INTERNATIONAL STANDARD

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Second edition
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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.

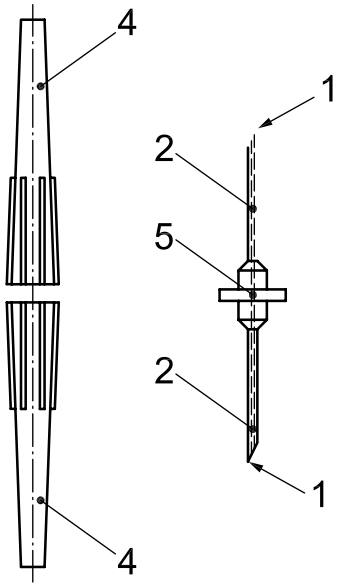


Figure 1 — Transfer set with one channel

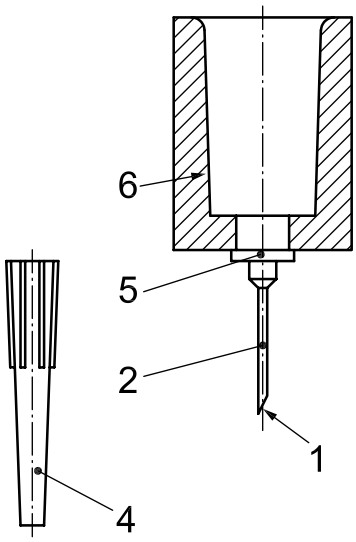


Figure 2 — Transfer set with one channel in combination with a Luer connector

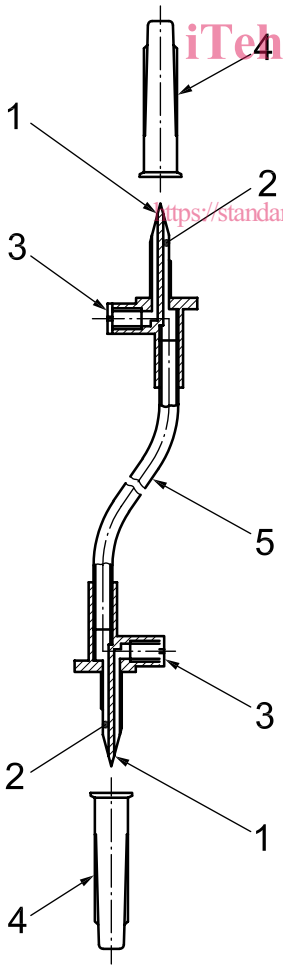


Figure 3 — Transfer set with an air inlet/air outlet

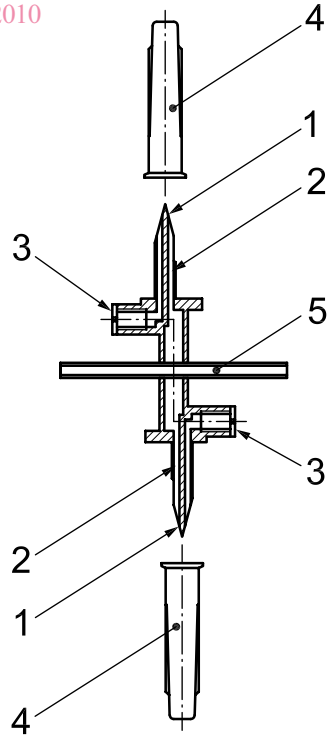


Figure 4 — Alternative transfer set with an air inlet/air outlet

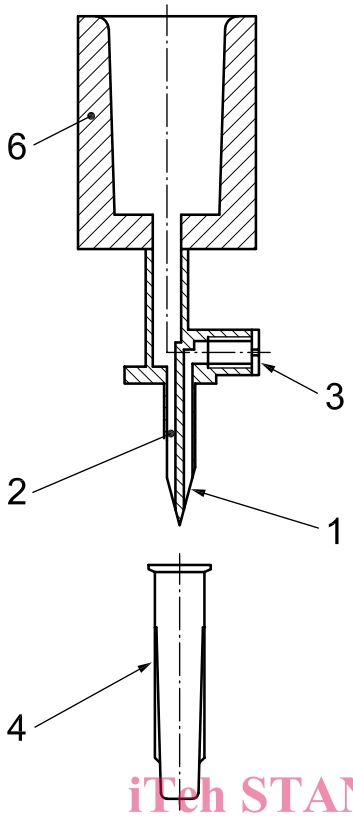


Figure 5 — Transfer set with an air inlet/air outlet in combination with a Luer connector

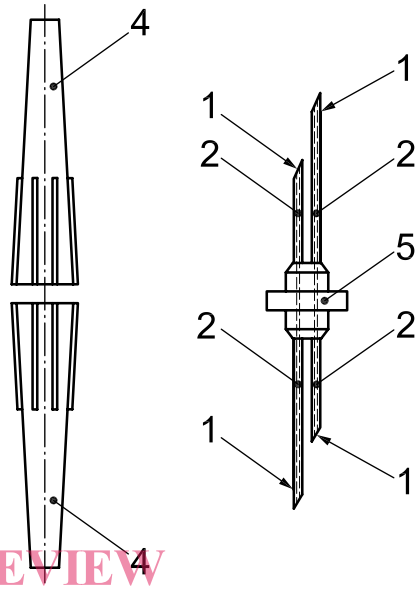


Figure 6 — Transfer set with two channels

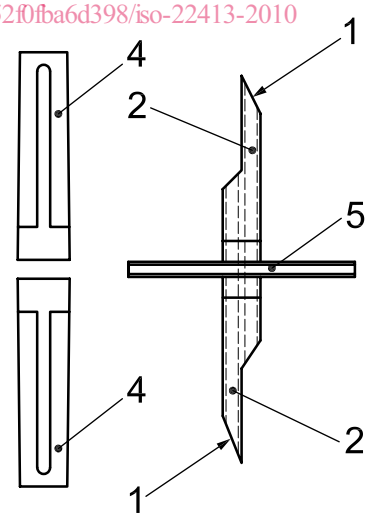


Figure 7 — Alternative transfer set with two channels

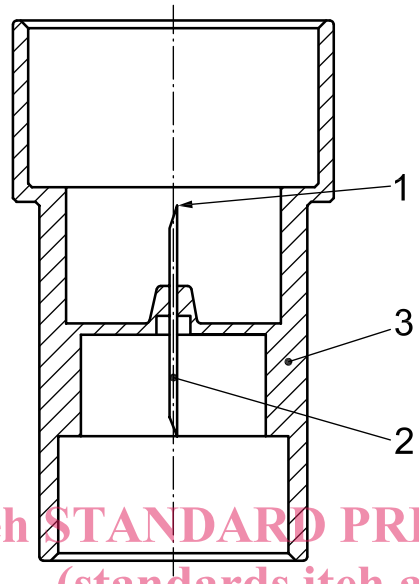
Key for Figures 1 to 7

1 piercing device
2 channel
3 channel with air filter for ventilation, optionally lockable
4 protective cap

5 connection of piercing devices by hub, grip plate or tube
6 female Luer connector

3.2 Design for a transfer set with housing

The design of a transfer set with housing is given in Figure 8. The drawing serves as an illustration of a possible transfer set. Other designs are acceptable.



Key
1 piercing device
2 channel
3 housing

Figure 8 — Transfer set with housing

3.3 Designation

Example 1:

A transfer set without housing (NH) is designated by the term “Transfer set”, the number of this International Standard and the initials NH as follows:

Transfer set ISO 22413 – NH

Example 2:

A transfer set with housing (WH) is designated by the term “Transfer set”, the number of this International Standard and the initials WH as follows:

Transfer set ISO 22413 – WH

4 Material

The materials for the transfer sets and their individual components shall comply with the requirements in accordance with Clause 5. If the components come into contact with the liquid to be transferred, the chemical and biological requirements in accordance with ISO 8536-4 shall be met.

Piercing devices are manufactured from appropriate materials, e.g. metal and/or plastic.

5 Physical requirements

5.1 Particulate contamination

Transfer sets shall be manufactured under such conditions that minimize particulate contamination. All parts shall be smooth and clean. When tested in accordance with 8.1 the evaluation number of the particulate contamination shall not exceed 90.

5.2 Tensile strength

5.2.1 When tested as specified in 8.2 the transfer set shall withstand a static tensile force of not less than 15 N for 15 s.

5.2.2 When using metal piercing devices the steadiness under tensile or compressible force without breaking shall comply with the values listed in Table 2 of ISO 7864:1993.

5.3 Tightness

The transfer set shall be air-tight, no leaks of air or liquid shall occur when tested in accordance with 8.3. Sterility shall be maintained.

5.4 Free flow

When tested in accordance with 8.4 a free flow of air and/or liquid shall be ensured.

5.5 Piercing device

The piercing devices shall be suitable for penetration of the intended closure system for injection and/or infusion containers made of glass or plastic. After puncture, a free flow shall be ensured. When tested in accordance with 8.5 the surface of the piercing devices shall be smooth and free of burrs.

The maximum diameter of the piercing device shall be $\leqslant$ 6,5 mm.

5.6 Penetration force

When tested in accordance with 8.6 the penetration forces determined in Table 1 shall not be exceeded.

Table 1 — Penetration force

Type of piercing device	Penetration force N max.	Counterpart
Transfer sets with metal piercing device	10	Injection stoppers ISO 8362-2 – 20 – A (7.2.2) Hardness: 40 Shore A to 55 Shore A
Transfer sets with plastic piercing device	80	Infusion stoppers ISO 8536-2 – 32 – A (Annex B) Hardness: 40 Shore A to 55 Shore A
NOTE Freeze-drying stoppers (FD stoppers) can have tight channels at the bottom which considerably affect the penetration force.		