International Standard

ISO 8362-2

Fourth edition
2024-03

Injection containers and accessories —

Part 2: Closures for injection vials

Récipients et accessoires pour produits injectables —

Partie 2: Bouchons pour flacons

Reference number
ISO 8362-2:2024(en)

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Published in Switzerland

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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This document was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/SS S02, *Transfusion equipment,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This fourth edition cancels and replaces the third edition (ISO 8362-2:2015), which has been technically revised. It also incorporates the Amendment ISO 8362-2:2015/Amd 1:2022.

The main changes are as follows:

— the tolerance for h_2 mm has been modified to ±0,25 as it has been proven well in industry, is well known and has historical relevance.

A list of all parts of the ISO 8362 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

The purpose of this document 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 document 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 document 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 documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 48-4, *Rubber, vulcanized or thermoplastic — Determination of hardness — Part 4: Indentation hardness by durometer method (Shore hardness)*

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

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

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

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

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 8871-5:2016, *Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 5: Functional requirements and testing*

3 Terms and definitions

No terms and definitions are listed in this document.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

4 Classification

Closures for injection vials shall be classified as follows:

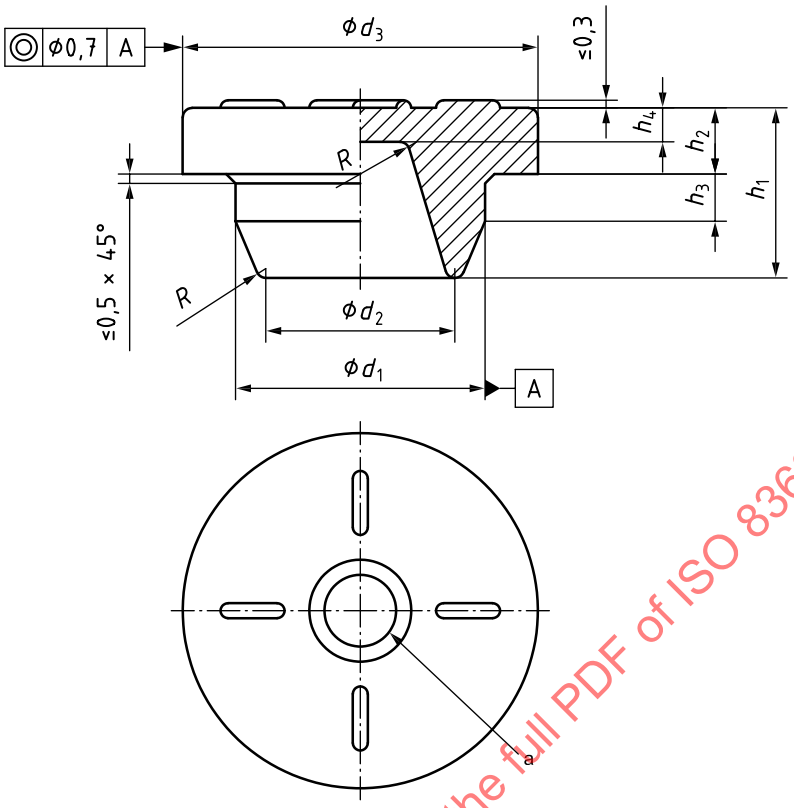
— Type A: closures for injection vials without no-pop/blow-back feature;

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

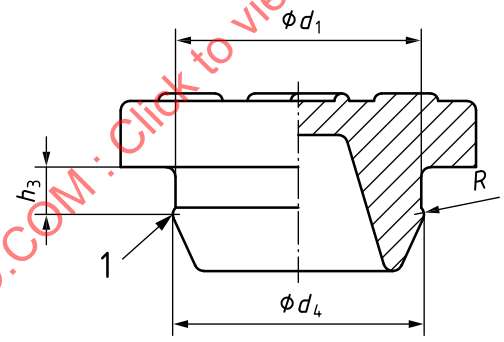
5 Shape and dimensions

5.1 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	7,5	5	12,5	—	6,2	2,0	2,0	1,5	2 R and 4 R	—
	20	13,2	10	18,8	—	8,5	3,3	2,0	1,5	6 R to 100 R	5 H to 100 H
B	13	7,4	5	12,5	7,6	6,2	2,0	2,0	1,5	—	2 I to 10 I
	20	13,0	10	18,8	13,3	8,5	3,3	2,0	1,5	—	6 H to 100 H

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

5.3 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 document.

5.4 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 conform with the tolerances specified in Table 1 for diameter, d_3.

5.5 All edges of the closure may be rounded.

6 Designation

Closures can be designated according to their type (see 5.1 and Figure 1). The designation is expressed as the number of this document 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 conforming with the requirements laid down in this document is designated as follows:

Injection closure ISO 8362-2 - 13 – A

7 Material

The elastomeric material used shall meet the requirements specified in Clause 8.

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, such as irradiation, are used, 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.

8 Performance requirements

8.1 General

The requirements specified in 8.2 to 8.4 represent minimum requirements which refer to the condition of the elastomeric closures on receipt by the user.

8.2 Physical requirements

8.2.1 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 48-4 on a special test specimen.

8.2.2 Penetrability

The requirements of ISO 8871-5:2016, 4.1 shall apply.

8.2.3 Fragmentation

The requirements of ISO 8871-5:2016, 4.2 shall apply.

8.2.4 Self-sealing and aqueous solution tightness test

The requirements of ISO 8871-5:2016, 4.3 shall apply.

8.2.5 Aqueous solution tightness

The requirements of ISO 8871-5:2016, 4.4 shall apply. If the test specimen conforms with 8.2.4, the requirements of this subclause have also been met and separate testing according to this subclause is not needed.

8.2.6 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.

8.3 Chemical requirements

The requirements of ISO 8871-1 shall apply.

8.4 Biological requirements

The requirements of ISO 8871-4 shall apply.

8.5 Particulate contamination requirements

Closures should be manufactured such that particulate contamination is minimized. The specification and method should be agreed upon by the manufacturer of the closure and the user. It is recommended that closures be tested according to ISO 8871-3.

9 Labelling

Packed closures that meet the requirements of this document may be labelled with the designation given in Clause 6.