INTERNATIONAL STANDARD

ISO 8872

Third edition
2022-11

Aluminium caps and aluminium/plastic caps for infusion bottles and injection vials — General requirements and test methods

Capsules en aluminium et capsules en aluminium/plastique pour flacons de perfusion et d'injection — Exigences générales et méthodes d'essai

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ISO 8872:2022
https://standards.iteh.ai/catalog/standards/sist/41ca6bc8-e51c-46a5-ad1a-c3230cd1409b/iso-8872-2022

Reference number
ISO 8872:2022(E)

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

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This document was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/SS S02, *Transfusion equipment,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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This third edition cancels and replaces the second edition (ISO 8872:2003) and ISO 10985:2009, which have been technically revised.

The main changes are as follows:

— integration of ISO 10985;

— addition of new terms;

— addition of a new Annex A, "Aluminium and aluminium plastic caps - Type drawings";

— addition of a new Annex B, "Opening and tear-off forces".

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Introduction

The primary materials from which containers, including their elastomeric closures, are made must be suitable for the storage of such products until the products are administered. However, in this document, aluminium caps and aluminium/plastic caps are not considered as primary packaging materials that will come into direct contact with pharmaceutical preparations. Aluminium and aluminium/plastic caps can be delivered to customers as non-sterile products or as sterile products.

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Aluminium caps and aluminium/plastic caps for infusion bottles and injection vials — General requirements and test methods

1 Scope

This document specifies general requirements and test methods for aluminium caps and aluminium/plastic caps intended for use on infusion bottles and/or injection vials.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 6892-1, *Metallic materials — Tensile testing — Part 1: Method of test at room temperature*

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

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

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

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ISO 8362-7, *Injection containers and accessories — Part 7: Injection caps made of aluminium-plastics combinations without overlapping plastics part*

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

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

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
coating
surface lacquer or polymer layer on the aluminium part of the cap

Note 1 to entry: The coating allows for better processing and product differentiation.

3.2
crimping
act of fixating the aluminium or aluminium/plastic cap over the rubber stopper and under the neck of a bottle or vial, such that the stopper is held firmly in place, thereby securing the container/closure integrity of the bottle or vial system

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3.3
earing
degree of undulation (waviness) of the processed edge of an aluminium cap

3.4
tear-off tab
all aluminium seal with a tear tab that allows prior-to-use removal of the ferrule that is scored on its skirt

Note 1 to entry: For a drawing, see ISO 8536-3:2009, Figure 2b) and Figure 3 b).

4 Requirements

4.1 General

For type drawings of aluminium and aluminium/plastic caps, see Annex A.

Aluminium and aluminium/plastic caps can be delivered to customers as non-sterile products or as sterile products. Specific requirements regarding, e.g. packaging, and specifications of sterile caps shall be agreed upon between supplier and customer.

4.2 Aluminium component

4.2.1 Mechanical characteristics

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The mechanical characteristics of the aluminium alloy shall be in accordance with the requirements specified for the three grades A, B or C in Table 1 and shall be tested in accordance with the test procedures described in 5.2.

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Table 1 — Grades of mechanical characteristics

Grade	Alloy[a]	Tensile strength R_m N/mm²		Proof stress of non-proportional elongation R_p N/mm²
		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.

4.2.2 Chemical composition

The aluminium component of the cap shall be produced from aluminium alloy as described in Table 1. Aluminium used for caps is coated at its surface with a suitable surface layer, typically a lacquer or polymer layer.

The chemical composition of the aluminium shall be verified in accordance with 5.3.

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4.2.3 Dimensions

Aluminium components shall conform with the dimensions and with the accepted tolerances as specified in ISO 8362-3, ISO 8362-6, ISO 8362-7, ISO 8536-3 or ISO 8536-7 as applicable. The thickness shall be measured in accordance with 5.4.

4.2.4 Contamination

Aluminium components shall be free from contamination from the manufacturing process; the presence of residual lubricants shall be reduced to an absolute minimum.

4.2.5 Earing

Aluminium components should be free from earing defects at the cutting processing edge. If earing occurs, the earing defect, as measured in accordance with 5.5, shall not be greater than 3 %.

4.2.6 Other defects

Burrs and bite marks shall be avoided in manufacturing of aluminium components.

4.3 Plastic component

4.3.1 Mechanical characteristics

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The plastic component of caps that are intended for steam sterilization shall be steam-sterilizable at 121 °C for 30 min. The material shall withstand a temperature of 130 °C for a short time (max. 5 min).

The plastic component of caps that are intended for irradiation sterilization shall withstand a representative irradiation cycle without change of mechanical characteristics, such as brittleness, that could have an impact on the functional requirements of the cap.

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4.3.2 Chemical composition

The requirements for plastic material for use in non-contact pharmaceutical components are given in national legislations.

NOTE For further information, see ISO 10993-18.

4.3.3 Dimensions

Plastic components shall conform with the dimensions and with the accepted tolerances for the corresponding size as specified in ISO 8362-6 or ISO 8536-7, as appropriate.

4.3.4 Contamination

Plastic components shall be free from contamination from the manufacturing process.

4.3.5 Other defects

The plastic component shall not have sharp edges or non-permissible protruding moulding flash.

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4.4 Functional requirements of aluminium and aluminium-plastic caps

4.4.1 Opening and tear-off forces for aluminium caps

When measured in accordance with the test method described in 5.6, the forces needed to remove the tabs or to tear them off completely shall conform with the limits for the corresponding size specified in ISO 8362-3 or ISO 8536-3, as applicable.

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

When the test in accordance with 5.6 is carried out, no parts of aluminium caps shall break except the bridges and score paths.

4.4.2 Joining of aluminium and plastic component

In the case of aluminium/plastic caps, the plastic component shall be combined with the aluminium component in such a way that complete joining is guaranteed.

4.4.3 Opening and tear-off forces for aluminium/plastic caps

When measured in accordance with the test methods described in 5.6, the forces needed to remove the plastic component or to tear the cap off completely shall conform with the limits for the corresponding size and type as specified in ISO 8362-6, ISO 8362-7 or ISO 8536-7, as applicable.

On removal of the plastic component, the opening exposed in the aluminium shell shall be so constructed that no injuries can occur during intended use.

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

When testing in accordance with 5.6 is carried out, no parts of the aluminium component shall break except the bridges and score paths and no part of the plastic component shall break either.

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4.4.4 Mechanical requirements after sterilization

4.4.4.1 Steam sterilization

Caps intended for steam sterilization, shall be able to withstand a steam sterilization cycle for 30 min at 121 °C.

When tested in accordance with the test method described in 5.7.1, upon visual inspection the coating of the surface shall remain integral and the soft cotton pad shall not show any coating residuals.

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

When tested in accordance with 5.7.2, aluminium or aluminium/plastic caps that will be terminally steam-sterilized shall show no signs of premature opening or deformation.

4.4.4.2 Irradiation sterilization

Caps intended for irradiation sterilization shall be able to withstand a suitable irradiation cycle.

When tested in accordance with the test method described in 5.7.1, upon visual inspection, the coating of the surface shall remain integral and the soft cotton pad shall not show any coating residuals.

5 Test methods

5.1 General

The tests shall be carried out on non-sterilized caps, except as specified in 5.7.

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5.2 Mechanical characteristics

The mechanical characteristics of the aluminium used for the aluminium components (tensile strength and proof stress of non-proportional elongation) shall be determined in accordance with ISO 6892-1.

5.3 Chemical composition

The analysis of chemical composition of the aluminium used for the aluminium components shall be carried out using an accepted method. The cap manufacturer may rely on a certificate of conformity given by the supplier.

5.4 Dimensions

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

The thickness of the aluminium component shall be measured at the top area where no deformation has occurred during cap manufacturing.

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

5.5 Earing

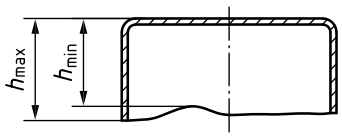
The earing (see Figure 1) on the cutting/processing edges of the caps shall be calculated, as a percentage, by comparing the maximum and minimum total heights, measured on the external side, using Formula (1):

$$\frac{h_{max} - h_{min}}{h_{min}} \times 100 \tag{1}$$

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.



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

5.6 Opening and tear-off forces of aluminium and aluminium/ plastic caps

Annex B shall apply.

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