INTERNATIONAL STANDARD

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Transfer sets for pharmaceutical preparations — Requirements and test methods

Ensemble de transfert pour préparations pharmaceutiques — Exigences et méthodes d'essai

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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 22413 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical and pharmaceutical use*.

This second edition cancels and replaces the first edition (ISO 22413:2007), of which the scope was enhanced by introducing further product groups like transfer sets with integrated Luer connectors and particle filters. In that framework the following major changes were introduced:

— the Introduction was amended by h) and j);

— the Normative references were updated;

— the Figures in 3.1 were updated;

— 5.11 and 8.10 on the physical requirements and testing for Luer connector were added;

— 5.12 and 8.11 on the physical requirements and testing for filter for particles were added.

Introduction

Transfer sets for pharmaceutical preparations transmit fluids from one container to another. The transfer sets mix fluids or dissolve dry substances and are used in combination with infusion and injection containers.

The transfer sets consist either of two piercing devices or of a piercing device in combination with a Luer connector, which may be connected with each other in different ways. Transfer sets may have a housing.

Examples of different designs:

a) two piercing devices connected to each other (similar to piercing devices of infusion containers);

b) a metal cannula, bevelled on both sides or a combination of a) and b);

c) metal cannulae mostly having a hub or a grip plate in the middle to be fixed to the plastic part;

d) plastic piercing devices directly connected to a grip plate, or held by a tube at a distance to allow a higher hydrostatic pressure;

e) piercing devices with an additional ventilation channel that may end in the other tip or outside;

f) piercing devices also with an air filter;

g) piercing devices with housings serving, among other things, as a guide and a fixation on the connected containers for a secure, injury-free and contactless application;

h) piercing device in combination with a Luer connector;

i) piercing device in combination with a Luer connector and a particle filter.

Transfer sets for pharmaceutical preparations — Requirements and test methods

1 Scope

This International Standard applies to sterilized single use transfer sets that are used for pharmaceutical preparations.

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 594-1, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements*

ISO 594-2, *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*

ISO 7864:1993, *Sterile hypodermic needles for single use*

ISO 8362 (all parts), *Injection containers and accessories*

ISO 8536 (all parts), *Infusion equipment for medical use*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 15747, *Plastic containers for intravenous injections*

ISO 15759, *Medical infusion equipment — Plastics caps with inserted elastomeric liner for containers manufactured by the blow-fill-seal (BFS) process*

3 Design and designation

3.1 Design

The designs of the individual components are given in Figures 1 to 7. The drawings serve as an illustration of possible transfer sets. Other designs are acceptable.

The Key for Figures 1 to 7 is to be found on page 3.