
**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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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.

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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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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.

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).

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.

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.

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*

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*

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