INTERNATIONAL STANDARD

ISO 10985

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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 d'injection — Spécifications et méthodes d'essai

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Foreword

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

This third edition cancels and replaces the second edition (ISO 10985:1999) Clause 2 of which has been updated.

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 aluminium-plastics combinations in accordance with ISO 8536-7 or ISO 8362-6 intended for use respectively on infusion bottles as specified in ISO 8536-1 and/or injection bottles as specified in ISO 8362-1 and ISO 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 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 7500-1, *Metallic materials — Verification of static uniaxial testing machines — Part 1: Tensile/compression testing machines — Verification and calibration of the force-measuring system*

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

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

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

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

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

ISO 8872:2003, *Aluminium caps for transfusion, infusion and injection bottles — General requirements and test methods*