International Standard

ISO 15747

Plastic containers for intravenous injections

Récipients en plastique pour injections intraveineuses

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 205, *Non-active medical devices,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This fourth edition cancels and replaces the third edition (ISO 15747:2018), which has been technically revised.

The main changes are as follows.

— The term “cannula” has been replaced by the better suited term “needle” throughout the document. Per common understanding, cannulas are flexible, while needles, such as 23G needles called for in A.10, as well as other so-called “transfer needles/devices” used to add medication through an injection point, whether they are sharp or blunt, need to be rigid to pierce said injection port and are typically made of stainless steel or moulded thermoplastic.

— Addition of subclauses 4.1.1, 4.2.1 and 4.3.1 to highlight the normative nature of the introductory subclauses A.1, A.2, B.1 and C.1, as they contain important information to properly conduct the tests. Those introductory clauses were not directly referenced in any requirement since they don’t describe test methods related to said requirements. Addition of those three subclauses led to the renumbering of all other subclauses of Clause 4.

— Usage of terms “procedure” and “method” clarified: “method” now used as way to perform a test, while “procedure” denotes a process to reach a certain state (e.g. thinking process or working process).

— Addition of a new Annex E (Rationale and guidance), to provide explanations about the history of the development of the standard and to summarize the different arguments discussed within ISO/TC 76 during the elaboration of the document.

— Addition of a new Annex F (Sustainability) and a new Annex G (Attributive and variable testing).

— Addition of references to pharmacopoeias pertaining to chemical requirements, in 4.2.

— Replacement of reference to ISO 2768-2 (withdrawn) by ISO 22081 in Figure D.1, Annex D and Clause 2. Consequently, Figure D.1 has been modified (addition of reference datums, etc.)

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Plastic containers for intravenous injections

1 Scope

This document specifies requirements to the safe handling and the physical, chemical and biological testing of plastic containers for parenterals.

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

NOTE 1 In some countries, national or regional pharmacopoeias or other government regulations are legally binding, and these requirements take precedence over this document.

NOTE 2 Annex E provides explanations about the history of the development of the standard and summarises the different arguments discussed within ISO/TC 76 during the elaboration of the document.

NOTE 3 Annex F provides recommendations regarding sustainability.

NOTE 4 Annex G provides information on attributive and variable testing.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 2768-1, *General tolerances — Part 1: Tolerances for linear and angular dimensions without individual tolerance indications*

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

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Requirements and general principles for the evaluation of biological safety within a risk management process*

ISO 10993-5, *Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity*

ISO 15510, *Stainless steels — Chemical composition*

ISO 22081, *Geometrical product specifications (GPS) — Geometrical tolerancing — General geometrical specifications and general size specifications*

3 Terms and definitions

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

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
access port
area of the *infusion container* (3.7) consisting of the *insertion point* (3.9) and the *injection point* (3.8), if applicable

3.2
cover
part that protects an *access port* (3.1) during storage and before use

Note 1 to entry: The cover can also envelop the entire container (e.g. outer bag).

3.3
empty container
raw container (3.11) with *identification* (3.6), which is suitable for the acceptance, storage and administration of the injection solution

3.4
gauge pressure
pressure zero-referenced against local atmospheric pressure

Note 1 to entry: Container internal gauge pressure is:

— positive when the container is pressurized above the surrounding atmospheric pressure, and is

— negative when the container is subjected to suction.

3.5
hanger
part of the container that is used to hang it up

3.6
identification
paper label, foil label, printing or embossing used to identify the product

3.7
infusion container
container filled to its *nominal capacity* (3.10) with parenteral injection product and with *identification* (3.6) for the storage and administration of the parenteral injection product

3.8
injection point
point where pharmaceuticals are injected

Note 1 to entry: The injection point and the insertion point can be identical.

Note 2 to entry: Some containers intentionally do not have an injection point.

3.9
insertion point
point which accepts the insertion part of the infusion device

3.10
nominal capacity
intended or declared fluid volume of a container

3.11
raw container
empty container (3.3) that has not yet been sterilized and has no *identification* (3.6) other than eventual embossing

3.12
sheeting
plastic material intended for the production of *empty container* (3.3)

3.13
type testing
conformity testing on the basis of one or more specimens of a product representative of the production

Note 1 to entry: type tests are carried out to demonstrate conformity with the requirements of this document and/or when a significant change is made in the product design, materials and/or method of manufacture, the effects of which cannot be predicted based on previous experience (see Clause 5).

4 Requirement

4.1 Physical requirements

4.1.1 General

The physical tests shall be carried out according to Annex A.

4.1.2 Manufacturing process compatibility

The infusion container shall be in accordance with the requirements given in 4.1.3 to 4.1.6 and 4.1.8 to 4.1.13 after the manufacturing process (such as sterilisation).

4.1.3 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.

4.1.4 Resistance to dropping

The infusion container shall sustain no damage, nor leak, after being dropped when tested as specified in A.4.

4.1.5 Transparency

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

4.1.6 Water vapour permeability

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

4.1.7 Particulate contamination

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

When empty containers are tested as specified in A.7, no more than 25 particles with a diameter ≥10 µm and no more than 3 particles with a diameter ≥25 µm shall be found per millilitre of nominal capacity. Finished parenteral solutions in the infusion containers shall be in accordance with relevant pharmacopoeial requirements for particulate matter in finished products.

4.1.8 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.