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Second edition
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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'essais

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

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 and pharmaceutical use.*

This second edition cancels and replaces the first edition (ISO 10985:1992), which has been technically revised.

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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.

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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) onto 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.

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2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 7500-1:1999 *Metallic materials — Verification of static uniaxial testing machines — Part 1: Tensile/compression testing machines — Verification and calibration of the force-measuring system.*

ISO 8362-1:1989, *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 accesories — 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 aluminium component shall meet the requirements given in 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 sharp edges or non-permissible protruding moulding flash.

3.3 Aluminium-plastics cap combination

On removal of the plastics component, the opening exposed in the aluminium shell shall be so constructed that no injuries may occur during normal use.

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4 Test methods

4.1 Aluminium component

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The results of the tests for the aluminium component shall meet the requirements given in ISO 8872:1988, 4.1 to 4.4.

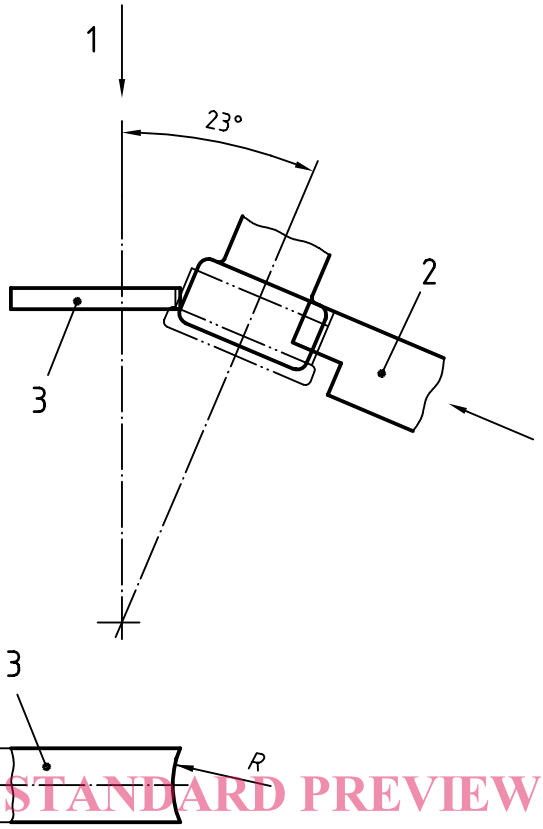
4.2 Aluminium-plastics cap combination

4.2.1 Apparatus

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

4.2.2 Determination of force required to pull off plastics component with central tear-out

The caps are clamped in the special holder of the traction test machine, as shown in Figure 1, and the plastics component is pulled off with a metal finger of dimensions as given in Table 1.



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Key

1 Direction of traction

2 Clamp jaws

3 Metal finger to lift off the plastics button (plan view)

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

Table 1 — Dimensions of metal finger

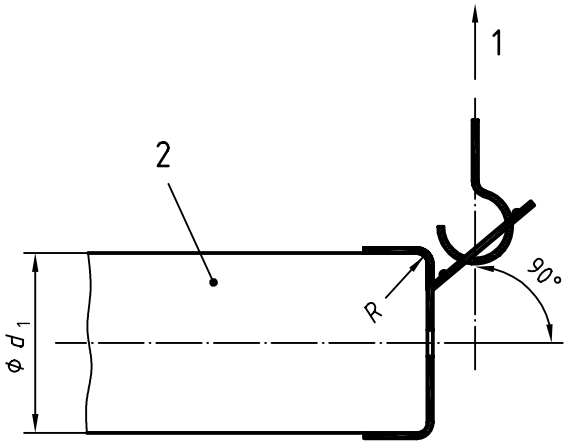
Dimensions in millimetres

Nominal size of cap		*R*	*b*
ISO 8362-6	ISO 8536-7		
13	—	8	8
20	—	12	10
—	**28**	16	12
—	**32**	20	15

The test results shall be determined and recorded. For the cap to pass the test, the results shall conform with the requirements of the International Standard for the corresponding size.

4.2.3 Determination of force required to remove tab

The cap is placed on a mandred of dimensions as given in Table 2. As shown in Figure 2, a hook is placed in the tear-out ring exposed or in the plastics disc (which shall be perforated). The hook is then moved by the traction/pressure machine in the direction shown until the aluminium cap has been opened completely.



Key

1 Direction of traction

2 Mandrel

Figure 2 — Apparatus to determine tear-off force

Table 2 — Dimensions of mandrel

Dimensions in millimetres

Nominal size of cap		d_1	R
ISO 8362-6	ISO 8536-7		
13	—	13,1	0,8
20	—	20,1	0,8
—	**28**	27,9	1,15
—	**32**	32,4	1,15

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The test results shall be determined and recorded. For the cap to pass the test, the results shall conform with the requirements of the International Standard for the corresponding size cap.

5 Cleaning, sterilization and coating

Cleaning, sterilization and coating shall be carried out in accordance with ISO 8872:1988, 5.1, 5.2 b) and 5.3.

6 Packaging

Packaging shall comply with the requirements given in ISO 8872.

7 Marking

Marking shall be in accordance with ISO 8872.

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