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Caps made of aluminium-plastics combinations for infusion bottles and injection vials — Requirements and test methods

Capsules en combinaison aluminium-plastique pour flacons de perfusion et injection — Spécifications et méthodes d'essai

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Contents

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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.

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.

International Standard ISO 10985 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical use*.

Introduction

The materials from which injection and infusion containers (including elastomeric closures) are made are suitable primary packaging materials for storing injectable products and infusion solutions until they are administered. However, in this International Standard, caps are not considered as primary packaging materials in direct contact with pharmaceutical preparations.

Caps made of aluminium-plastics combinations for infusion bottles and injection vials — Requirements and test methods

1 Scope

This International Standard specifies general requirements and test methods for caps made of an aluminium-plastics combination intended for use on infusion bottles as specified in ISO 8536-1, and/or injection bottles as specified in ISO 8362-1 and 8362-4.

The purpose of this International Standard is to specify caps that provide

a) guarantee of originality of the closure up to the point of administration;

b) compression of the sealing element (rubber closure) on to the sealing surfaces of the infusion and/or injection bottles;

c) protection of the sealing element against soiling and mechanical damage;

d) simple and injury-free opening of the closure in order to expose the penetration area of the rubber closure and/or to permit total removal of the cap.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 7500-1:1986, *Metallic materials — Verification of static uniaxial testing machines — Part 1: Tensile testing machines.*

ISO 8362-1:1989, *Injection containers for injectables and accessories — Part 1: Injection vials made of glass tubing.*

ISO 8362-4:1989, *Injection containers for injectables and accessories — Part 4: Injection vials made of moulded glass.*

ISO 8362-6:1992, *Injection containers for injectables and accessories — Part 6: Caps made of aluminium-plastics combinations for injection vials.*

ISO 8536-1:1991, *Infusion equipment for medical use — Part 1: Infusion glass bottles.*

ISO 8536-7:1992, *Infusion equipment for medical use — Part 7: Caps made of aluminium-plastics combinations for infusion bottles.*

ISO 8872:1988, *Aluminium caps for transfusion, infusion and injection bottles — General requirements and test methods.*

3 Requirements

3.1 Aluminium component

The requirements shall be in accordance with ISO 8872:1988, clause 3.

3.2 Plastics component

3.2.1 Material

Thermoplastics materials shall meet the producing countries regulations for use in non-contact pharmaceutical components. The material shall be steam-sterilizable at 121 °C for 30 min. Plastics material shall withstand a temperature of 130 °C for a short time (max. 5 min).

3.2.2 Quality of finish

The plastics component shall be combined with the aluminium component such that a complete joining is guaranteed.

The plastics component shall not have any non-permissible protruding moulding flash, nor sharp edges.

3.3 Beaded cap

On removal of the plastics component (opening of the beaded cap), the opening exposed in the beaded cap shall be so constructed that no injuries may occur during normal use.

4 Test methods

4.1 Aluminium component

The requirements shall be in accordance with ISO 8872:1988, subclauses 4.1 to 4.4.

4.2 Beaded cap (aluminium-plastics combinations)

4.2.1 Equipment

Traction/pressure test machine class 1 in accordance with ISO 7500-1 with special attachment as, for example, shown in figure 1, where the traction speed, v, is 100 mm/min over a measuring range of 100 N.

4.2.2 Force required to pull off plastics component with central tear-out

The beaded caps are clamped in the special holder as shown in figure 1 and the plastics component is pulled off.

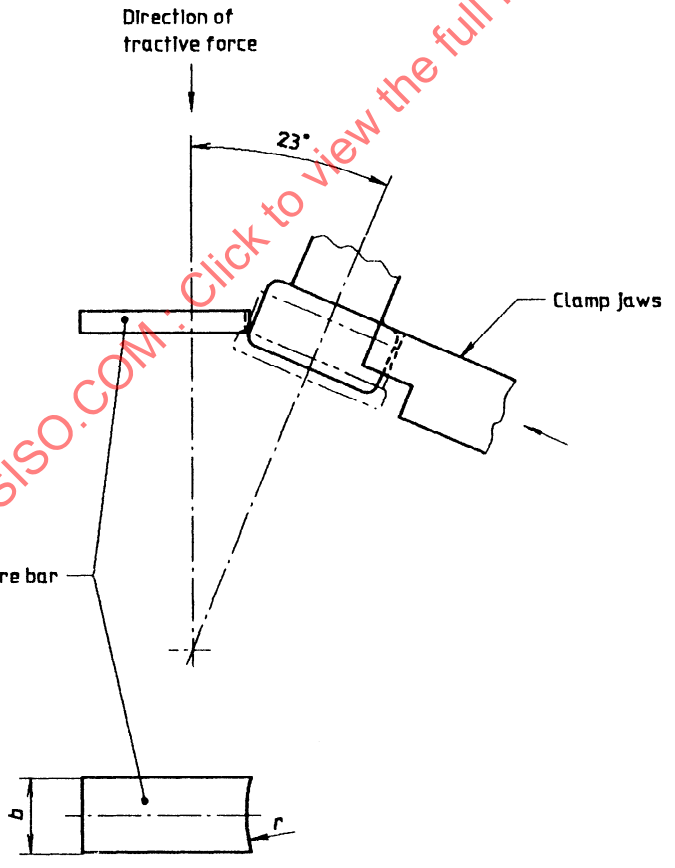

Figure 1 — Equipment to determine forces to pull off plastics component