INTERNATIONAL STANDARD

ISO 8362-7

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Injection containers for injectables and accessories —

Part 7:
Injection caps made of aluminium-plastics combinations without overlapping plastics part

Récipients et accessoires pour produits injectables —

Partie 7: Capsules d'injection en combinaison aluminium-plastique avec élément plastique non débordant

Reference number
ISO 8362-7:1995(E)

Contents

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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.

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 8362-7 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical use*.

ISO 8362 consists of the following parts, under the general title *Injection containers for injectables and accessories*:

— *Part 1: Injection vials made of glass tubing*

— *Part 2: Closures for injection vials*

— *Part 3: Aluminium caps for injection vials*

— *Part 4: Injection vials made of moulded glass*

— *Part 5: Freeze drying closures for injection vials*

— *Part 6: Caps made of aluminium-plastics combinations for injection vials*

— *Part 7: Injection caps made of aluminium-plastics combinations without overlapping plastics part*

Introduction

The materials from which injection containers (including elastomeric closures) are made are suitable primary packaging materials for storing injectable products until they are administered. However, in this part of ISO 8362, caps are not considered as primary packaging materials in direct contact with pharmaceutical preparations.

During the processing of injection vials 2R and 4R according to ISO 8362-1 and injection vials 6R, 8R, 10I, 5H, 7H and 8H according to ISO 8362-1 and ISO 8362-4 respectively, difficulties may arise by using injection caps made of aluminium-plastics combinations corresponding to ISO 8362-6 because the diameter, d_2, of the plastics element is larger than the diameter, d, of the injection vial body.

In order to avoid problems during the automatic working process, e.g. labelling of the vials, it is necessary to establish a cap made of aluminium-plastics combinations having a plastics element which does not overlap the diameter of the vial body.

Injection containers for injectables and accessories —

Part 7:
Injection caps made of aluminium-plastics combinations without overlapping plastics part

1 Scope

This part of ISO 8362 specifies aluminium-plastics combinations for the injection caps of injection vials as specified in ISO 8362-1 and ISO 8362-4 where the plastics part does not overlap the diameter of the vial body.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 8362. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 8362 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 2768-1:1989, *General tolerances — Part 1: Tolerances for linear and angular dimensions without individual tolerance indications.*

ISO 2768-2:1989, *General tolerances — Part 2: Geometrical tolerances for features without individual tolerance indications.*

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

ISO 8362-1:1989, *Injection containers for injectables and accessories — Part 1: Injection vials made of glass tubing.*

ISO 8362-3:1989, *Injection containers for injectables and accessories — Part 3: Aluminium caps for injection vials.*

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 accessories — Part 6: Caps made of aluminium-plastics combinations for injection vials.*

ISO 8872:1988, *Aluminium caps for transfusion, infusion and injection bottles — General requirements and test methods.*

3 Classification of types

Caps shall be classified as follows:

— Type OB: Aluminium cap with central opening, and without overlapping plastics component;

— Type OD: Aluminium cap with complete tear-off tab, and without overlapping plastics component.

4 Dimensions and tolerances

4.1 Dimensions

All cover versions (flat, ring-shaped or other) of caps shall meet the dimensions given in figure 1 and table 1.

NOTE 1 The configuration of the cap shown in figure 1 is informative only.

4.2 Tolerances

The tolerances shall be in accordance with ISO 2768-1 and ISO 2768-2.

5 Designation

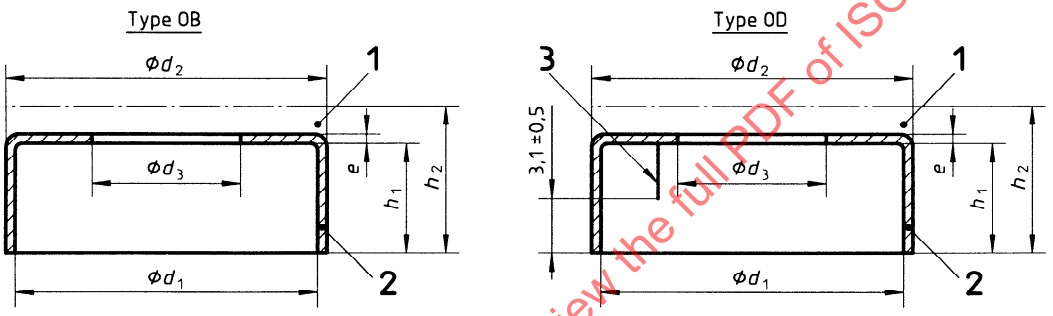
Aluminium-plastics caps shall be designated according to type: the designation shall be expressed as the word "cap", the number and part of this International Standard followed by the type letters, followed by the nominal size of the container.

EXAMPLE

A type OD aluminium-plastics cap of nominal size 13 complying with the requirements laid down in this part of ISO 8362 is designated:

Cap ISO 8362-7 — OD — 13

Dimensions in millimetres



1 Plastics component

2 Aluminium cap in accordance with ISO 8362-3

3 Score line

Figure 1 — Configuration of cap

Table 1 — Dimensions of cap

Dimensions in millimetres

Nominal size	d_1 $^{+0,1}_{0}$	d_2 1)		d_3 2)		e 3)		h_1	h_2 4)	
		min.	max.	min.	max.	min.	max.	± 0,2	min.	max.
13	13,3	13	15,8	3	8	0,168	0,242	6,3	7,3	8,4
20	20,3	20	20,9	6	10			7,3	8,7	9,8

1) The diameter d_2 shall be agreed between the manufacturer and user. It shall not differ from the nominal value by more than ± 0,25 mm. The extreme limits are given without tolerance.

2) After plastics element removal. The diameter d_3 shall be agreed between the manufacturer and user.

3) The thickness e shall be agreed between the manufacturer and user. It shall not differ from the nominal value by more than ± 0,022 mm. The extreme limits are given without tolerance.

4) The height h_2 shall be agreed between the manufacturer and user. It shall not differ from the nominal value by more than ± 0,3 mm. The extreme limits are given without tolerance.

6 Requirements

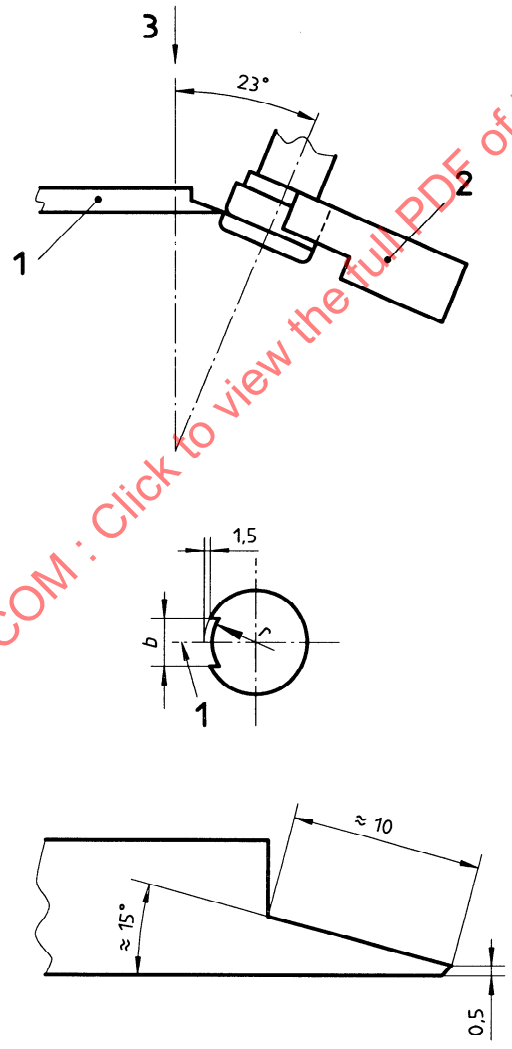
6.1 General requirements

The requirements shall be in accordance with ISO 8362-6:1992, with the exception of the forces to tear off the plastics component and the corresponding test.

6.2 Force to tear off plastics component

6.2.1 The required force to remove the plastics component is determined in a traction/pressure test machine class 1 in accordance with ISO 7500-1 with a special attachment as, for example, shown in figure 2, with a traction speed, v, of 100 mm/min over a measuring range of 100 N. The values shall be in accordance with table 2 and table 3.

Dimensions in millimetres



1 Pressure bar
2 Clamp jaws
3 Direction of tractive force

Figure 2 — Equipment to determine force to tear off plastics component

Table 2 — Dimensions of pressure bar

Dimensions in millimetres

Nominal size	*r*	*b*
13	5	8
20	9	10

Table 3 — Force required to remove plastics component and tear off tab completely

Forces in newtons

Nominal size	Force to remove plastics component max.	Force to tear off tab completely max.
13	25	30
20	35	40

6.2.2 For incoming control of as-received caps, a minimum value for the tear-off tab removal force shall be agreed between the supplier and user. The injection caps shall also withstand a sterilization process in accordance with ISO 8872:1988, subclauses 5.1 and 5.2 b).

7 Packaging

Packaging shall comply with the requirements of ISO 8872.

8 Marking

Marking shall be in accordance with ISO 8872 and the designation shall be as specified in clause 5.

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