

U.S. PHARMACOPEIA

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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%).

Residual solvents { 467 } : meets the requirements.

(Official January 1, 2007)

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 C₃H₅NaO₃.

Auxiliary Information— *Staff Liaison* : [Daniel K. Bempong, Ph.D., Scientist](#)

Expert Committee : (MDPS05) Monograph Development-Pulmonary and Steroids

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