
Snap-on bottles for metering pumps —
Part 1:
Tubular glass

Flacons encliquetables pour pompes doseuses —
Partie 1: Verre étiré

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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.

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 documents 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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*.

A list of all parts in the ISO 24166 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

This document is part of a series of International Standards for containers made from different materials used in combination with metering pumps for medicinal applications.

Glass containers are mainly used for that purpose. Plastic containers can be used as an alternative.

This document can be used for the development of standardized filling and assembling equipment.

Based on the dimensions of the containers, appropriate components, such as metering pumps and other closure systems can also be standardized. As such, this document provides important inputs for developing entire packaging systems for medicinal applications.

Primary packaging materials are an integral part of medicinal products. Thus, depending on the jurisdiction, the principles of the current Good Manufacturing Practices (cGMP) can apply to the manufacturing of these components (e.g. ISO 15378).

The containers referred to as bottles in the title of this document are usually referred to as “vials” if they are made of tubular glass. For this reason, the text of this document refers to “vials” rather than “bottles” in order to differentiate them from containers made of moulded glass and plastic.

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Snap-on bottles for metering pumps —

Part 1: Tubular glass

1 Scope

This document specifies the shape, dimensions, fill capacities and performance requirements of tubular glass vials for metering pumps. It also specifies the material for the manufacturing of such containers as well as the secondary packaging.

This document provides also requirements for packaging of the tubular glass vials and addresses nonsterile, ready to sterilize or sterile as three possible options.

This document is applicable to colourless or amber containers made of tubular glass and intended to be used for packaging, storage or transportation of products intended for medicinal use.

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 719, *Glass — Hydrolytic resistance of glass grains at 98 °C — Method of test and classification*

ISO 720, *Glass — Hydrolytic resistance of glass grains at 121 °C — Method of test and classification*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 11607-2, *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes*

ISO 4802-1, *Glassware — Hydrolytic resistance of the interior surfaces of glass containers — Part 1: Determination by titration method and classification*

ISO 4802-2, *Glassware — Hydrolytic resistance of the interior surfaces of glass containers — Part 2: Determination by flame spectrometry and classification*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

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/>

3.1

base foil

packaging component for protection of the pallet load from contamination

3.2
bottle
vial

container made of a suitable material, which is intended for packaging, storage and application of liquid medicinal products

EXAMPLE Tubular glass, moulded glass or plastic.

3.3
brimful capacity

volume of water required to fill a container, placed on a flat, horizontal surface

[SOURCE: ISO 4802-1:2016, 3.3]

3.4
chemical indicator

test system that reveals change in one or more pre-defined process variables based on a chemical change resulting from exposure to a process

[SOURCE: ISO 11139:2018, 3.43, modified — "pre-specified" was replaced with "pre-defined", "or physical" was deleted.]

3.5
customer

business entity that purchases bottles for metering pumps and conducts further processing or filling as appropriate

[SOURCE: ISO 21882:2019, 3.1 modified — "sterilized ready for filling vials" was replaced with "bottles for metering pumps".]

3.6
dip-tube

conduit, part of the metering pump, which delivers the product from the vial to the metering mechanism

3.7
foil bag

gas permeable or non-permeable bag

Note 1 to entry: Foil bags can be used as *sterile barrier system* (3.16) or as *protective packaging* (3.13), depending on final usage.

3.8
label

written, printed or graphic information appearing on the item itself, on the packaging of each item or on the packaging of multiple items

[SOURCE: IMDRF/GRRP WG/N52:2019, 3.17, modified – replaced "unit" and "devices" with "item".]

3.9
manufacturer

business entity that manufactures or is otherwise responsible for the manufacturing of the bottles ready to be filled by the *customer* (3.5)

[SOURCE: ISO 21882:2019, 3.4, modified — "performs" was replaced with "manufactures", "vials" was replaced with "bottles".]

3.10
metering pump

device actuated by the user to deliver a specific dose of liquid

3.11**packaging system**

combination of a sterile barrier system and protective packaging

[SOURCE: ISO 11139:2018, 3.192]

3.12**pallet**

construction for transportation and storage of goods

3.13**protective packaging**

configuration of materials designed to prevent damage to the sterile barrier system and its contents from the time of their assembly until the point of use

[SOURCE: ISO 11139:2018, 3.219]

3.14**sealing ring**

bottle feature on top of the flange to support tightness

3.15**snap-on bottle**

container with press-fit for metering pumps

3.16**sterile barrier system****SBS**

minimum package that minimizes the risk of ingress of microorganisms and allows aseptic presentation of the sterile contents at the point of use

[SOURCE: ISO 11139:2018, 3.272]

3.17**transport cover**

outside packaging layer protecting against environmental hazards and keeping the package units in place

4 Symbols

t	bottom concavity
d_1	outer diameter body
d_2	outer diameter neck
h_1	total length
h_2	length cylindrical part of the body
h_3	inner depth
r_1	shoulder radius
r_2	bottom radius
s_1	wall thickness body
s_2	wall thickness bottom

a circular run-out tolerance

T tubular

5 Dimensions

5.1 General

The dimensions including tolerances are a function of manufacturing processes and materials.

The dimensions and tolerances are established to achieve a neck that allows a snap-on functionality with the metering pump. This functionality can be challenged by a tightness test. An example of a snap-on process including positioning of the dip-tube as well as a typical tightness test is given in [Annex A](#) and [Annex B](#).

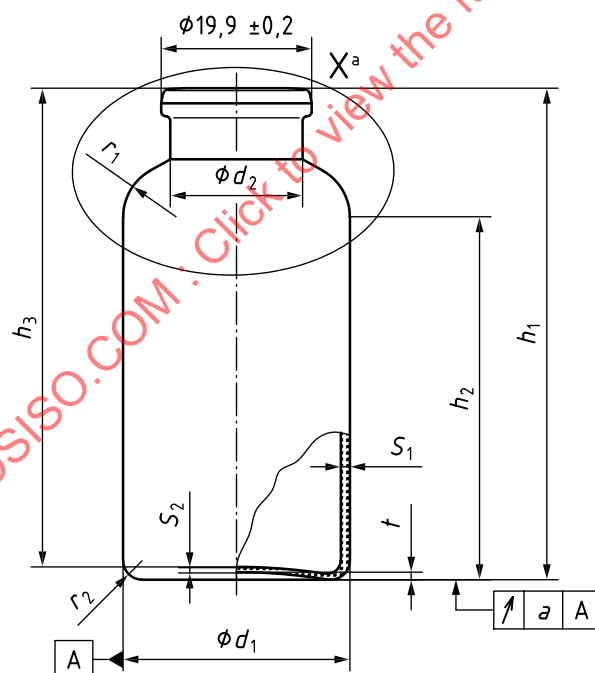
A test method for the inner depth as shown in [Table 1](#) and [Table 2](#) is described in [Annex C](#).

The vials can be manufactured with or without a sealing ring.

5.2 Vials without sealing ring

The dimensions of snap-on vials made of tubular glass shall meet the requirements of [Figure 1](#) and [Figure 2](#), as appropriate, and [Table 1](#). The brimful capacity shall be as shown in [Table 1](#).

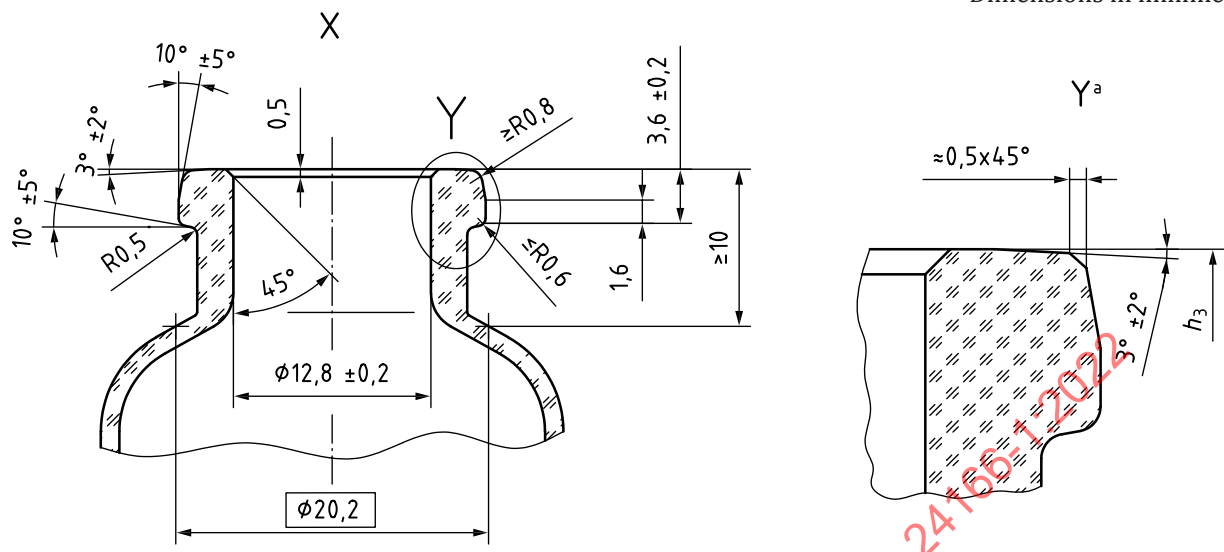
Dimensions in millimetres



a See [Figure 2](#).

Figure 1 — Snap-on vials without sealing ring

Dimensions in millimetres



a MinR0,8 (a chamfer shaped with $\approx 45^\circ$ and rounded edges is alternatively also feasible).

Figure 2 — Vial neck without sealing ring

Table 1 — Brimful capacity, mass and dimensions of snap-on vials made of tubular glass without sealing ring

Dimensions in millimetres

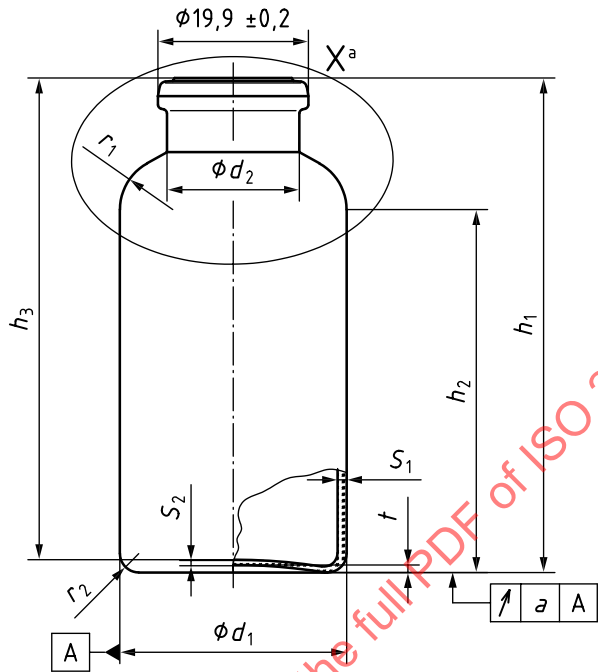
Size of vial	Brimful capacity		d_1		d_2	h_1		h_2	h_3		r_1	r_2	s_1		s_2	t	a	Mass approx.	
	ml	tol.		Tol.	max.		Tol.	min.		Tol.	≈	≈		Tol.	min.	max.		clear	g
6T	10,0	±0,5	22,0			40,0		26,0	38,5		3,5							8,0	8,3
8T	11,5	±0,5				45,0		31,0	43,5									8,9	9,2
10T	13,5	±1,0	±0,2		16,5	45,0	±0,5	29,0	43,5	±1,1	4,0		1,0	±0,04	0,7		0,6	9,3	9,6
12T	16,4	±1,0				53,0		37,0	51,5									10,8	11,1
15T	19,0	±1,0	24,0			60,0		44,0	58,5						0,7			12,0	12,5
20T	26,0	±1,5				55,0		35,0	53,1									16,4	17,0
25T	32,5	±1,5	±0,25		17,5	65,0	±0,7	45,0	63,1	±1,6	5,5	2,5	1,2	±0,05		1,0	0,7	19,0	19,6
30T	37,5	±1,5				75,0		55,0	73,1									21,5	22,2
50T	62,0	±4,0	±0,4			73,0	±0,75	49,0	70,6	±1,9	6,0	4,0	1,5	±0,07	0,9	1,5	0,9	33,7	34,9
100T	123,0	±7,0	±0,5			100,0		75,0	97,4	±2,0	6,5		1,7				1,1	60,2	62,2

Due to the manufacturing process, dimension h_3 (inner depth) is a resulting dimension of total length (h_1), bottom wall-thickness (s_2) and bottom concavity (t). Bottom forming is the last step in the vial forming process and this results in the total length of the vials. The bottom wall-thickness of the vials is controlled by the glass temperature and thus h_3 is the resulting dimension. The usual tolerance chain consideration for h_1 , h_3 , s_2 and t can therefore not apply here.

5.3 Vials with sealing ring

The dimensions of snap-on vials made of tubular glass shall meet the requirements of [Figure 3](#) and [Figure 4](#), as appropriate, and [Table 2](#). The brimful capacity shall be as shown in [Table 2](#).

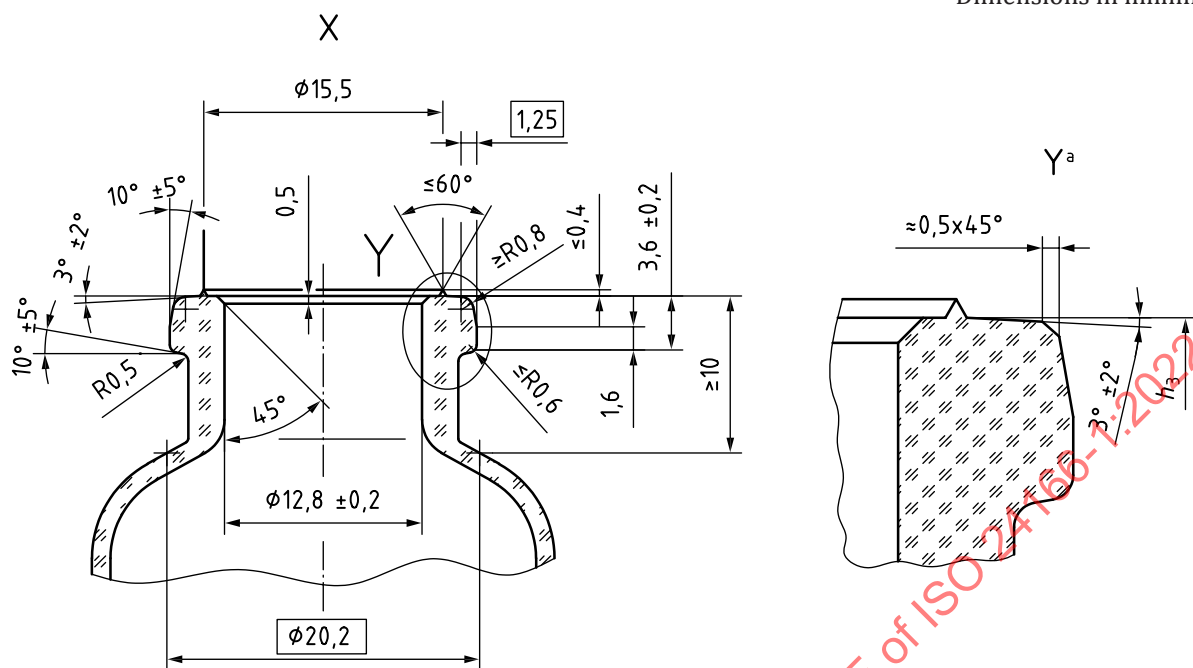
Dimensions in millimetres



^a See [Figure 2](#).

Figure 3 — Snap-on vial with sealing ring

Dimensions in millimetres



- ^a MinR0,8 (a chamfer shaped with $\approx 45^\circ$ and rounded edges is alternatively also feasible).

Figure 4 — Vial neck with sealing ring

Table 2 — Brimful capacity, mass and dimensions of snap-on vials made of tubular glass with sealing ring

Dimensions in millimetres

Size of vial	Brimful capacity		d_1		d_2	h_1		h_2	h_3		r_1	r_2	s_1		s_2	t	a	Mass approx. g	
	ml	Tol.		Tol.	max.		Tol.	min.		Tol.	≈	≈			ml	Tol.		Tol.	max.
6T	10,0	±0,5	22,0			40,4		26,0			3,5							8,0	8,3
8T	11,5	±0,5				45,4		31,0										8,9	9,2
10T	13,5	±1,0	24,0	±0,2	16,5	45,4	±0,5	29,0	±1,1		4,0	2,0	1,0	±0,04	0,7	0,6		9,3	9,6
12T	16,4	±1,0				53,4		37,0										10,8	11,1
15T	19,0	±1,0				60,4		44,0										12,0	12,5
20T	26,0	±1,5				55,4		35,0										16,4	17,0
25T	32,5	±1,5	30,0	±0,25	17,5	65,4	±0,7	45,0	±1,6		5,5	2,5	1,2	±0,05	1,0	0,7		19,0	19,6
30T	37,5	±1,5				75,4		55,0										21,5	22,2
50T	62,0	±4,0	40,0	±0,4		73,4	±0,75	49,0	±1,9		6,0	4,0	1,5	±0,07	0,9	1,5	0,9	33,7	34,9
100T	123,0	±7,0	47,0	±0,5		100,4		75,0										60,2	62,2

Due to the manufacturing process, dimension h_3 (inner depth) is a resulting dimension of total length (h_1), bottom wall-thickness (s_2) and bottom concavity (t). Bottom forming is the last step in the vial forming process and this results in the total length of the vials. The bottom wall-thickness of the vials is controlled by the glass temperature and thus h_3 is the resulting dimension. The usual tolerance chain consideration for h_1 , h_3 , s_2 and t can therefore not apply here.

≈ Approximately

6 Materials

Materials for tubular glass vials for use with metering pumps shall be suitable for the manufacturing process, the sterilization method, storage, and fill-finish process with assembly of metering pumps.

Colourless (cl) or amber (br) borosilicate glass or soda-lime glass of one of the following hydrolytic resistance grain classes shall be used:

- ISO 720 – HGA 1;
- ISO 719 – HGB 3 or ISO 720 – HGA 2.

The following should be considered depending on the application and the intended use, as specified by the customer:

- conformity to applicable pharmacopoeia monographs;
- material composition requirements to meet specific drug/container interactions;
- shelf-life limitation requirements.

7 Requirements

7.1 General requirements

The following requirements shall be met to enable the functionality between the vial and the metering pump:

- snap-on vial sealing surfaces shall be free from grooves, ripples and undulations sufficient to affect the sealing performance when combined with the metering pump;
- the bottom shall have a shape and an inner surface that allows the dip-tube of the metering pump moving into a position of the vial to minimize the residual volume;
- the supplier and the customer shall agree on the specifications for such sealing and bottom surfaces.

7.2 Physical requirements

7.2.1 Vertical force

The vials shall resist a vertical force of min. 600 N. The supplier and the customer shall agree on an Acceptable Quality Limit (AQL) for this limit value. A test method is given in [Annex D](#).

7.2.2 Particulate contaminations

Tubular glass vials for snap-on metering pumps shall be manufactured by processes that minimize the risk of particulate contamination.

The manufacturer and the customer should agree upon the size and number of visible particles and the test method.

NOTE 1 Currently no particle specifications are assigned for sub-visible particles regarding devices for non-parenteral products.

NOTE 2 Current pharmacopoeias identify visible particulates as undesirable but do not define the size or put a limit on the allowable number for non-parenteral products.

7.3 Chemical requirements

Tubular glass vials shall have hydrolytic resistance requirements as described in ISO 4802-1 and/or ISO 4802-2.

7.4 Sterilization

If the tubular glass vials are provided sterile, the sterilization method shall be validated in accordance with a suitable sterilization International Standard (e.g. ISO 11135, ISO 17665-1, ISO 11137-1 or ISO 14937).

NOTE Gamma irradiation is typically not used for clear glass as it causes a yellow discoloration.

8 Marking of the vial

Since marking of individual tubular glass vials is not possible for technical reasons, see [9.1](#).

9 Packaging options

9.1 General packaging requirements

In general, there are three different conditions of packaging for the vials due to the requirements of the customer. The product can be provided nonsterile, ready to sterilize or sterile.

The packaging shall protect the product from alteration, contamination or damage when exposed to expected conditions and hazards during processing, storage, handling and distribution.

All packaging configurations shall include the following parts (from outside to inside):

- pallet;
- label;
- transport cover;
- foil bags.

NOTE It can be agreed between customer and supplier to use an additional holding tray to ensure that the vial rows maintain in place in the foil bag and/or to support the de-packing operation at the customer or to add an additional pallet protection, e.g. base foil.

An example is given in [Annex E](#).

9.2 Packaging for nonsterile glass vials

This packaging configuration is not designed for sterilization of the vials. In addition to the packaging components specified in [9.1](#), the glass vials shall be packaged in double foil bags with a closure or seal that prevents contamination of the content.

9.3 Ready to sterilize or sterile glass vials

The packaging shall be designed and validated as a packaging system with protective packaging and sterile barrier system(s) in accordance with the requirements of ISO 11607-1 and ISO 11607-2 and compatible with the selected sterilization process. In addition to the packaging components specified in [9.1](#), the following requirements apply:

- the vials shall be sealed in minimum 2 layers of foil bags. As a minimum, the last inner layer foil bag shall be designed and validated as a SBS. Further foil bags can be validated as a SBS depending on the requirement of the customer.

- the packaging shall be provided with an appropriate chemical indicator that indicates that the product has been exposed to the specified sterilization process.

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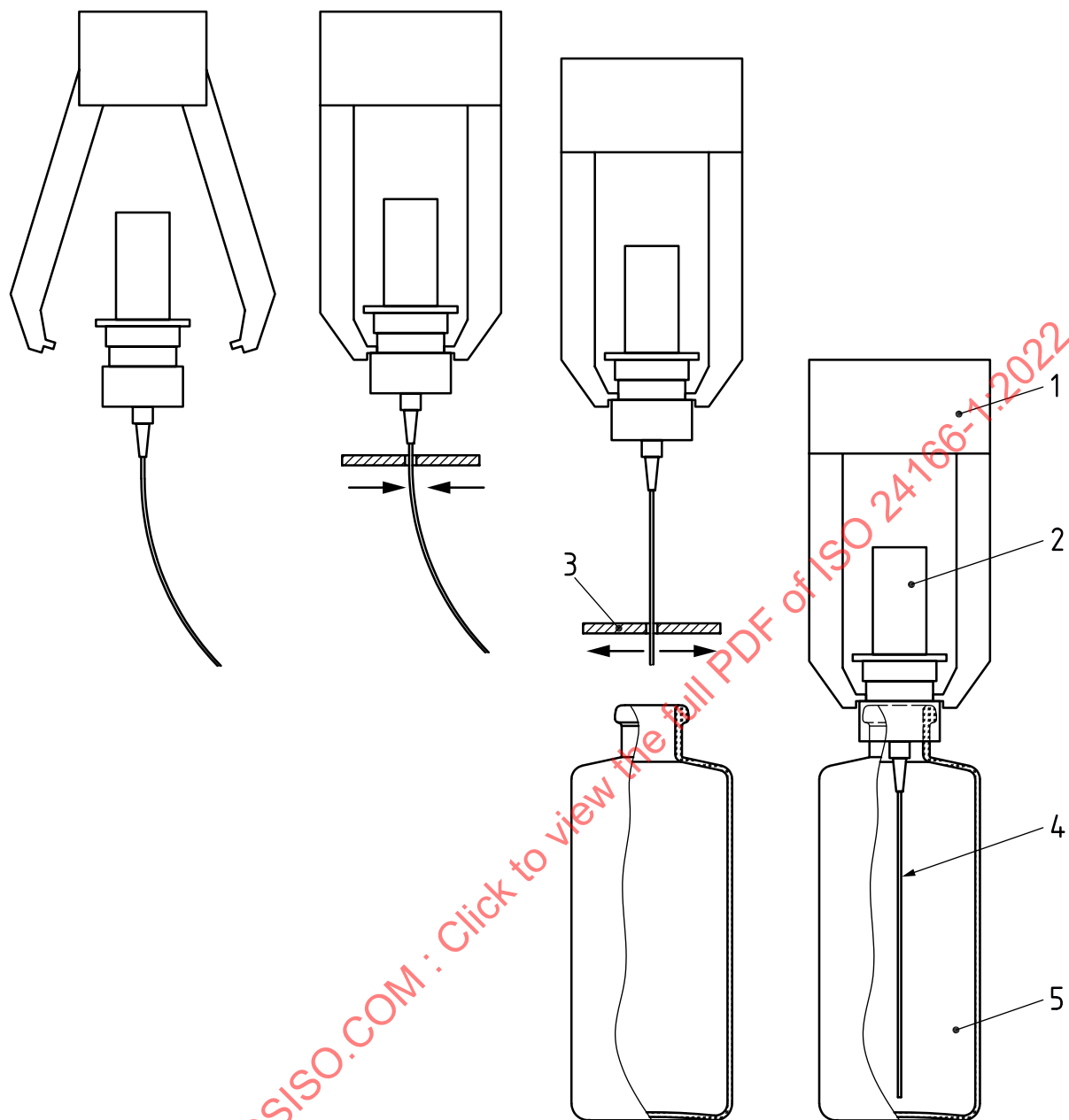
Annex A (informative)

Snap-on considerations

The following considerations are important for an efficient and safe snap-on process:

- the neck finish dimensions (see [Clause 5](#));
- the material of the vial;
- the correct positioning of metering pump, dip-tube and vial;
- the way how the force is applied to achieve the snap on.

[Figure A.1](#) shows an example of a snap-on process using a mechanical gripper system and a dip-tube stripper prism that maintains the dip-tube in a middle position. In this example, the force is transferred over the metering pump snap body, and not over the nasal adapter, to ensure that the resulting pressure is distributed evenly over the entire closure sealing rim.



Key

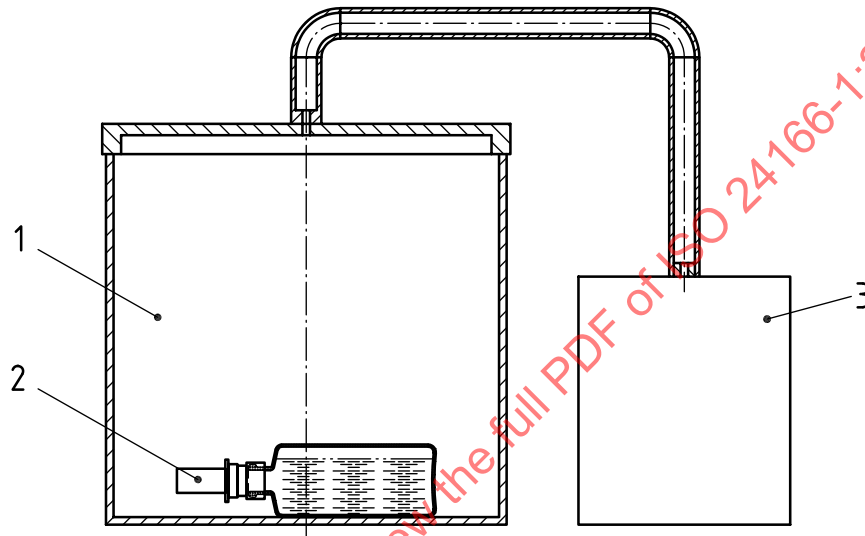
- 1 mechanical gripper system
- 2 metering pump
- 3 dip-tube stripper prism
- 4 dip-tube
- 5 vial

Figure A.1 — Snap-on process

Annex B (informative)

Tightness test

This annex proposes a test method suitable for verifying the integrity of the entire system. An example of a test equipment is shown in [Figure B.1](#).



Key

- 1 desiccator
- 2 test device filled with liquid, e.g. methylene blue solution
- 3 vacuum pump

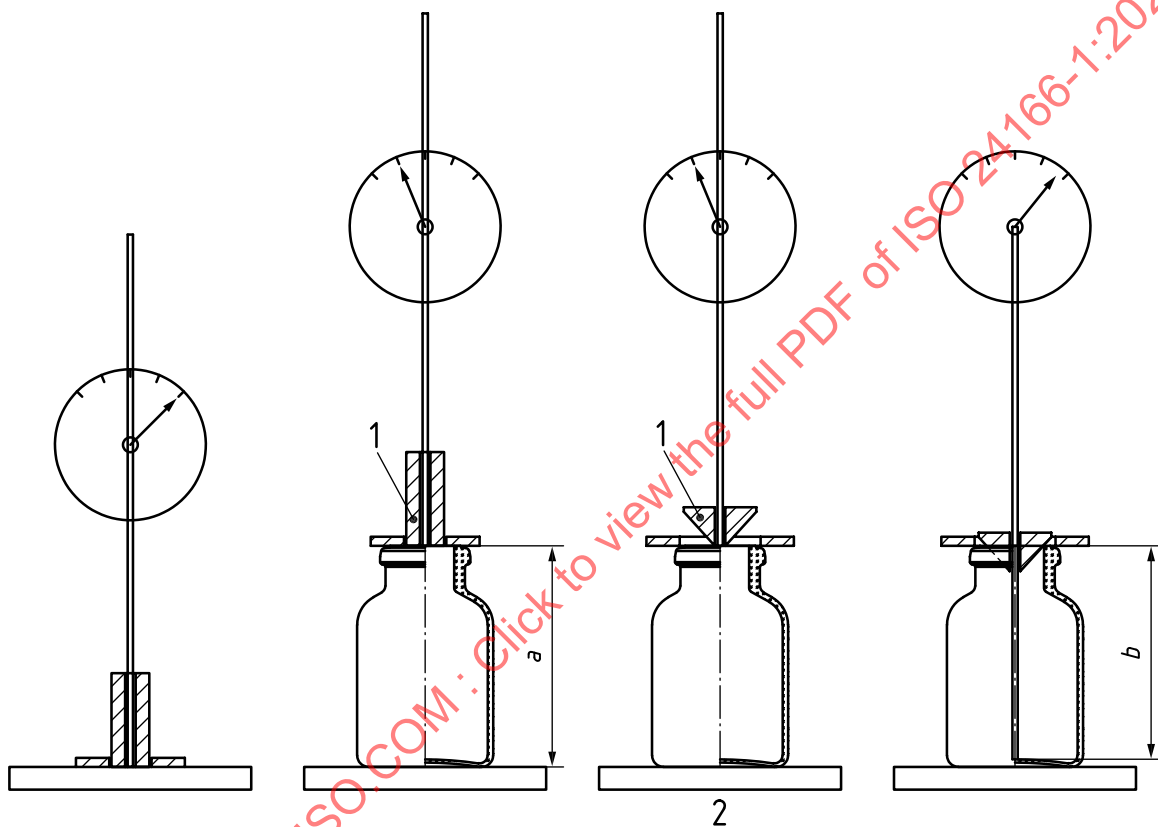
Figure B.1 — Schematic test description

The filled device is placed for 10 min in a desiccator at 500 hPa absolute pressure. After the storage time the system is checked if any liquid leaked from the container. If yes, the test failed.

Annex C (informative)

Inner depth measuring

Place the vial on a flat, horizontal surface. The inner depth of the vial results from the approached highest point at the neck finish area and the centre of the bottom of the vial. An example of a measuring device is shown in [Figure C.1](#).



Key

- 1 centring
- 2 90°-rotated view
- a* vial height
- b* inner depth

Figure C.1 — Vial inner depth measurement