INTERNATIONAL STANDARD

ISO 8362-3

Second edition
2001-12-01

Injection containers and accessories —

Part 3: Aluminium caps for injection vials

Récipients et accessoires pour produits injectables —

Partie 3: Capsules en aluminium pour flacons

Reference number
ISO 8362-3:2001(E)

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Printed in Switzerland

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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 3.

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 part of ISO 8362 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 8362-3 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 8362-3:1989), which has been technically revised.

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 the elastomeric closures) are made are suitable primary packaging materials for storing injectable products until they are administered. However, in this part of ISO 8362, aluminium caps are not considered as primary packaging materials in direct contact with pharmaceutical preparations.

Injection containers and accessories —

Part 3:
Aluminium caps for injection vials

1 Scope

This part of ISO 8362 specifies aluminium caps for injection vials as described in ISO 8362-1 and ISO 8362-4.

2 Normative reference

The following normative document contains provisions which, through reference in this text, constitute provisions of this part of ISO 8362. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 8362 are encouraged to investigate the possibility of applying the most recent edition of the normative document indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

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

3 Dimensions and designation

3.1 Dimensions

The dimensions of aluminium caps shall be as shown in Figure 1 and as given in Table 1.

3.2 Designation

Aluminium caps are designated according to type: the four types A, B, C and D are illustrated in Figure 1. The designation is expressed as the number and part of this International Standard, followed by the nominal size of the container, followed by the type letter.

EXAMPLE A type B (i.e. two-bridge tab) aluminium cap (B) of nominal size 13 complying with the requirements laid down in this part of ISO 8362 is designated.

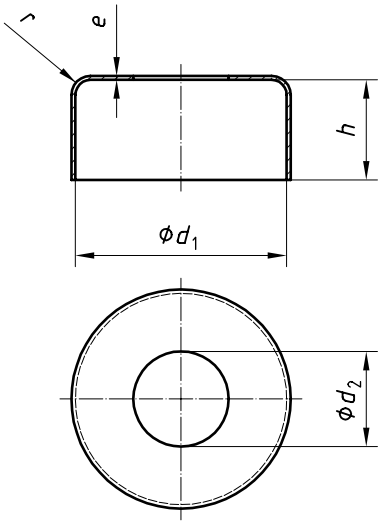
Aluminium cap ISO 8362-3-13-B

4 Requirements

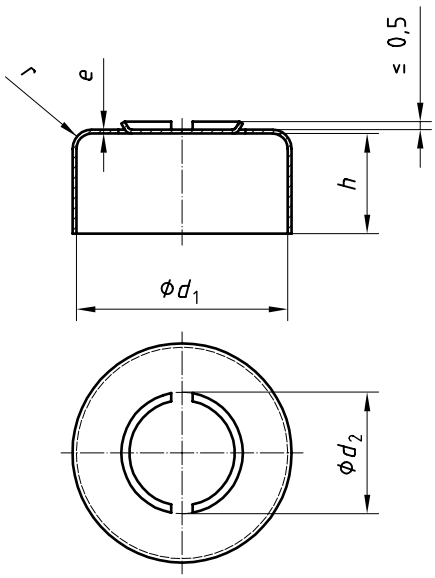
4.1 General

The caps shall meet the requirements of ISO 8872.

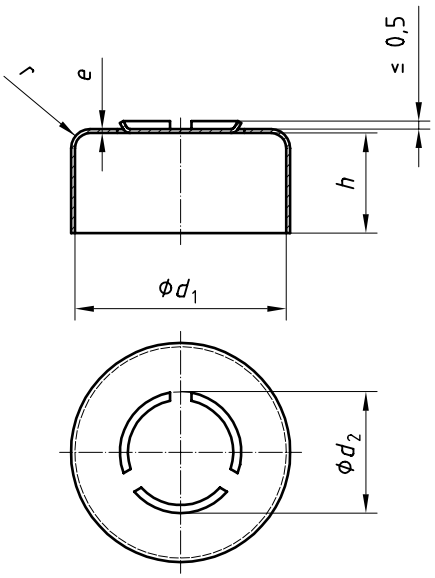
Dimensions in millimetres



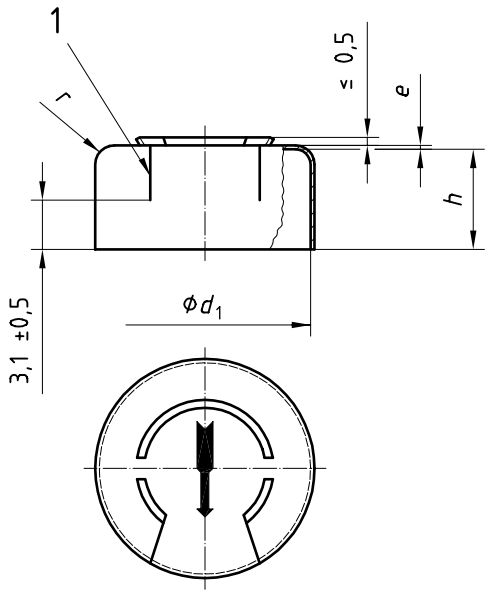
a) Type A — Aluminium cap with centre hole



b) Type B — Aluminium cap with two-bridge tab



c) Type C — Aluminium cap with three-bridge tab



Key

1 Tear-off perforation

d) Type D — Aluminium cap with complete tear-off tab

NOTE The width and the number of bridges for types B, C and D depend on the degree of resistance intended.

Figure 1 — Dimensions and configuration of aluminium caps

Table 1 — Dimensions of aluminium caps

Dimensions in millimetres

Nominal size	d_1 $^{+0,1}_{-0,05}$	d_2[b] $\pm$ 0,2 Type		e[a]	h[b] $\pm$ 0,2	r $\pm$ 0,2
		A, B and C	D			
13	13,35	3 to 8	8 to 9	0,242 max., 0,168 min.	6,3	1,0
20	20,35	6 to 11	10 to 13		7,3 to 7,8	

[a] The thickness shall be agreed between manufacturer and user within the given range. The thickness shall not differ from the nominal value by more than 0,022 mm. The extreme limits are given without tolerance.

[b] The diameter d_2 and the height h shall be agreed between manufacturer and user. The dimensions shall not differ from the nominal value by more than $\pm$ 0,2 mm. The extreme limits are given without tolerance.

4.2 Force required to remove tab

4.2.1 Two- or three-bridge tabs (types B and C)

The force needed to remove the tab shall be determined in accordance with ISO 8872 and shall be within the range given in Table 2.

Table 2 — Minimum and maximum forces to remove tabs with two (type B) or three (type C) bridges

Force in newtons

Nominal size	Force			
	Type B tabs		Type C tabs	
	min.	max.	min.	max.
13 and 20	25	60	46	76

4.2.2 Complete tear-off tab (type D)

The force needed to remove the tab completely shall be determined in accordance with ISO 8872 and shall be within the range given in Table 3.

Table 3 — Minimum and maximum forces to remove cap of complete tear-off tab (type D)

Force in newtons

Nominal size	Force to break bridges		Force to tear off tab completely	
	min.	max.	min.	max.
13 and 20	30[a]	50	5	25

[a] In the case of multiple bridges, the resistance against pressure shall be sufficient, but the individual breaking force will be reduced accordingly.

5 Packaging

The packaging of aluminium caps shall comply with the requirements of ISO 8872.

6 Marking

The aluminium caps shall be marked in accordance with ISO 8872 and with the designation as specified in 3.2.

ICS 11.040.20

Price based on 3 pages