INTERNATIONAL STANDARD

ISO 8362-3

First edition
1989-11-15

Injection containers for injectables 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 : 1989 (E)

Contents

International Organization for Standardization
Case postale 56 • CH-1211 Genève 20 • Switzerland

Printed in Switzerland

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 8361-3 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*

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 for injectables 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 standard contains provisions which, through reference in this text, constitute provisions of this part of ISO 8362. At the time of publication, the edition indicated was 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 edition of the standard indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

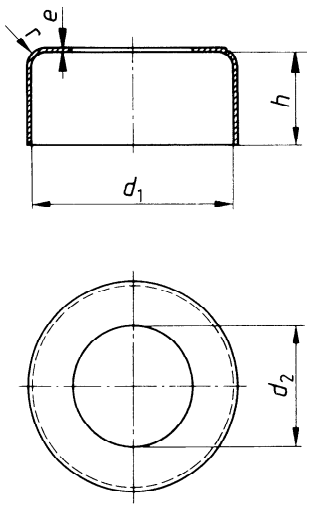
ISO 8872 : 1988, *Aluminium caps for transfusion, infusion and injection bottles — General requirements and test methods.*

3 Dimensions and designation

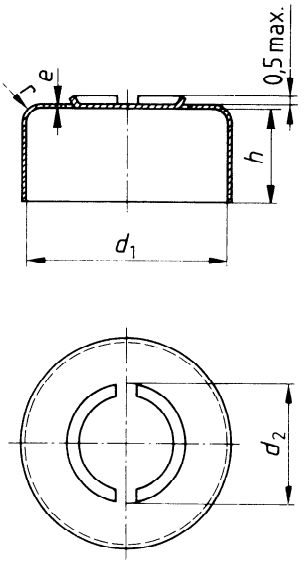
3.1 Dimensions

The dimensions of aluminium caps shall be as shown in figure 1 and as given in table 1.

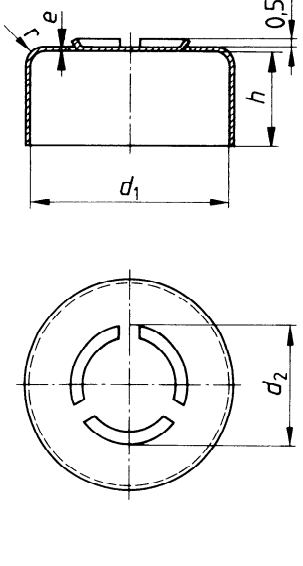
Dimensions in millimetres



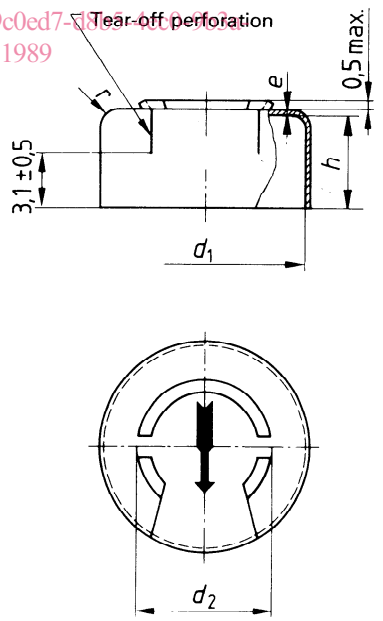
a) Type A — Aluminium cap with centre hole



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



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



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 $^{+0,1}_{0}$	d_2 ±0,2 Type			e[1]	h ±0,2	r ±0,2
		A	B and C	D			
13	13,3	6	8	9	0,242 max.	6,3	1,2
20	20,3		10	13	0,168 min.	7,3	

1) 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.

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.

For 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.

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.

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

Force in newtons

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

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[1]	50	5	25

1) 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.

UDC 615.014.87-034.71 : 666.171 : 615.456.014.83

Descriptors : medical equipment, parenteral infusion equipment, containers, flasks, aluminium products, caps (containers), specifications, dimensions, designation.

Price based on 3 pages