

Transfer sets for pharmaceutical preparations — Requirements and test methods

ICS 11.040.20

National foreword

This British Standard was published by BSI. It is the UK implementation of ISO 22413:2007.

The UK participation in its preparation was entrusted to Technical Committee CH/212, IVDs.

A list of organizations represented on CH/212 can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 March 2007

© BSI 2007

ISBN 978 0 580 50411 2

Amendments issued since publication

Amd. No.	Date	Comments

INTERNATIONAL STANDARD

ISO
22413

First edition
2007-03-01

Transfer sets for pharmaceutical preparations — Requirements and test methods

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



Reference number
ISO 22413:2007(E)
Documents
Document Sharing Hub

Contents

Page

Foreword.....	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Design and designation	2
3.1 Design	2
3.2 Designation for a transfer set with housing	4
3.3 Designation	4
4 Material	4
5 Physical requirements.....	5
5.1 Particulate contamination.....	5
5.2 Tensile strength	5
5.3 Tightness	5
5.4 Free flow	5
5.5 Piercing device.....	5
5.6 Penetration force	5
5.7 Fragmentation	6
5.8 Air inlet and air outlet.....	6
5.9 Protective caps	6
5.10 Transfer sets with a housing	6
6 Chemical requirements	6
7 Biological requirements	6
8 Testing of physical requirements	6
8.1 Particulate contamination.....	6
8.2 Tensile strength	6
8.3 Tightness of transfer set.....	7
8.4 Free flow	7
8.5 Piercing device.....	7
8.6 Penetration force	7
8.7 Testing on fragmentation.....	7
8.8 Effectiveness of air inlet and air outlet with air filter	7
8.9 Efficiency of protective caps	7
9 Testing of chemical requirements	7
10 Testing of biological requirements	7
11 Packaging	7
12 Storage.....	8
13 Labelling	8
13.1 Unit container.....	8
13.2 Shelf or multi-unit container.....	8
Annex A (normative) Testing of fragmentation of transfer sets with plastic piercing devices	9
Annex B (normative) Testing of fragmentation of transfer sets with metal piercing devices	11
Bibliography	13

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*.

Introduction

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

The transfer sets consist of at least two piercing devices, 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.