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Organ Preservation Solutions

General Notices

(Solutions for Organ Preservation, Ph. Eur. monograph 1264)

Ph Eur

DEFINITION

Solutions for organ preservation are sterile, aqueous preparations intended for the storage, protection and/or perfusion of mammalian body organs, particularly pending transplantation.

They contain electrolytes, typically in concentrations close to the intracellular electrolyte composition.

They may contain carbohydrates (such as glucose or mannitol), amino acids, calcium-complexing agents (such as citrate or phosphate), hydrocolloids (such as starch or gelatin derivatives) and other suitable excipients, in order, for example, to adjust the tonicity of the preparation relative to blood, to adjust or stabilise the pH or to stabilise the preparation. The excipients do not adversely affect the intended action of the preparation or, at the concentrations used, cause toxicity or undue local irritation. Solutions for organ preservation may also contain active substances or these may be added immediately before use.

Solutions for organ preservation may also be supplied as concentrated solutions to be diluted to the prescribed volume with a prescribed liquid immediately before use. After dilution, they comply with the requirements for solutions for organ preservation.

Before use, solutions for organ preservation are usually cooled, typically to 2 °C to 6 °C, to lower the temperature of the organ and slow its metabolism.

Where applicable, containers for solutions for organ preservation comply with the requirements for *Materials used for the manufacture of containers* (*3.1* and subsections) and *Containers* (*3.2* and subsections).

Solutions for organ preservation are supplied in glass containers (*3.2.1*) or in other containers such as plastic containers (*3.2.2*) and prefilled syringes. The tightness of the container is ensured by suitable means. Closures ensure a good seal, prevent micro-organisms and other contaminants from entering the container and closure system and usually permit the withdrawal of part or all of the contents without removal of the closure. The plastic materials or elastomers (*3.2.9*) of which the closures are composed are sufficiently firm and elastic to allow the passage of a needle with the least possible shedding of particles.

PRODUCTION

Solutions for organ preservation are prepared using materials and methods designed to ensure sterility and to avoid the introduction of contaminants and the growth of micro-organisms; recommendations on this aspect are provided in general chapter *5.1.1*. *Methods of preparation of sterile products*.

Unless otherwise justified and authorised, solutions for organ preservation are prepared from *water for injections R* and do not contain preservatives.

Solutions for organ preservation, examined under suitable conditions of visibility, are clear and practically free from particles.

Recommendations on testing for visible particles are given in general chapter 5.17.2.

TESTS

pH (*2.2.3*)

5.0 to 8.0.

Osmolality (*2.2.35*)

250 mosmol/kg to 380 mosmol/kg.

Hydroxymethylfurfural

If the solution contains glucose, it complies with the following test. To a volume of the preparation to be examined containing the equivalent of 25 mg of glucose, add 5.0 mL of a 100 g/L solution of *p-toluidine R* in *2-propanol R* containing 10 per cent *V/V* of *glacial acetic acid R* and then add 1.0 mL of a 5 g/L solution of *barbituric acid R*. The absorbance (*2.2.25*), determined at 550 nm after allowing the mixture to stand for 2 min to 3 min, is not greater than that of a standard prepared at the same time and in the same manner using a solution containing 10 µg of *hydroxymethylfurfural R* in the same volume as the preparation to be examined.

Particulate contamination: sub-visible particles (*2.9.53*)

Use 50 mL of the preparation to be examined. The solution contains not more than 50 particles per millilitre larger than 10 µm in size and not more than 5 particles per millilitre larger than 25 µm.

Products whose labels state that the product is to be used with a final filter are exempted from these requirements.

Particulate contamination: visible particles (*2.9.20*)

Solutions for organ preservation, examined under suitable conditions of visibility, are practically free from visible particles.

Recommendations on testing for visible particles are given in general chapter 5.17.2.

Sterility (*2.6.1*)

The preparation complies with the test.

Bacterial endotoxins (*2.6.14*)

Less than 0.5 IU/mL.

Pyrogens (*2.6.8*)

Preparations for which a validated test for bacterial endotoxins cannot be carried out comply with the test for pyrogens. Inject 10 mL of the preparation per kilogram of the rabbit's mass, unless otherwise justified and authorised.

LABELLING

The label states:

— that the solution is not to be used for injection;

— the formula of the solution for organ preservation, expressed in grams per litre and in millimoles per litre;

— the nominal volume of the solution for organ preservation in the container;

— the osmolality, expressed in milliosmoles per kilogram;

— that any unused portion of the ready-to-use solution, of the concentrated solution or of the diluted solution is to be discarded;

— the storage conditions;

— where applicable, that the solution is to be used in conjunction with a final filter;

— for concentrated solutions, that the solution is to be diluted with a suitable liquid immediately before use.
