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

Parenteral Nutrition Solutions

General Notices

Parenteral Nutrition

NOTE: *This monograph has been developed to cover unlicensed formulations.*

Action and use

Used for parenteral nutrition.

DEFINITION

Parenteral Nutrition Solutions are infusions containing essential nutrition requirements in the form of protein (amino acids), carbohydrate (glucose) and fat (lipids), together with electrolytes, trace elements and vitamins. The infusions will contain some, but not necessarily all, of these ingredients.

The infusion complies with the requirements stated under Parenteral Preparations and with the following requirements. Where appropriate, the infusion also complies with the requirements stated under Unlicensed Medicines.

PREPARATION

A suitable assessment is carried out to demonstrate that the appropriate amount of glucose is present.

For lipid-containing formulations a suitable method should be carried out to demonstrate the stability of the lipid emulsion, for example a method to determine the globule size distribution.

NOTE: *In order to minimise the risk of exposure to aluminium, only Calcium Gluconate Injection and sodium glycerophosphate that have been stored in plastic containers should be used in the preparation of Parenteral Nutrition Solutions.*

Content of calcium, Ca, magnesium, Mg, potassium, K, sodium, Na, chloride, Cl, as appropriate

90.0 to 110.0% of the stated amount.

IDENTIFICATION

The infusion complies with the following tests, as appropriate.

A. When heated with *cupri-tartaric solution R1*, a red precipitate is produced (identification of glucose).
B. Yields reaction (a) characteristic of *calcium salts*, Appendix VI.
C. Yields reaction (b) characteristic of *magnesium salts*, Appendix VI.
D. Yields reaction (b) characteristic of *potassium salts*, Appendix VI.
E. Yields reaction (b) characteristic of *sodium salts*, Appendix VI.
F. Yields reaction (a) characteristic of *chlorides*, Appendix VI.

TESTS

Aluminium

Not more than 50 µg/L, when determined by the following method.

Carry out the method for *atomic absorption spectrophotometry*, Appendix II D, using the following solutions. Use a matrix modifier (for example, *nitric acid* and *magnesium nitrate* in *water*) in the same quantity for each solution.

(1) Dilute the infusion with *water*, if necessary, to a concentration suitable for the instrument to be used.
(2) *By Method I (direct calibration)* Prepare the standard solutions using *aluminium standard solution (50 ppm Al)*, diluting with acidified *water*.

By Method II (standard additions) Prepare at least three reference solutions in the range spanning the expected aluminium concentration of the test solution by diluting *aluminium standard solution (50 ppm Al)* with solution (1).

(3) *Water* (blank).

Measure the *absorbance* at 309.3 nm using an aluminium hollow-cathode lamp as the radiation source and a graphite furnace.

Bacterial endotoxins

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

Sterility

Complies with the test for *sterility*, Appendix XVI A.

ASSAY

Carry out the following Assays, as appropriate.

For calcium

Carry out the method for *atomic absorption spectrophotometry*, Appendix II D, Method I, using the following solutions.

(1) Dilute the infusion with *water*, if necessary, to a concentration suitable for the instrument to be used; add 10 mL of a 2% w/v solution of *lanthanum chloride heptahydrate* to the final solution.
(2) Prepare the standard solutions using *calcium standard solution (400 ppm Ca)* and adding 10 mL of a 2% w/v solution of *lanthanum chloride heptahydrate* to the final solutions.

Measure the absorbance at 422.7 nm using a calcium hollow-cathode lamp as the radiation source and an air-propane or air-acetylene flame.

For magnesium

Carry out the method for *atomic absorption spectrophotometry*, Appendix II D, Method I, using the following solutions.

(1) Dilute the infusion with *water*, if necessary, to a concentration suitable for the instrument to be used; add 10 mL of a 2% w/v solution of *lanthanum chloride heptahydrate* to the final solution.
(2) Prepare the standard solutions using *magnesium standard solution (100 ppm Mg)* and adding 10 mL of a 2% w/v solution of *lanthanum chloride heptahydrate* to the final solutions.

Measure the absorbance at 285.2 nm using a magnesium hollow-cathode lamp as the radiation source and an air-propane or air-acetylene flame.

For potassium

Carry out the method for *atomic absorption spectrophotometry*, Appendix II D, Method I, using the following solutions.

(1) Dilute the infusion with *water*, if necessary, to a concentration suitable for the instrument to be used; add 10 mL of a 2% w/v solution of *lanthanum chloride heptahydrate* to the final solution.
(2) Prepare the standard solutions using *potassium standard solution (100 ppm K)* and adding 10 mL of a 2% w/v solution of *lanthanum chloride heptahydrate* to the final solutions.

Measure the absorbance at 766.5 nm using a potassium hollow-cathode lamp as the radiation source and an air-propane or air-acetylene flame.

For sodium

Carry out the method for *atomic absorption spectrophotometry*, Appendix II D, Method I, using the following solutions.

(1) Dilute the infusion with *water*, if necessary, to a concentration suitable for the instrument to be used; add 10 mL of a 2% w/v solution of *lanthanum chloride heptahydrate* to the final solution.
(2) Prepare the standard solutions using *sodium standard solution (200 ppm Na)* and adding 10 mL of a 2% w/v solution of *lanthanum chloride heptahydrate* to the final solutions.

Measure the absorbance at either 589.0 nm or 589.6 nm (sodium emits as a doublet) using a sodium hollow-cathode lamp as the radiation source and an air-propane or air-acetylene flame.

For chloride

Dilute an accurately measured volume of the infusion containing the equivalent of about 0.68 mEq of chloride with a volume of *water* sufficient to immerse the electrode. Carry out a *potentiometric titration*, Appendix VIII B, using 0.1M *silver nitrate*. Take the point between the two points of inflexion as the end point. Each mL of 0.1M *silver nitrate* is equivalent to 3.545 mg of Cl.

STORAGE

Parenteral Nutrition Solutions should be protected from light and stored at a temperature of 2° to 8°.

LABELLING

The label states: (1) the formula of the solution for parenteral nutrition, giving the total quantities of available nitrogen (in grams), calories and electrolytes (in mmol) and vitamins in the final container; (2) the nominal volume of the solution; (3) where applicable, the name and amount of any added antioxidant; (4) the conditions under which it should be stored.