$$\text{Result} = \{[(V_S - V_B) \times N \times F]/W\} \times 100$$

V_S	= volume of the *Titrant* consumed by the *Sample* (mL)
V_B	= volume of the *Titrant* consumed by the *Blank* (mL)
N	= actual normality of the *Titrant* (mEq/mL)
F	= equivalency factor, 190.1 mg/mEq
W	= weight of the *Sample* (mg)

 Acceptance criteria: 98.0%–100.5% on the anhydrous basis
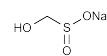
IMPURITIES
- **HEAVY METALS,** *Method II* ⟨231⟩: NMT 10 ppm

SPECIFIC TESTS
- **WATER DETERMINATION,** *Method I* ⟨921⟩: 8.5%–10.0%

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

Sodium Formaldehyde Sulfoxylate

CH_3NaO_3S 118.09
Methanesulfinic acid, hydroxy-, monosodium salt.
Monosodium hydroxymethanesulfinate   [149-44-0].
Dihydrate   154.11   [6035-47-8].

» Sodium Formaldehyde Sulfoxylate contains an amount of CH_3NaO_3S equivalent to not less than 45.5 percent and not more than 54.5 percent of SO_2, calculated on the dried basis. It may contain a suitable stabilizer, such as sodium carbonate.

Packaging and storage—Preserve in well-closed, light-resistant containers, and store at controlled room temperature.

Clarity and color of solution—Dissolve 1 g in 20 mL of water, and transfer 10 mL to a 20- × 150-mm test tube. Compare with water in a similar test tube: the liquids are equally clear and, when viewed transversely by transmitted light, exhibit no apparent difference in color.

Identification—

A: Dissolve about 4 g in 10 mL of water in a test tube, and add 1 mL of silver-ammonia-nitrate TS: metallic silver is produced, either as a finely divided, gray precipitate or as a bright metallic mirror on the inner surface of the tube.

B: Dissolve about 40 mg of salicylic acid in 5 mL of sulfuric acid, add about 50 mg of Sodium Formaldehyde Sulfoxylate, and warm very gently: a permanent, deep red color appears.

Alkalinity—Dissolve 1.0 g in 50 mL of water, add phenolphthalein TS, and titrate with 0.10 N sulfuric acid: not more than 3.5 mL is required for neutralization.

pH ⟨791⟩: between 9.5 and 10.5, in a solution (1 in 50).

Loss on drying ⟨731⟩—Dry it at 105° for 3 hours: it loses not more than 27.0% of its weight.

Sulfide—Dissolve 6 g in 14 mL of water in a test tube, and wet a strip of lead acetate test paper with the clear solution: no discoloration is evident within 5 minutes.

Iron—Transfer 1.0 g to a suitable crucible, and carefully ignite, initially at a low temperature until thoroughly charred, and finally, preferably in a muffle furnace, at 500° to 600° until the carbon is all burned off. Cool, dissolve the residue in 2 mL of hydrochloric acid, and dilute with water to 50 mL. Add about 50 mg of ammonium persulfate and 5 mL of ammonium thiocyanate TS, mix, and transfer to a color-comparison tube. Treat in the same manner 5.0 mL of a solution of ferric ammonium sulfate, prepared by dissolving 43.2 mg of ferric ammonium sulfate in 10 mL of 2 N sulfuric acid and adding water to make 1000 mL, each mL representing 5 µg of Fe. The color of the test solution is not deeper than that of the solution containing the standard iron solution (0.0025%).

Sodium sulfite—Transfer 4.0 mL of the solution prepared for the *Assay* to a conical flask containing 100 mL of water. Add 2 mL of formaldehyde TS, and titrate with the same 0.1 N iodine VS that is used for the *Assay*, adding 3 mL of starch TS as the endpoint is approached. Calculate the percentage of Na_2SO_3 in the Sodium Formaldehyde Sulfoxylate taken by the formula:

$$(1.25)(63.02)(V_2 - V_1)(N / W)$$

in which 63.02 is the equivalent weight of sodium sulfite; V_1 and V_2 are the volumes, in mL, of 0.1 N iodine VS consumed in this titration and in the titration performed in the *Assay*, respectively; N is the exact normality of the iodine solution; and W is the weight, in g, of Sodium Formaldehyde Sulfoxylate taken for the *Assay*: not more than 5.0% of Na_2SO_3, calculated on the dried basis, is found.

Assay—Transfer about 1 g of Sodium Formaldehyde Sulfoxylate, accurately weighed, to a 50-mL volumetric flask, dissolve in about 25 mL of water, dilute with water to volume, and mix. Reserve a portion of this solution for the test for *Sodium sulfite*. Transfer 4.0 mL of this solution to a conical flask containing 100 mL of water, and titrate with 0.1 N iodine VS, adding 3 mL of starch TS as the endpoint is approached. Each mL of 0.1 N iodine is equivalent to 1.602 mg of SO_2.

Sodium Hydroxide

NaOH 40.00
Sodium hydroxide [1310-73-2].

DEFINITION
Sodium Hydroxide contains NLT 95.0% and NMT 100.5% of total alkali, calculated as sodium hydroxide (NaOH), including NMT 3.0% of sodium carbonate (Na_2CO_3).
[**CAUTION**—Exercise great care in handling sodium hydroxide, because it rapidly destroys tissues.]

IDENTIFICATION
• **A. IDENTIFICATION TESTS—GENERAL,** *Sodium* ⟨191⟩: A solution (1 in 25) meets the requirements.

ASSAY
• **PROCEDURE**
Sample solution: 1.5 g of Sodium Hydroxide in 40 mL of carbon dioxide-free water. Cool the solution to room temperature.
Blank: 40.0 mL of carbon dioxide-free water
Titrimetric system
(See *Titrimetry* ⟨541⟩.)
Mode: Direct titration
Titrant: 1 N sulfuric acid
Endpoint detection: Visual
Analysis: To the *Sample*, add phenolphthalein TS. Titrate with 1 N sulfuric acid VS. At the discharge of the pink color of the indicator, record the volume of *Titrant* (V_{S1}). Add methyl orange TS, and continue the titration until a persistent pink color is produced. Record the volume of *Titrant* (V_{S2}). Perform a blank determination, and make any necessary corrections.
Calculate the percentage of total alkali, calculated as sodium hydroxide (NaOH), in the *Sample* taken:

$$Result = \{[(V_{S1} - V_B) \times N \times F_1]/W\} \times 100$$

V_{S1} = volume of *Titrant* consumed by the *Sample* to the first endpoint (mL)
V_B = volume of *Titrant* consumed by the *Blank* (mL)
N = actual normality of the *Titrant* (mEq/mL)
F_1 = equivalency factor, 40.00 (mg/mEq)
W = weight of the *Sample* (mg)
Calculate the percentage of sodium carbonate (Na_2CO_3) in the *Sample* taken:

$$Result = \{[(V_{S2} - V_{S1}) \times N \times F_2]/W\} \times 100$$

V_{S2} = volume of *Titrant* consumed by the *Sample* to the second endpoint (mL)
V_{S1} = volume of *Titrant* consumed by the *Sample* to the first endpoint (mL)
N = actual normality of the *Titrant* (mEq/mL)
F_2 = equivalency factor, 106.0 (mg/mEq)
W = weight of the *Sample* (mg)
Acceptance criteria: 95.0%–100.5% of total alkali; NMT 3.0% of sodium carbonate (Na_2CO_3)

IMPURITIES
• **POTASSIUM**
Sample solution: 1 in 20
Analysis: Acidify 5 mL of the *Sample solution* with 6 N acetic acid, then add 5 drops of sodium cobaltinitrite TS.
Acceptance criteria: No precipitate is formed.
• **HEAVY METALS** ⟨231⟩
Test preparation: Dissolve 0.67 g in a mixture of 5 mL of water and 7 mL of 3 N hydrochloric acid. Heat to boiling, cool, and dilute with water to 25 mL.