ISO 15747:2018 (E)

Plastic containers for intravenous injections

Contents

Foreword

1 Scope

2 Normative references

3 Terms and definitions

4 Requirements

- 4.1 Physical requirements
- 4.1.1 Manufacturing process compatibility
- 4.1.2 Resistance to temperature, pressure and leakage
- 4.1.3 Resistance to dropping
- 4.1.4 Transparency
- 4.1.5 Water vapour permeability
- 4.1.6 Particulate contamination
- 4.1.7 Cover
- 4.1.8 Access port — Penetration ability of the insertion point
- 4.1.9 Access port — Adhesion strength of the infusion device and impermeability of the insertion point
- 4.1.10 Access port — Tightness of the injection point
- 4.1.11 Hanger
- 4.1.12 Identification
- 4.2 Chemical requirements
- 4.2.1 Requirements for the raw container or the sheeting
- 4.2.2 Requirements for the test fluid
- 4.3 Biological requirements
- 4.3.1 Impermeability for microorganisms
- 4.3.2 Migration

5 Application of tests

Annex A (normative) Physical tests

- A.1 General
- A.2 Sampling
- A.3 Resistance to temperature, pressure and leakage
- A.4 Resistance to dropping
- A.5 Transparency
- A.6 Water vapour permeability
- A.7 Particulate contamination
- A.8 Access port — Penetration ability of the insertion point
- A.9 Access port — Adhesion strength of the infusion device and impermeability of the insertion point
- A.10 Access port — Tightness of the injection point
- A.11 Hanger
- A.12 Identification

Annex B (normative) Chemical tests

- B.1 General
- B.2 Determination of the residue on ignition
- B.3 Determination of metals in the plastic
- B.4 Preparation of the test fluid
- B.5 Determination of turbidity and coloration
- B.6 Determination of acidity or alkalinity
- B.7 Determination of the UV absorbance

B.8 Determination of the evaporation residue
B.9 Determination of the oxidizable constituents
B.10 Determination of ammonia
B.11 Determination of metals
B.12 Determination of heavy metals

Annex C (normative) Biological tests

C.1 Preparation of the test fluids
C.1.1 General
C.1.2 Test fluid I (polar extractant)
C.1.3 Test fluid II (non-polar extractant)
C.2 Testing for impermeability to microorganisms
C.3 Testing for bacterial endotoxins
C.4 Testing for cytotoxicity

Annex D (normative) Reference spike

Page count: 16