

ISO 22413:2021 (E)

Transfer sets for pharmaceutical preparations — Requirements and test methods

Contents

- Foreword
 - Introduction
 - 1 Scope
 - 2 Normative references
 - 3 Terms and definitions
 - 4 Design and designation
 - 4.1 Design for transfer sets without housing
 - 4.2 Design for a transfer set with housing
 - 4.3 Designation
 - 5 Materials
 - 6 Physical requirements
 - 6.1 Particulate contamination
 - 6.2 Tensile strength
 - 6.3 Leakage
 - 6.4 Free flow
 - 6.5 Piercing device
 - 6.6 Penetration force
 - 6.7 Fragmentation
 - 6.8 Air inlet and air outlet
 - 6.9 Protective caps
 - 6.10 Transfer sets with housing
 - 6.11 Small-bore connectors
 - 6.12 Fluid filter
 - 7 Chemical requirements
 - 8 Biological requirements
 - 9 Packaging
 - 10 Labelling
 - 10.1 General
 - 10.2 Unit container
 - 10.3 Shelf or multi-unit container
 - 11 Disposal
- Annex A (normative) Physical tests
- A.1 General
 - A.2 Test for particulate contamination
 - A.3 Test of tensile strength
 - A.4 Test for leakage
 - A.5 Test for free flow
 - A.6 Test of piercing device
 - A.7 Tests of penetration force
 - A.8 Testing on fragmentation

- A.8.1 Plastic piercing devices**
- A.8.1.1 General**
- A.8.1.2 Principle**
- A.8.1.3 Apparatus**
- A.8.1.4 Test samples and counterparts (see Table A.1).**
- A.8.1.5 Pre-treatment**
- A.8.1.6 Procedure**
- A.8.1.7 Evaluation**
- A.8.2 Metal piercing devices**
- A.8.2.1 General**
- A.8.2.2 Principle**
- A.8.2.3 Apparatus**
- A.8.2.4 Test samples and counterparts (see Table A.2).**
- A.8.2.5 Pre-treatment**
- A.8.2.6 Procedure**
- A.8.2.7 Evaluation**
- A.9 Test for stress cracking of small-bore connectors**

Page count: 14