

bleach (nominally 5.25% w/v) provided that the commercial laundry bleach was recently acquired.

**Packaging and storage**—Preserve in tight, light-resistant 1-liter plastic containers, and store at controlled room temperature.

**Labeling**—Label it to indicate that its strength is 0.025 percent, and to state the correct beyond-use date. [NOTE—For external use only; it may be applied to wounds and burns.]

**pH** (791): between 7.8 and 8.2.

**Beyond-use date**—Seven days after the day on which it was compounded.

**Assay**—Transfer 50.0 mL of the Solution to a glass-stoppered flask, and add 0.5 g of potassium iodide and 10 mL of 6 N acetic acid. Titrate the liberated iodine with 0.1 N sodium thiosulfate VS, adding 2 mL of starch TS as the endpoint is approached. Perform a blank determination and make any necessary correction. Each mL of 0.1 N sodium thiosulfate is equivalent to 3.722 mg of NaClO.

## Sodium Iodide

NaI 149.89  
Sodium iodide [7681-82-5].

### DEFINITION

Sodium Iodide contains NLT 99.0% and NMT 101.5% of NaI, calculated on the anhydrous basis.

### IDENTIFICATION

• **A. IDENTIFICATION TESTS—GENERAL, Sodium** (191)

**Sample solution:** 50 mg/mL

**Acceptance criteria:** Meets the requirements

• **B. IDENTIFICATION TESTS—GENERAL, Iodide** (191)

**Sample solution:** 50 mg/mL

**Acceptance criteria:** Meets the requirements

### ASSAY

• **PROCEDURE**

**Sample:** 500 mg

**Analysis:** Dissolve the *Sample* in 10 mL of water. Add 35 mL of hydrochloric acid, and titrate with 0.05 M potassium iodate VS until the dark brown solution that is produced becomes pale brown. Add 1 mL of amaranth TS, and continue the titration slowly until the red color just changes to yellow. Each mL of 0.05 M potassium iodate is equivalent to 14.99 mg of NaI.

**Acceptance criteria:** 99.0%–101.5% on the anhydrous basis

### IMPURITIES

• **IODATE**

**Iodate solution:** Dilute 1 mL of potassium iodate solution (1 in 2500) with water to 100 mL.

**Standard solution:** Dissolve 100 mg of Sodium Iodide in ammonia- and carbon dioxide-free water and add 1 mL of *iodate solution* to obtain 10 mL of solution. Transfer to a color-comparison tube.

**Sample solution:** Dissolve 1.1 g in sufficient ammonia- and carbon dioxide-free water to obtain 10 mL of solution. Transfer to a color-comparison tube.

**Analysis:** To each color comparison tube add 1 mL of starch TS and 0.25 mL of 1.0 N sulfuric acid, and mix.

**Acceptance criteria:** Any color produced in the *Sample solution* does not exceed that in the *Standard solution* (NMT 4 ppm).

• **THIOSULFATE AND BARIUM**

**Sample solution:** Dissolve 0.5 g in 10 mL of ammonia- and carbon dioxide-free water.

**Analysis:** Add 2 drops of 2 N sulfuric acid to the *Sample solution*.

**Acceptance criteria:** No turbidity develops within 1 min.

• **POTASSIUM**

**Sample solution:** Dissolve 1.0 g in 2 mL of water.

**Acceptance criteria:** The *Sample solution* yields no precipitate with 1.0 mL of sodium bitartrate TS.

• **LIMIT OF NITRATE, NITRITE, AND AMMONIA**

**Sample solution:** Dissolve 1.0 g in 5 mL of water.

**Analysis:** To the *Sample solution* contained in a test tube of 40-mL capacity add 5 mL of 1 N sodium hydroxide and about 200 mg of aluminum wire. Insert a pledget of purified cotton in the upper portion of the test tube, and place a piece of moistened red litmus paper over the mouth of the tube. Heat the test tube and its contents on a steam bath for 15 min.

**Acceptance criteria:** No blue coloration of the paper is discernible.

• **HEAVY METALS** (231)

**Sample solution:** Dissolve 2.0 g in 25 mL of water.

**Acceptance criteria:** NMT 10 ppm

### SPECIFIC TESTS

• **ALKALINITY**

**Sample solution:** Dissolve 1.0 g in 10 mL of water.

**Analysis:** Add 0.15 mL of 0.10 N sulfuric acid and 1 drop of phenolphthalein TS to the *Sample solution*.

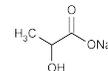
**Acceptance criteria:** No red color is produced.

• **WATER DETERMINATION, Method I** (921): NMT 2.0%

### ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in tight containers.

## Sodium Lactate Injection



C<sub>3</sub>H<sub>5</sub>NaO<sub>3</sub> 112.06

Propanoic acid, 2-hydroxy-, monosodium salt.

Sodium lactate [72-17-3].

» Sodium Lactate Injection is sterile Sodium Lactate Solution in Water for Injection, or a sterile solution of Lactic Acid in Water for Injection prepared with the aid of Sodium Hydroxide. It contains not less than 95.0 percent and not more than 110.0 percent of the labeled amount of C<sub>3</sub>H<sub>5</sub>NaO<sub>3</sub>.

**Packaging and storage**—Preserve in single-dose glass or plastic containers. Glass containers are preferably of Type I or Type II glass.

**Labeling**—The label states the total osmolar concentration in mOsmol per L. Where the contents are less than 100 mL, or where the label states that the Injection is not for direct injection but is to be diluted before use, the label alternatively may state the total osmolar concentration in mOsmol per mL. The label includes also the warning: "Not for use in the treatment of lactic acidosis."

**USP Reference standards** (11)—

USP Endotoxin RS

**Identification**—Overlay 2 mL of Injection on 5 mL of a 1 in 100 solution of catechol in sulfuric acid: a deep red color is produced at the zone of contact.

**Bacterial endotoxins** (85)—It contains not more than 2.0 USP Endotoxin Units per mEq.

**pH** (791): between 6.0 and 7.3, the Injection being diluted with water, if necessary, to approximately 0.16 M (20 mg per mL).

**Particulate matter** (788): meets the requirements under small-volume injections.

**Heavy metals** (231)—Evaporate a volume of Injection, equivalent to 2.0 g of sodium lactate, to 5 mL, and dilute with 1 N acetic acid to 25 mL: the limit is 0.001%.

**Other requirements**—It meets the requirements under *Injections* (1).

**Assay**—Pipet into a small beaker a volume of Injection, equivalent to about 300 mg of sodium lactate, and evaporate to dryness. Add to the residue 60 mL of a 1 in 5 mixture of acetic anhydride in glacial acetic acid, and stir until the residue is completely dissolved. Titrate with 0.1 N perchloric acid VS, determining the endpoint potentiometrically. Perform a blank determination, and make any necessary correction. Each mL of 0.1 N perchloric acid is equivalent to 11.21 mg of  $C_3H_5NaO_3$ .

## Sodium Lactate Solution

» Sodium Lactate Solution is an aqueous solution containing not less than 50.0 percent, by weight, of monosodium lactate. It contains not less than 98.0 percent and not more than 102.0 percent of the labeled amount of  $C_3H_5NaO_3$ .

**Packaging and storage**—Preserve in tight containers.

**Labeling**—Label it to indicate its content of sodium lactate.

**Identification**—It responds to the tests for *Sodium* (191) and for *Lactate* (191).

**pH** (791): between 5.0 and 9.0.

**Chloride** (221)—A portion, equivalent to 1 g of sodium lactate, shows no more chloride than corresponds to 0.7 mL of 0.020 N hydrochloric acid (0.05%).

**Sulfate**—To 10 mL of a solution (1 in 100) add 2 drops of hydrochloric acid and 1 mL of barium chloride TS: no turbidity is produced.

**Heavy metals, Method I** (231)—Dilute a quantity of Solution, equivalent to 2.0 g of sodium lactate, with 1 N acetic acid to 25 mL: the limit is 0.001%.

**Sugars**—To 10 mL of hot alkaline cupric tartrate TS add 5 drops of Solution: no red precipitate is formed.

**Limit of citrate, oxalate, phosphate, or tartrate**—Dilute 5 mL with recently boiled and cooled water to 50 mL. To 4 mL of this solution add 6 N ammonium hydroxide or 3 N hydrochloric acid, if necessary, to bring the pH to between 7.3 and 7.7. Add 1 mL of calcium chloride TS, and heat in a boiling water bath for 5 minutes: the solution remains clear.

**Limit of methanol and methyl esters**—

*Potassium permanganate and phosphoric acid solution*—Dissolve 3 g of potassium permanganate in a mixture of 15 mL of phosphoric acid and 70 mL of water. Dilute with water to 100 mL.

*Oxalic acid and sulfuric acid solution*—Cautiously add 50 mL of sulfuric acid to 50 mL of water, mix, cool, add 5 g of oxalic acid, and mix to dissolve.

*Standard preparation*—Prepare a solution containing 10.0 mg of methanol in 100 mL of dilute alcohol (1 in 10).

*Test preparation*—Place 40.0 g in a glass-stoppered, round-bottom flask, add 10 mL of water, and add cautiously 30 mL of 5 N potassium hydroxide. Connect a condenser to the flask, and steam-distill, collecting the distillate in a suitable 100-mL graduated vessel containing 10 mL of alcohol. Continue the distillation until the volume in the receiver reaches approximately 95 mL, and dilute the distillate with water to 100.0 mL.

*Procedure*—Transfer 10.0 mL each of the *Standard preparation* and the *Test preparation* to 25-mL volumetric flasks, to each add 5.0 mL of *Potassium permanganate and phosphoric acid solution*, and mix. After 15 minutes, to each add 2.0 mL of *Oxalic*

*acid and sulfuric acid solution*, stir with a glass rod until the solution is colorless, add 5.0 mL of fuchsin-sulfurous acid TS, and dilute with water to volume. After 2 hours, concomitantly determine the absorbances of both solutions in 1-cm cells at the wavelength of maximum absorbance at about 575 nm, with a suitable spectrophotometer, using water as the blank: the absorbance of the solution from the *Test preparation* is not greater than that from the *Standard preparation* (0.025%).

**Assay**—Weigh accurately into a suitable flask a volume of Solution, equivalent to about 300 mg of sodium lactate, add 60 mL of a 1 in 5 mixture of acetic anhydride in glacial acetic acid, mix, and allow to stand for 20 minutes. Titrate with 0.1 N perchloric acid VS, determining the endpoint potentiometrically. Perform a blank determination, and make any necessary correction. Each mL of 0.1 N perchloric acid is equivalent to 11.21 mg of  $C_3H_5NaO_3$ .

## Sodium Monofluorophosphate



$Na_2PFO_3$  143.95

Phosphorofluoridic acid, disodium salt.

Disodium phosphorofluoridate [10163-15-2].

» Sodium Monofluorophosphate contains not less than 91.7 percent and not more than 100.5 percent of  $Na_2PFO_3$ , calculated on the dried basis.

**Packaging and storage**—Preserve in well-closed containers.

**USP Reference standards** (11)—

USP Sodium Fluoride RS

**Identification**—

**A:** Place about 1 g in a platinum crucible in a well-ventilated hood, and add 15 mL of sulfuric acid. Cover the crucible with a piece of clear, polished glass, and heat on a steam bath for 1 hour. Remove the glass cover, rinse it in water, and dry: the glass surface exposed to vapors from the crucible is etched.

**B:** A solution (1 in 10) with silver nitrate TS yields a white precipitate, which is soluble in diluted nitric acid and in dilute ammonium hydroxide (1 in 2).

**C:** A solution responds to the tests for *Sodium* (191).

**pH** (791): between 6.5 and 8.0, in a solution (1 in 50).

**Loss on drying** (731)—Dry it at 105° to constant weight: it loses not more than 0.2% of its weight.

**Arsenic, Method I** (211): 3 ppm.

**Heavy metals, Method I** (231)—Dissolve 400 mg in 25 mL of water: the limit is 0.005%.

**Limit of fluoride ion**—[NOTE—Use plasticware throughout this test.]

*Buffer solution*—To 55 g of sodium chloride in a 1000-mL volumetric flask add 500 mg of sodium citrate, 255 g of sodium acetate, and 300 mL of water. Shake to dissolve, and cautiously add 115 mL of glacial acetic acid with mixing. Cool to room temperature, add 300 mL of isopropyl alcohol, dilute with water to volume, and mix: the pH of this solution is between 5.0 and 5.5.

*Standard stock solution*—Dissolve an accurately weighed quantity of USP Sodium Fluoride RS quantitatively in water to obtain a solution containing 1105 µg per mL. Each mL of this solution contains 500 µg of fluoride ion. Store in a tightly closed, plastic container.

*Standard preparations*—To four 100-mL volumetric flasks transfer, respectively, 2.0-, 4.0-, 10.0-, and 20.0-mL portions of the *Standard stock solution*, dilute each with *Buffer solution* to volume, and mix to obtain solutions having fluoride ion concentrations of 10, 20, 50, and 100 µg per mL, respectively.