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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

Reference number
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Contents

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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council. They are approved in accordance with ISO procedures requiring at least 75 % approval by the member bodies voting.

International Standard ISO 8872 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical use*.

Annex A of this International Standard is for information only.

Introduction

This International Standard specifies requirements in general 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.

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 infusion and transfusion bottles.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards listed below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 6892 : 1984, *Metallic materials — Tensile testing.*

ISO 7500-1 : 1986, *Metallic materials — Verification of static uniaxial testing machines — Part 1 : Tensile testing machines.*

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 and C (see table 1) and shall be tested in accordance with the test procedures described in 4.2.

Table 1 — Grades of mechanical characteristics

Grade	Alloy 1)	Tensile strength R_m N/mm² min.	Tensile strength R_m N/mm² max.	Proof stress of non-proportional elongation R_p N/mm² min.
A	Al Fe Si annealed or coated	100	150	80
B	Al Fe Si	130	170	110
C	Al Mn Cu	140	180	120

1) 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 the table.

3.1.2 Chemical composition

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

NOTE — The chemical composition of widely used aluminium alloys is given as an example in annex A.

The chemical composition shall be checked in accordance with 4.3.

3.2 Caps

3.2.1 Dimensions

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

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 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 When tested in accordance with 5.2, the aluminium caps, put in place by a crimping process as described in 4.6, shall not show ruptures or important signs of deformation.

NOTE — This requirement only applies to caps that will be subject to sterilization.

3.2.5.2 When measured in accordance with the test methods 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 pertinent International Standards.

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.

3.2.6 Cleaning effect

All types of aluminium caps shall be resistant to the cleaning processes which are usually applied.

When the test in accordance with 5.1 is carried out, no visible alterations shall occur on the surface. An existing surface coating shall not swell or become detached. The degree of resistance needed for specific individual applications shall be subject to an agreement between the manufacturer of the aluminium sheeting and the producer of the aluminium caps.

3.2.7 Sterilization effect

Only those aluminium caps which have to pass a final sterilization process shall be subjected to this test.

The capped injection vials or infusion bottles, as described in 4.6, shall only be subjected to a steam sterilization process.

NOTE — Caps in bulk may be subjected to a hot-air or a steam sterilization process.

When tested in accordance with 5.2, aluminium caps, which have passed the test described in 5.1, shall not show any visible alteration at the surface.

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

3.2.8 Coating

When tested in accordance with 5.3, the lacquer on the caps, which have passed the tests described in 5.1 and 5.2, shall be resistant to a mixture of 80 % (V/V) ethanol and 20 % (V/V) water.

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 3.2.7).

4.2 Mechanical characteristics

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

4.3 Chemical composition

The analysis shall be obtained by 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 a measuring gauge or a micrometer.

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

4.5 Earing

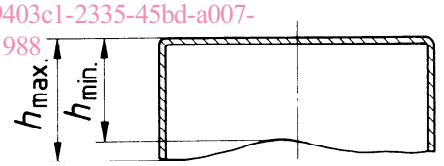
The earing defect on the cutting/processing edges of the caps shall be calculated, as a percentage, by comparing the maximum and minimum total heights, measured on the external side, using the following equation:

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

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.



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, in accordance with the method required by the user.

4.7 Resistance of bridges for two- or three-bridge tabs

4.7.1 Apparatus

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

4.7.1.2 Motorized device, capable of pushing at a speed of 100 mm/min.

4.7.1.3 Compression dynamometer, class 1 in accordance with ISO 7500-1.

4.7.2 Procedure

Place the cap in the socket (4.7.1.1).

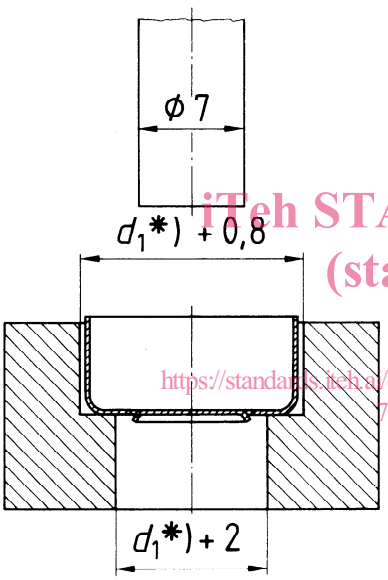
Fit the motorized device (4.7.1.2) to the dynamometer (4.7.1.3), which in turn is fitted to the punch pushing the tab.

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

Dimensions in millimetres



*) Dimensions d_1 and d_2 are given in the pertinent International Standards.

Figure 2 — Socket and punch for testing resistance of bridges

4.8 Resistance of bridges and ability to remove tear-off tab completely

4.8.1 Apparatus

4.8.1.1 Motorized device, capable of pulling at a speed of 100 mm/min.

4.8.1.2 Traction dynamometer, fitted to the motorized device (4.8.1.1).

4.8.2 Procedure

In the same radial plane, punch two holes out (see figure 3) to allow two hooks to be positioned, one fixed and the other one linked to the dynamometer (4.8.1.2).

4.8.3 Expression of results

The following two parameters shall be determined and recorded:

a) the force necessary to break the first bridge;

b) the force necessary for a tab to be completely torn off (tearing of incisions).

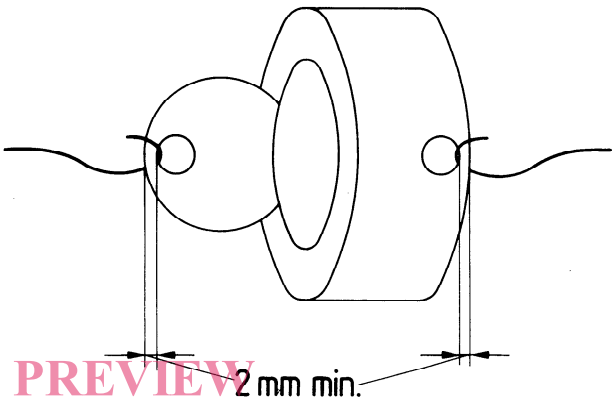


Figure 3 — Test set-up for determining force required to tear tab off completely

5 Cleaning, sterilization and coating

5.1 If the aluminium caps are usually subjected to a cleaning process by the customer, the caps shall be tested by subjecting them to the appropriate cleaning process.

5.2 The aluminium caps subjected to sterilization, which have passed the test as described in 5.1, shall be submitted to the following process:

a) treatment in hot air: 180 °C for 1 h

b) treatment in saturated steam:

heating time = 30 min

holding time (plateau) = 30 min at 121 °C ± 2 °C

cooling time = 30 min to reach 60 °C

5.3 If the aluminium caps are lacquered, they shall also be exposed for 30 s to a mixture of 80 % (*V*/*V*) ethanol and 20 % (*V*/*V*) water (provided that they have passed the tests as described in 5.1 and 5.2). When being rubbed with a soft cotton pad, the surface shall not show any sign of deterioration of the coating.

6 Packaging

The packaging shall protect the aluminium caps during transportation and storage in such a way that their functional characteristics are not adversely affected and are protected from any contamination. Plastics bags shall be used as an inside container, whereas foldable cardboard boxes resistant to standard transportation conditions or drums should be used as an outer packaging material.

7 Marking

The following information shall be legibly marked on the package:

a) the name of the manufacturer;

b) the characteristics of the product;

c) the designation as specified in the pertinent International Standard;

d) the batch number and/or the date of manufacture;

e) the quantity of caps.

NOTE — Further information may also be included.

Annex A
(informative)

Example of chemical composition of wrought product

An example of the ranges for the proportions, as a percentage by mass, of the aluminium alloys is given in table 2.

Table 2 — Example of chemical composition

Element	Proportion, % (*m*/*m*)
Silicon	0,5 to 0,9
Iron	0,5 to 1,0
Copper	0,05 to 0,20
Manganese	0,10 to 1,5
Zinc	0,1 max.
Titanium	0,08 max.
Other elements : single	0,06 max.
total	0,25 max.
Aluminium	Balance