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Aluminium caps for transfusion, infusion and injection bottles — General requirements and test methods

Capsules en aluminium pour flacons de transfusion, perfusion et injection — Spécifications générales 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 8872 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical and pharmaceutical use*.

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This second edition cancels and replaces the first edition (ISO 8872:1988), which has been technically revised.

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Introduction

This International Standard specifies requirements for aluminium caps for vials and bottles in the field of transfusion, infusion and injection. The primary materials from which containers, including their elastomeric closures, are made have to be suitable for the storage of such products until the products are administered. However, in this International Standard, aluminium caps are not considered as primary packaging materials that will come into direct contact with pharmaceutical preparations or blood.

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Aluminium caps for transfusion, infusion and injection bottles — General requirements and test methods

1 Scope

This International Standard specifies general requirements and test methods for aluminium caps for injection vials, and for infusion and transfusion bottles.

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 6892:1998, *Metallic materials — Tensile testing at ambient temperature*

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

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ISO 8362-3:2001, *Injection containers and accessories — Part 3: Aluminium caps for injection vials*

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ISO 8536-3:1999, *Infusion equipment for medical use — Part 3: Aluminium caps for infusion bottles*

3 Requirements

3.1 Wrought products

3.1.1 Mechanical characteristics

The mechanical characteristics shall comply with the requirements specified for the three grades A, B or C (see Table 1) and shall be tested in accordance with the test procedures described in 4.2.

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Table 1 — Grades of mechanical characteristics

Grade	Alloy[a]	Tensile strength R_m N/mm^2		Proof stress of non-proportional elongation R_p N/mm^2
		min.	max.	min.
A	AlFeSi annealed or coated	100	150	80
B	AlFeSi	130	170	110
C	AlMnCu	140	180	120

[a] These alloys present a selection of widely used aluminium alloys for manufacture of caps. Other alloys are permitted, provided that they otherwise meet the requirements in this table.

3.1.2 Chemical composition

The wrought (sheet and strip) used for the manufacture of caps shall be produced from aluminium alloy.

The chemical composition shall be verified in accordance with 4.3.

3.2 Caps

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3.2.1 Dimensions

Aluminium caps shall comply with the dimensions and with the accepted tolerances as specified in the relevant International Standards.

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The thickness shall be measured in accordance with 4.4.

3.2.2 Contamination

Aluminium caps shall be free from contamination; the presence of residual lubricants shall be reduced to an absolute minimum and burrs shall be avoided.

3.2.3 Earing

Aluminium caps should be free from earing defects at the cutting processing edge. If earing occurs, the earing defect, as measured in accordance with 4.5, shall not be greater than 3 %.

3.2.4 Crimping

Aluminium caps shall fit properly when subjected to the crimping process as described in 4.6.

3.2.5 Resistance of caps

3.2.5.1 Seals that will be terminally steam-sterilized shall be crimped on a vial/closure combination in accordance with 4.6 and tested in accordance with 5.1. The seals shall show no signs of premature opening or deformation.

3.2.5.2 When measured in accordance with the test method described in 4.7 and 4.8, the forces needed to remove the tabs or to tear them off completely shall comply with the limits specified in the relevant International Standards.

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During removal, the complete tear-off tab shall be torn off only as determined by the score path.

When the test in accordance with 4.7 and 4.8 is carried out, no parts of aluminium caps shall break except the bridges and score paths.

3.2.5.3 Seals shall be crimped on a vial/closure combination in accordance with 4.6. When subjected to conditions as described in 5.2, the seals shall not show any visible alteration at the surface.

NOTE Plain aluminium alloys have a tendency to produce spots during treatment in a steam sterilizer.

3.2.6 Coating

When tested in accordance with 5.2, the lacquer on the caps which have been subjected to the tests described in 5.1 shall not show any sign of deterioration of the coating.

4 Test methods

4.1 General

The tests shall be carried out on non-sterilized caps (except as specified in 3.2.5.1 and 3.2.5.3).

4.2 Mechanical characteristics

The mechanical characteristics (tensile strength and proof stress of non-proportional elongation) shall be determined in accordance with ISO 6892.

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4.3 Chemical composition

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The analysis of chemical composition shall be carried out using an accepted method. The cap manufacturer may rely upon a certificate of conformity given by the supplier of the wrought product.

4.4 Dimensions

The dimensions shall be measured using an appropriate gauge or a micrometer.

The thickness shall be measured at the top area where no deformation has occurred.

For measurement of the inner diameter, the use of a pin gauge set or optical comparator is recommended.

4.5 Earing

The earing (see Figure 1) on the cutting/processing edges of the caps shall be calculated, as a percentage, by comparing the maximum and minimum total heights, measured on the external side, using the following equation:

$$\frac{h_{\max} - h_{\min}}{h_{\min}} \times 100$$

where

$h_{\max}$ is the maximum height of the external side of the cap where earing occurs;

$h_{\min}$ is the minimum height of the external side of the cap where earing occurs.

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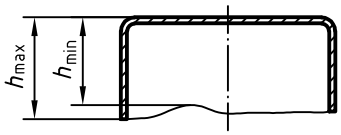

NOTE Cross-section has been stylized to illustrate both the minimum and maximum heights, measured on the external side, where earing occurs.

Figure 1 — Illustration of earing on aluminium cap

4.6 Crimping

Fill the glass containers with water to their nominal volume. Place the aluminium caps on a rubber closure fitted on bottles or vials. Crimp the cap by means of a crimping tool or a capping machine.

4.7 Test for resistance of bridges for centre-tear tabs

4.7.1 Apparatus

4.7.1.1 **Socket and punch**, as shown in Figure 2.

4.7.1.2 **Motorized loading device**, capable of exerting a compressive force at a speed of 100 mm/min.

4.7.1.3 **Compression dynamometer**, class 1 in accordance with ISO 7500-1, load cell, or other device capable of measuring and recording the maximum compression load generated during the test.

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4.7.2 Procedure

Place the cap in the socket (4.7.1.1).

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Fit the motorized device (4.7.1.2) to the dynamometer (4.7.1.3), which in turn is fitted to the punch pushing the tab.

Place all the elements so that they are submitted to an axial force exerted by the motorized device.

4.7.3 Expression of results

Record the maximum value of the axial force necessary to break the first bridge.

4.8 Test for resistance of bridges and ability to remove tear-off tab completely

4.8.1 Apparatus

4.8.1.1 **Motorized loading device**, capable of exerting a tensile force at a speed of 100 mm/min.

4.8.1.2 **Traction dynamometer**, load cell, or other device capable of measuring and recording the maximum tensile load generated during the test.

4.8.2 Procedure

The cap is placed in a device in accordance with Figure 3 and the tear-off tab is hung in a traction dynamometer in accordance with 4.8.1.2.

4.8.3 Expression of results

The maximum force necessary for a tab to be completely torn off (tearing of incisions) shall be determined and recorded.

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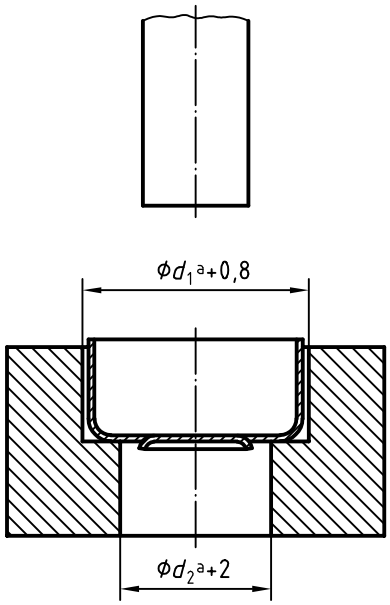
Dimensions in millimetres



NOTE Dimensions and design of the punch should be adapted to the design of the centre-tear tab.

a Dimensions d_1 and d_2 shall be in accordance with ISO 8362-3 and ISO 8536-3.

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Figure 2 — Socket and punch for testing resistance of bridges

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Dimensions in millimetres

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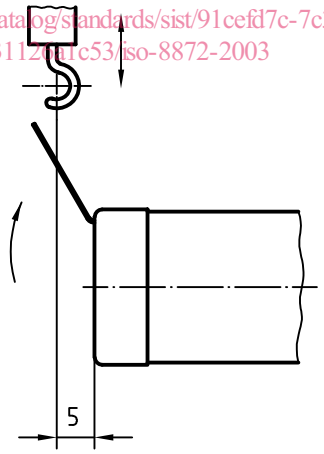

Figure 3 — Test set-up for determining force required to tear tab off completely

5 Sterilization and coating

5.1 The aluminium caps subjected to sterilization shall be submitted to an autoclave sterilization for 30 min at 121 °C.

5.2 Lacquered caps shall be rubbed for 30 s with a soft cotton pad saturated with a mixture of 80 % ethanol and 20 % water. Then the same caps shall be rubbed for 30 s with a soft cotton pad saturated with 70 % isopropanol and 30 % water.

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