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**Injection containers and accessories —**

Part 7:

**Injection caps made of aluminium-  
plastics combinations without  
overlapping plastics part**

*Réipients et accessoires pour produits injectables —*

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

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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.

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

This second edition cancels and replaces the first edition (ISO 8362-7:1995), of which it constitutes a minor revision.

ISO 8362 consists of the following parts, under the general title *Injection containers 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, injection 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 when 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 or intermediate storage on a turntable, injection caps made of aluminium-plastics combinations are designed in such a way that the plastics element does not overlap the diameter of the vial body.

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# Injection containers 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 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 2768-1, *General tolerances — Part 1: Tolerances for linear and angular dimensions without individual tolerance indications*

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

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*

ISO 8362-1:2003, *Injection containers and accessories — Part 1: Injection vials made of glass tubing*

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

ISO 8362-4:2003, *Injection containers and accessories — Part 4: Injection vials made of moulded glass*

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

ISO 8872:2003, *Aluminium caps for transfusion, infusion and injection bottles — General requirements and test methods*

### 3 Classification of types

Injection 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 injection caps shall meet the dimensions given in Figure 1 and Table 1.

The dimensions of injection vials made of glass tubing shall be in accordance with ISO 8362-1:2003, Clause 4.

The dimensions of injection vials made of moulded glass shall be in accordance with ISO 8362-4:2003, Clause 4.

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

### 4.2 Tolerances

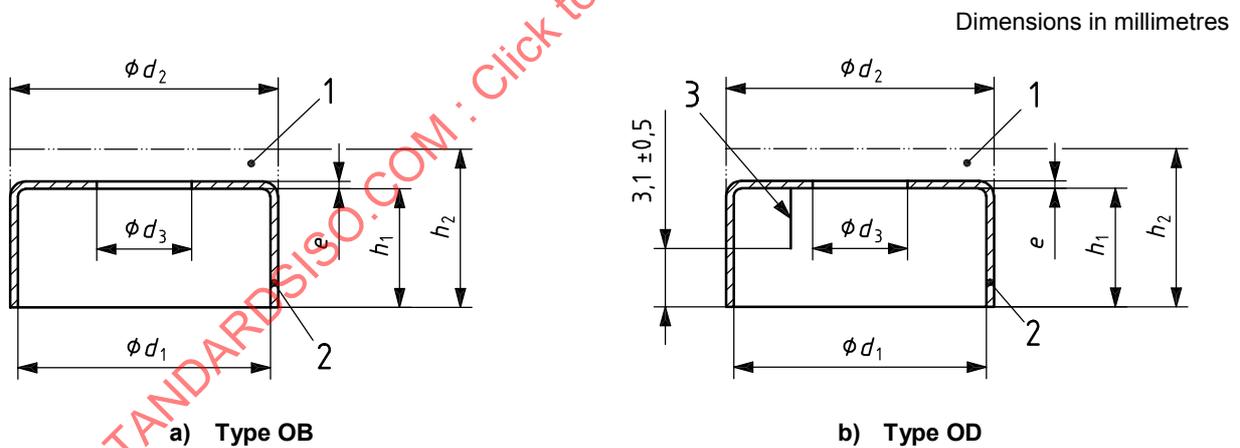
The tolerances shall be in accordance with ISO 2768-1 and ISO 2768-2.

## 5 Designation

Aluminium-plastics injection 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 injection 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



#### Key

- 1 plastics component
- 2 aluminium injection cap in accordance with ISO 8362-3
- 3 score line

NOTE For dimensions of parameters, see Table 1.

Figure 1 — Configuration of injection cap

Table 1 — Dimensions of injection cap

Dimensions in millimetres

Nominal size	Parameters									
	$d_1$ +0,1 0	$d_2^a$		$d_3^b$		$e^c$		$h_1$ ± 0,2	$h_2^d$	
		min.	max.	min.	max.	min.	max.		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

<sup>a</sup> 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.

<sup>b</sup> After plastics element removal. The diameter  $d_3$  shall be agreed between the manufacturer and user.

<sup>c</sup> 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.

<sup>d</sup> 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, with the exception of the force required to remove the plastics component and tear off the tab completely, and the corresponding test.

### 6.2 Force required to remove plastics component and tear off tab completely

**6.2.1** The force required to remove the plastics component and tear off the tab completely is determined in a traction/pressure test machine class 1, in accordance with ISO 7500-1, with a special attachment as shown for example 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 Tables 2 and 3.

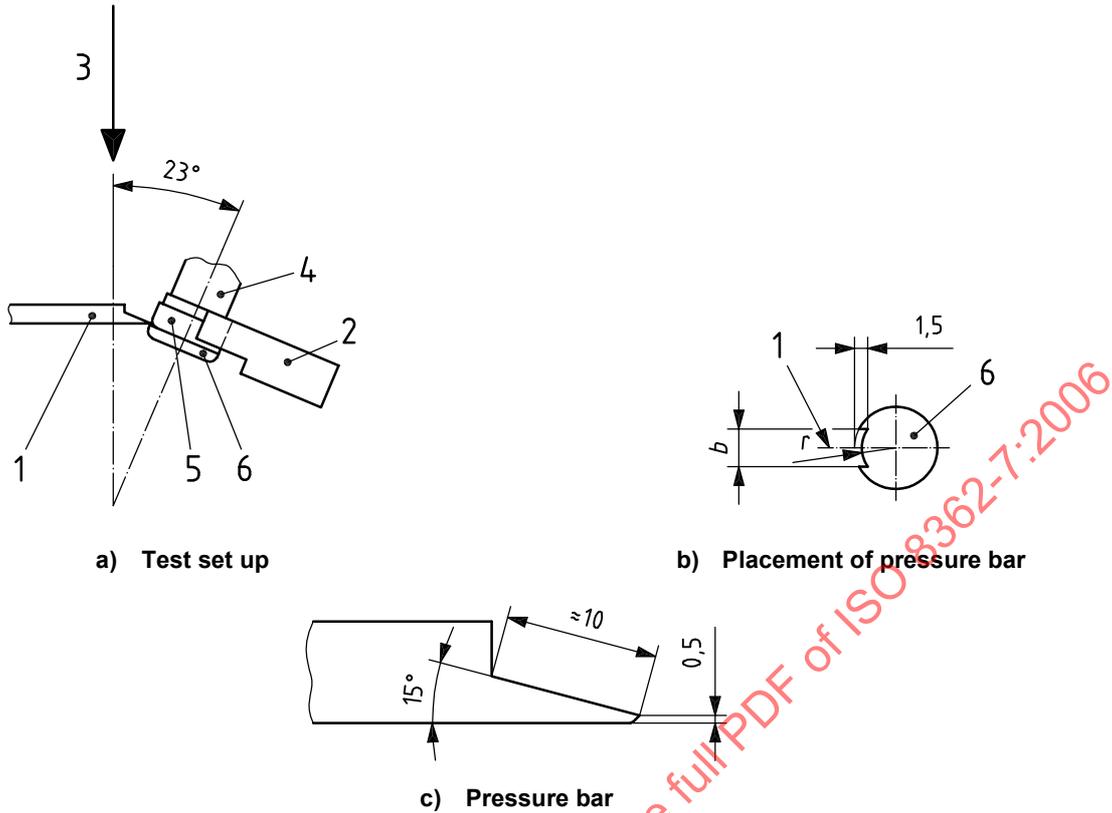
**6.2.2** For incoming control of as-received injection caps, the minimum value for the tear-off tab removal force shall be agreed between the supplier and user. The injection caps shall also withstand a sterilization process in accordance with ISO 8872:2003, 5.1.

## 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.



**Key**

- 1 pressure bar
- 2 clamp jaws
- 3 direction of tractive force
- 4 bottle
- 5 aluminium injection cap
- 6 plastics component

**Figure 2 — Example of equipment to determine force required to remove plastics component and tear off tab completely**

**Table 2 — Dimensions of pressure bar**

Dimensions in millimetres

Nominal size	<i>r</i>	<i>b</i>
13	5	8
20	9	10

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

Force in newtons

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