

Parenteral Nutrition Solutions

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Details for the public consultation of this monograph are as follows:

EAG	ULM: Unlicensed Medicines
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Notes: It is recognised that it is not possible to include methods for the determination of every potential component in these solutions and the monograph is intended to cover some of the most common components. Advice is sought on the limits for aluminium and on a suitable assay for Glucose.	

NOTE: This monograph was developed to cover unlicensed formulations.

DEFINITION

Parenteral nutrition solutions contain essential nutrition requirements in the form of protein (amino acids), carbohydrate (glucose) and fat (lipids), together with electrolytes, trace elements and vitamins.

The solutions comply with the requirements stated under Parenteral Preparations and with the following requirements. Where appropriate the solutions also comply with the requirements stated under Unlicensed Medicines.

Content of anhydrous glucose, C₆H₁₂O₆, sodium, Na, potassium, K, calcium, Ca, magnesium, Mg, chloride, Cl, as appropriate.

90.0 to 110.0% of the stated amount.

IDENTIFICATION

The solutions comply with the following tests, as appropriate.

- When heated with *cupri-tartaric solution R1*, a red precipitate is produced (*identification of glucose*).
- Yield reaction (a) characteristic of *calcium salts*, Appendix VI.
- Yield reaction reaction (b) characteristic of *magnesium salts*, Appendix VI.
- Yield reaction reaction (b) characteristic of *potassium salts*, Appendix VI.

E. Yield reaction (b) characteristic of *sodium salts*, Appendix VI.

F. Yield reaction (a) characteristic of *chlorides*, Appendix VI.

TESTS

Aluminium

Not more than 25 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 solution being examined 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 (25 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 (25 ppm Al)* with the test solution.

(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 less than 0.05 IU per mL, Appendix XIV C.

Sterility

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

ASSAY

Carry out the following Assays, as appropriate.

For Glucose

A suitable Assay is carried out to demonstrate that the appropriate amount [range] of glucose is present.

For calcium

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

(1) Dilute the solution being examined 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 solution being examined 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 solution being examined 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 solution being examined 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 solution being examined 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.

LABELLING

The label states: (1) the formula of the solution for parenteral nutrition; (2) the nominal volume of the solution; (3) the conditions under which the solution should be stored.