INTERNATIONAL STANDARD

ISO 15747

First edition
2003-11-15

Plastics containers for intravenous injection

Récipients en plastique pour injections intraveineuses

Reference number
ISO 15747:2003(E)

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Published in Switzerland

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 15747 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical and pharmaceutical use*.

Introduction

In some countries, national or regional pharmacopoeia or other government regulations are legally binding and their requirements take precedence over this International Standard.

Plastics containers for intravenous injection

1 Scope

This International Standard contains requirements related to the safe handling and the physical, chemical and biological testing of plastic containers for parenterals.

This International Standard is applicable to plastic containers for parenterals having one or more chambers and having a total nominal capacity in the range from 50 ml to 5 000 ml, such as film bags or blow-moulded plastic bottles for direct administration of infusion (injection) solutions.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 8536-4, *Infusion equipment for medical use — Part 4: Infusion sets for single use, gravity feed*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
access port
area of the infusion container consisting of the insertion point and the injection point, if applicable

3.2
cover
part which protects the access port during storage and also provides evidence if the infusion container has been tampered with

NOTE The cover can also envelop the entire container (e.g. outer bag).

3.3
empty container
raw container with identification which is suitable for the acceptance, storage and administration of the injection solution

3.4
hanger
that part of the container which is used to hang it up

3.5
identification
paper or foil label or printing or embossing

3.6
infusion container
container filled to its nominal capacity with parenteral injection product and with identification for the storage and administration of the parenteral injection product

3.7
injection point
point for injecting pharmaceuticals

NOTE 1 The injection point and the insertion point can be identical.

NOTE 2 Some containers intentionally do not have an injection point.

3.8
insertion point
point which accepts the insertion part of the infusion device

3.9
nominal capacity
intended or declared fluid volume of a container

3.10
raw container
empty container that has not yet been sterilized and has no identification

3.11
sheeting
plastic film, foil or sheeting intended for the production of empty containers

4 Requirements

4.1 Physical requirements

4.1.1 Manufacturing process compatibility

The infusion container shall comply with the requirements given in 4.1.2 to 4.1.5 and 4.1.7 to 4.1.10 after the manufacturing process (such as sterilization).

4.1.2 Resistance to temperature, pressure and leakage

The infusion container shall withstand alternating thermal stress, shall be resistant to pressure, and shall be leak-free when tested as specified in A.3.

4.1.3 Resistance to dropping

The infusion container shall sustain no damage after being dropped when tested as specified in A.4.

4.1.4 Transparency

The infusion container shall be sufficiently transparent so that suspended particles, turbidity and discoloration can be recognized when tested as specified in A.5.

4.1.5 Water vapour permeability

Unless otherwise defined for specific applications or uses, the packed infusion container shall not lose more than 5 % of its mass during the period of usability, when tested as specified in A.6.

4.1.6 Particulate contamination

Infusion containers shall be manufactured so that contamination with particles is avoided.

When empty infusion containers are tested as specified in A.7, no more than 20 particles with a diameter $\geqslant$ 5,0 µm shall be found per millilitre of nominal capacity. Finished parenteral solutions in the infusion containers shall comply with relevant pharmacopoeial requirements for finished product particulate matter.

4.1.7 Cover

The access port shall be protected by a cover. Its intactness is determined by visual inspection. It shall be possible to remove the cover without using mechanical aids.

4.1.8 Access port

It shall be possible to pierce the insertion point with the insertion part of an infusion device as specified in ISO 8536-4. The force shall not exceed 200 N at an insertion rate of 500 mm · min^{-1} when tested as specified in A.8.

4.1.9 Adhesion strength of the infusion device and impermeability of the insertion point

The material and design of the access port shall be suitable for accepting the insertion part of an infusion device in accordance with ISO 8536-4, for sealing off the insertion point and for holding the insertion part firmly when subject to tensile load. When tested as specified in A.9, no leakage shall occur and the insertion part shall not slide out from the insertion point. The removal force shall be greater than 15 N.

4.1.10 Injection point

If the container has an injection point, this shall not leak after puncturing and removal of the cannula when tested as specified in A.10.

4.1.11 Hanger

It shall be possible to hang up the infusion container when it is in use. The hanger shall withstand a tensile load when tested as specified in A.11.

4.1.12 Identification

The identification characters shall be clearly legible, and affixed labels shall not become detached when tested as specified in A.12.

4.2 Chemical requirements

4.2.1 Requirements for the raw container or the sheeting

The sheeting shall fulfil the requirements given in the relevant pharmacopoeias. Alternatively, it may be tested as described in Table 1.

Table 1

Requirements	Maximum permissible value	Test as specified in
Residue on ignition:		B.2
Polyolefins	5 mg/g	
Polyvinyl chloride containing plasticizers	1 mg/g	
Metals: Ba, Cd, Cr, Cu, Pb, Sn	for each metal, 3 mg/kg	B.3

4.2.2 Requirements for the test fluid

The test fluid shall be prepared as specified in B.4. No coloration, but weak opalescence of the test fluid is permissible. It shall fulfil the requirements specified in Table 2.

Table 2

Requirements	Maximum permissible value	Testing as specified in
Acidity or alkalinity	0,4 ml sodium hydroxide solution [c(NaOH) = 0,01 mol/l] 0,8 ml hydrochloric acid [c(HCl) = 0,01 mol/l]	B.6
UV absorbance	in the range from 230 nm to 360 nm $\leqslant$ 0,25 for infusion containers with a nominal capacity $\leqslant$ 100 ml $\leqslant$ 0,2 for infusion containers with a nominal capacity $>$ 100 ml	B.7
Evaporation residue	5 mg or 50 mg/l	B.8
Oxidizable constituents	1,5 ml	B.9
Ammonia	0,8 mg/l	B.10
Metals: Ba, Cr, Cu, Pb Sn, Cd Al	 for each metal, 1 mg/l for each metal, 0,1 mg/l 0,05 mg/l	B.11
Heavy metals	2 mg/l	B.12

4.3 Biological requirements

4.3.1 Impermeability to microorganisms

The infusion container shall be impermeable to microorganisms when tested as specified in C.2.

4.3.2 Migration/tolerance

The materials used for the manufacture of infusion containers (e.g. films, wrappings, adhesives, adhesion promoters, printing inks) shall not release to the infusion solution any substances in such quantities that they have a pyrogenic or toxic effect when tested as specified in C.3 and C.4.

5 Identification

Identification shall be in accordance with the relevant laws and specifications.

6 Application of tests

A distinction is made between type testing and batch testing. All tests specified in Annexes A to D are type testing. They shall be repeated if one or more of the following conditions are changed significantly so that the requirements as specified in Clause 4 might be affected:

— the design;

— the plastic composition;

— the process of manufacturing the infusion container;

— the sterilization process.