

For the results of the testing on type samples to remain valid, it is important that:

- there is no change in the composition of the material as defined for the type samples,
- there is no change in the manufacturing process as defined for the type samples, especially as regards the temperatures to which the plastic material is exposed during conversion or subsequent procedures such as sterilisation,
- scrap material is not used.

Recycling of excess material of well-defined nature and proportions may be permitted after appropriate validation.

Subject to satisfactory testing for compatibility of each different combination of container and contents, the materials described in the Pharmacopoeia are recognised as being suitable for the specific purposes indicated, as defined above.

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corrected 6.0

### 3.2.2.1. PLASTIC CONTAINERS FOR AQUEOUS SOLUTIONS FOR INFUSION

#### DEFINITION

Plastic containers for aqueous solutions for infusion are manufactured from one or more polymers, if necessary with additives. The containers described in this section are not necessarily suitable for emulsions. The polymers most commonly used are polyethylene, polypropylene and poly(vinyl chloride). The specifications of this text are to be read in conjunction with section 3.2.2. *Plastic containers and closures for pharmaceutical use.*

The containers may be bags or bottles. They have a site suitable for the attachment of an infusion set designed to ensure a secure connection. They may have a site that allows an injection to be made at the time of use. They usually have a part that allows them to be suspended and which will withstand the tension occurring during use. The containers must withstand the sterilisation conditions to which they will be submitted. The design of the container and the method of sterilisation chosen are such that all parts of the containers that may be in contact with the infusion are sterilised. The containers are impermeable to micro-organisms after closure. The containers are such that after filling they are resistant to damage from accidental freezing which may occur during transport of the final preparation. The containers are and remain sufficiently transparent to allow the appearance of the contents to be examined at any time, unless otherwise justified and authorised.

The empty containers display no defects that may lead to leakage and the filled and closed containers show no leakage.

For satisfactory storage of some preparations, the container has to be enclosed in a protective envelope. The initial evaluation of storage has then to be carried out using the container enclosed in the envelope.

#### TESTS

**Solution S.** Use solution S within 4 h of preparation. Fill a container to its nominal capacity with *water R* and close it, if possible using the usual means of closure; otherwise close using a sheet of pure aluminium. Heat in an autoclave so that a temperature of  $121 \pm 2$  °C is reached within 20 min

to 30 min and maintain at this temperature for 30 min. If heating at 121 °C leads to deterioration of the container, heat at 100 °C for 2 h.

**Blank.** Prepare a blank by heating *water R* in a borosilicate-glass flask closed by a sheet of pure aluminium at the temperature and for the time used for the preparation of solution S.

**Appearance of solution S.** Solution S is clear (2.2.1) and colourless (2.2.2, *Method II*).

**Acidity or alkalinity.** To a volume of solution S corresponding to 4 per cent of the nominal capacity of the container add 0.1 ml of *phenolphthalein solution R*. The solution is colourless. Add 0.4 ml of 0.01 M sodium hydroxide. The solution is pink. Add 0.8 ml of 0.01 M hydrochloric acid and 0.1 ml of *methyl red solution R*. The solution is orange-red or red.

**Absorbance (2.2.25).** Measure the absorbance of solution S from 230 nm to 360 nm, using the blank (see solution S) as the compensation liquid. At these wavelengths, the absorbance is not greater than 0.20.

**Reducing substances.** To 20.0 ml of solution S add 1 ml of dilute sulphuric acid *R* and 20.0 ml of 0.002 M potassium permanganate. Boil for 3 min. Cool immediately. Add 1 g of potassium iodide *R* and titrate immediately with 0.01 M sodium thiosulphate, using 0.25 ml of starch solution *R* as indicator. Carry out a titration using 20.0 ml of the blank. The difference between the titration volumes is not greater than 1.5 ml.

**Transparency.** Fill a container previously used for the preparation of solution S with a volume equal to the nominal capacity of the primary opalescent suspension (2.2.1) diluted 1 in 200 for a container made from polyethylene or polypropylene and 1 in 400 for other containers. The cloudiness of the suspension is perceptible when viewed through the container and compared with a similar container filled with *water R*.

#### LABELLING

The label accompanying a batch of empty containers includes a statement of:

- the name and address of the manufacturer,
- a batch number which enables the history of the container and of the plastic material of which it is manufactured to be traced.

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### 3.2.3. STERILE PLASTIC CONTAINERS FOR HUMAN BLOOD AND BLOOD COMPONENTS

Plastic containers for the collection, storage, processing and administration of blood and its components are manufactured from one or more polymers, if necessary with additives. The composition and the conditions of manufacture of the containers are registered by the appropriate competent authorities in accordance with the relevant national legislation and international agreements.

When the composition of the materials of the different parts of the containers correspond to the appropriate specifications, their quality is controlled by the methods indicated in those specifications (see 3.1. *Materials used for the manufacture of containers* and subsections).