INTERNATIONAL STANDARD

ISO 8362-2

Second edition
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Injection containers and accessories —

Part 2: Closures for injection vials

Récipients et accessoires pour produits injectables —

Partie 2: Bouchons pour flacons

Reference number
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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 8362-2 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 8362-2:1988) which has been technically revised in order to align this part with ISO 8871-1, ISO 8871-4 and ISO 8871-5.

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 purpose of this part of ISO 8362 is to specify the shape and dimensions of, and the requirements for, elastomeric closures intended for pharmaceutical use. Closures made from elastomeric materials are suitable primary packaging materials for parenteral preparations. In order to provide seal integrity of the container closure systems the dimensions of the elastomeric closures have to be compatible with the dimensions of the glass vials and the caps as specified in corresponding parts of ISO 8362.

Primary packaging components made of elastomeric materials are an integral part of medicinal products and thus the principles of current Good Manufacturing Practices (cGMP) apply to the manufacturing of these components.

Principles of cGMP are described in, for example, ISO 15378 or GMP Guidelines as published by the European Community and the United States of America.

Injection containers and accessories —

Part 2:
Closures for injection vials

1 Scope

This part of ISO 8362 specifies the shape, dimensions, material, performance requirements and labelling of closures for injection vials covered by ISO 8362-1 and ISO 8362-4.

The dimensional requirements are not applicable to barrier-coated closures.

Closures specified in this part of ISO 8362 are intended for single use only.

NOTE The potency, purity, stability and safety of a medicinal product during its manufacture and storage can strongly be affected by the nature and performance of the primary packaging.

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 48, *Rubber, vulcanized or thermoplastic — Determination of hardness (hardness between 10 IRHD and 100 IRHD)*

ISO 3302-1, *Rubber — Tolerances for products — Part 1: Dimensional tolerances*

ISO 3302-2, *Rubber — Tolerances for products — Part 2: Geometrical tolerances*

ISO 7619-1, *Rubber, vulcanized or thermoplastic — Determination of indentation hardness — Part 1: Durometer method (Shore hardness)*

ISO 8871-1, *Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 1: Extractables in aqueous autoclavates*

ISO 8871-4, *Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 4: Biological requirements and test methods*

ISO 8871-5:2005, *Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 5: Functional requirements and testing*

3 Classification

Closures for injection vials shall be classified as follows:

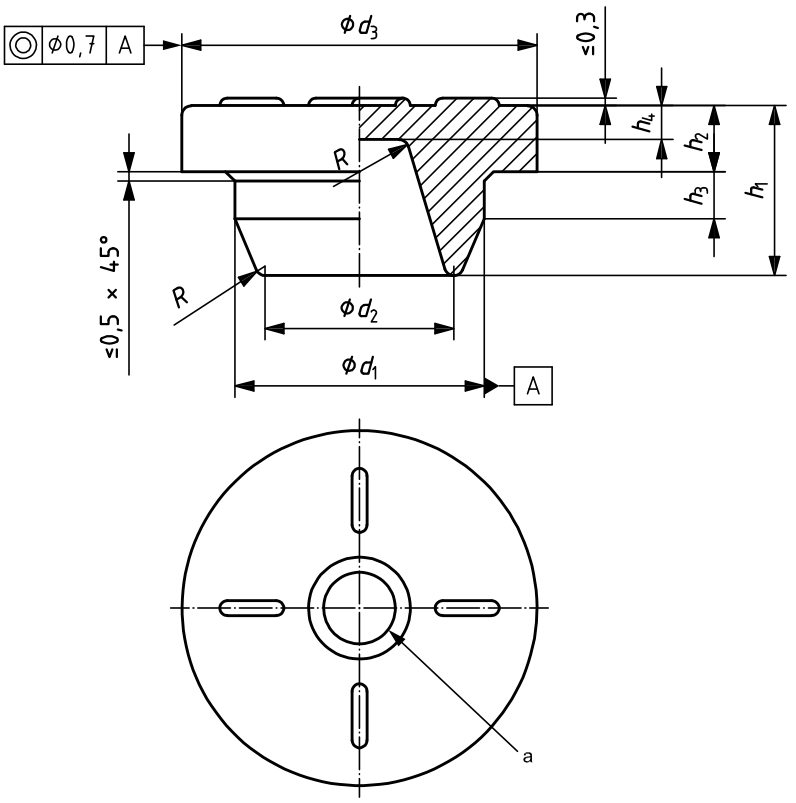
— Type A: closures for injection vials without no-pop/blow-back feature.

— Type B: closures for injection vials with no-pop/blow-back feature.

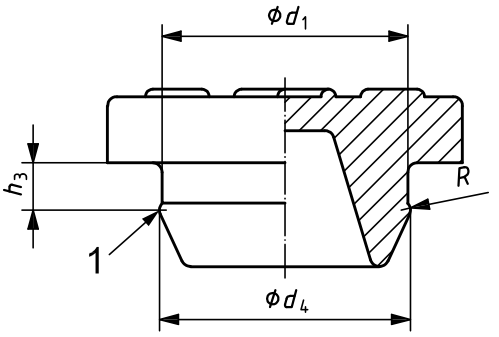
4 Shape and dimensions

4.1 The shape and dimensions of closures shall be as shown in Figure 1 and as given in Table 1. Figure 1 illustrates two types of closures, Types A and B.

Dimensions in millimetres



a) Type A



b) Type B

Key

1 no-pop/blow-back feature

[a] Inner diameter shall not be wider than inner lumen.

Figure 1 — Dimensions and configuration of Types A and B closures

Table 1 — Dimensions of injection closures

Dimensions in millimetres

Type	Nominal size	d_1 ± 0,15	d_2 max.	d_3 ± 0,2	d_4 ± 0,2	h_1 min.	h_2 ± 0,25	h_3 min.	h_4 min.	Injection vials	
										ISO 8362-1	ISO 8362-4
A	13	7,50	5	12,5	—	6,2	2,00	2,0	1,5	2 R and 4 R	—
	20	13,20	10	18,8	—	8,5	3,30	2,0	1,5	6 R to 30 R	5 H to 100 H
B	13	7,40	5	12,5	7,6	6,2	2,00	2,0	1,5	—	2 I to 10 I
	20	13,00	10	18,8	13,3	8,5	3,30	2,0	1,5	—	6 H to 100 H

4.2 If not otherwise specified, general dimensional tolerances shall be in accordance with ISO 3302-1 and ISO 3302-2.

4.3 If spacers are located on top of the flange, they shall not interfere with the marks for the piercing area (see Figure 1). The height of the spacers shall not exceed 0,3 mm.

NOTE The spacers in Figure 1 for Type A and Type B closures are shown for illustrative purposes only and do not form part of the requirements of this part of ISO 8362.

4.4 If the flange of the closure has a slightly conical shape, it shall be 0,3 mm maximum in relation to the diameter in order to facilitate production. The tolerances of the trimming edge of the flange shall comply with the tolerances specified in Table 1 for diameter d_3.

4.5 All edges of the closure may be rounded.

5 Designation

Closures can be designated according to their type (see 4.1 and Figure 1). The designation is expressed as the number of this part of ISO 8362 followed by the nominal size of the closure followed by the type letter.

EXAMPLE A Type A closure for injection vials of nominal size 13 complying with the requirements laid down in this part of ISO 8362 is designated as follows:

Injection closure ISO 8362-2 - 13 - A

6 Material

The elastomeric material used shall meet the requirements specified in Clause 7.

The elastomeric material shall withstand two sterilization cycles when autoclaving in saturated steam at (121 ± 2) °C for 30 min without exceeding the specified limits and without impairment of its performance characteristics under the conditions of normal use. In case other sterilization methods are used, e.g. irradiation, the suitability of the material shall be evaluated.

Closures shall be made from the elastomeric formulation originally tested and approved by the end user. The closure manufacturer shall ensure the conformance of each delivery with the type sample and the compliance with previously agreed functional and compendial requirements.

7 Performance requirements

7.1 General

The requirements specified in 7.2 to 7.4 represent minimum requirements which refer to the condition of the elastomeric closures on receipt by the user.

7.2 Physical requirements

7.2.1 Hardness

The hardness agreed between manufacturer and user shall not differ from the nominal value by more than ± 5 Shore A when tested in accordance with ISO 7619-1 on a special test specimen. Alternatively, the hardness can be tested on the closures in accordance with ISO 48. If tested in accordance with ISO 48, the microhardness shall not differ by more than ± 5 IRHD from the type sample.

7.2.2 Penetrability

The requirements of ISO 8871-5:2005, 4.1, shall apply.

7.2.3 Fragmentation

The requirements of ISO 8871-5:2005, 4.2, shall apply.

7.2.4 Self-sealing and container closure seal integrity

The requirements of ISO 8871-5:2005, 4.3, shall apply.

7.2.5 Container closure seal integrity

The requirements of ISO 8871-5:2005, 4.4, shall apply. If the test specimen complies with 7.2.4, the requirements of this subclause have also been met and separate testing according to this subclause is not needed.

7.2.6 Resistance to ageing

The maximum time between the date of manufacture and pharmaceutical use should be agreed upon between the manufacturer of the closures and the user.

The closures shall maintain their performance characteristics throughout the entire shelf-life of the medicinal product, which is tested as part of the stability test by the user.

NOTE Ageing depends upon the storage and handling conditions. Guidelines for storage of vulcanized rubber are given in ISO 2230.

7.3 Chemical requirements

The requirements of ISO 8871-1 shall apply.

7.4 Biological requirements

The requirements of ISO 8871-4 shall apply.

8 Labelling

Packed closures that meet the requirements of this part of ISO 8362 may be labelled with the designation given in Clause 5.

Bibliography

[1] ISO 2230, *Rubber products — Guidelines for storage*

[2] ISO 15378, *Primary packaging materials for medicinal products — Particular requirements for the application of ISO 9001:2000, with reference to Good Manufacturing Practice (GMP)*

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