Edition: BP 2025 (Ph. Eur. 11.6 update)

Compound Sodium Lactate Infusion

General Notices

Compound Sodium Lactate Injection; Compound Sodium Lactate Intravenous Infusion; Hartmann's Solution for Injection; Ringer-Lactate Solution for Injection

DEFINITION

Compound Sodium Lactate Infusion is a sterile solution containing 0.32% w/v of sodium lactate with 0.6% w/v of Sodium Chloride, 0.04% w/v of Potassium Chloride and 0.027% w/v of Calcium Chloride Dihydrate in Water for Injections. It may be prepared from Sodium Lactate Solution or from Lactic Acid. It is supplied as a ready-to-use solution.

The infusion complies with the requirements stated under Parenteral Preparations and with the following requirements.

Content of sodium, Na

0.27 to 0.32% w/v.

Content of potassium, K

0.019 to 0.022% w/v.

Content of total chloride, Cl

0.37 to 0.42% w/v.

Content of calcium chloride dihydrate, $CaCl_2,2H_2O$

0.025 to 0.029% w/v.

Content of lactate, calculated as $C_3H_6O_3$

0.23 to 0.28% w/v.

CHARACTERISTICS

A colourless solution.

IDENTIFICATION

A. When warmed with *potassium permanganate*, acetaldehyde is evolved.
B. The residue obtained by evaporation, when moistened with *hydrochloric acid* and introduced on a platinum wire into a flame, imparts a yellow colour to the flame. When viewed through a suitable blue glass, the flame is tinged with reddish purple.

C. 5 mL of the infusion yields reaction C characteristic of *calcium salts*, Appendix VI.

TESTS

Acidity or alkalinity

pH, 5.0 to 7.0, Appendix V L.

Bacterial endotoxins

The endotoxin limit concentration is 0.25 IU per mL, Appendix XIV C.

ASSAY

For Na

Prepare a suitable dilution in *water* and determine by *atomic emission spectrophotometry*, Appendix II D, measuring at 589 nm and using *sodium standard solution (200 ppm Na)*, suitably diluted with *water*, for the standard solutions.

For K

Prepare a suitable dilution in *water* and determine by *atomic emission spectrophotometry*, Appendix II D, measuring at 767 nm and using *potassium standard solution (600 ppm K)*, suitably diluted with *water*, for the standard solutions.

For total chloride

To 20 mL add 30 mL of *water*, 50 mL of *0.1M silver nitrate VS* and 2 mL of *nitric acid*, filter, wash the precipitate with *water* slightly acidified with *nitric acid* and titrate the excess of silver nitrate with *0.1M ammonium thiocyanate VS* using *ammonium iron(III) sulfate solution R2* as indicator. Each mL of *0.1M silver nitrate VS* is equivalent to 3.545 mg of total Cl.

For calcium chloride dihydrate

To 50 mL add 5 mL of *0.01M magnesium sulfate VS* and 5 mL of *ammonia buffer pH 10.9* and titrate with 0.01M *disodium edetate VS* using *mordant black 11 triturate* as indicator. From the volume of 0.01M *disodium edetate VS* required subtract the volume of *0.01M magnesium sulfate VS* added. Each mL of the remainder is equivalent to 1.470 mg of $CaCl_2,2H_2O$.

For lactate, calculated as $C_3H_6O_3$

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions.

(1) Use the preparation being examined.
(2) 0.28% w/v of *lithium lactate BPCRS* in the mobile phase.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (20 cm × 4.6 mm) packed with *end-capped octadecylsilyl silica gel for chromatograpy* (10 µm) (Nucleosil C18 is suitable).
(b) Use isocratic elution and the mobile phase described below.
(c) Use a flow rate of 2 mL per minute.
(d) Use an ambient column temperature.
(e) Use a detection wavelength of 210 nm.
(f) Inject 20 µL of each solution.

MOBILE PHASE

10 volumes of a 2% v/v solution of *octylamine* in *acetonitrile* and 90 volumes of *water*, the pH of the final mixture being adjusted to 7.0 with a 10% v/v solution of *orthophosphoric acid*.

DETERMINATION OF CONTENT

Calculate the content of lactate, as $C_3H_6O_3$, in the infusion from the chromatograms obtained and using the declared equivalent content of $C_3H_6O_3$ in *lithium lactate BPCRS*.

LABELLING

The label states (1) that solutions containing visible solid particles must not be used; (2) that the Infusion contains, in millimoles per litre, the following approximate amounts of the ions present: sodium, 131; potassium, 5; calcium, 2; bicarbonate (as lactate), 29 and chloride, 111.