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Snap-on bottles for metering pumps —

Part 3: Plastic

Flacons encliquetables pour pompes doseuses —

Partie 3: Plastique

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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).

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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 be developed and 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).

Snap-on bottles for metering pumps —

Part 3:
Plastic

1 Scope

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

The document provides requirements for packaging of the plastic bottles and addresses nonsterile, ready to sterilize or sterile as three possible options.

This document is applicable to colourless or coloured containers moulded from plastic and intended to be used in the 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 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*

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 bottle 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* (3.17) 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* (3.4)

[SOURCE: ISO 21882:2019, 3.14 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
shipper box
protective packaging for the foil bags

3.16
snap-on bottle
container with press-fit for metering pumps

3.17
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]

3.18
transport cover
outside packaging layer protecting against environmental hazards and keeping the *shipper boxes* (3.15) in place

4 Symbols

t	bottom concavity
d_1	outer diameter body
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
P	plastic

5 Dimensions

5.1 General

The dimensions including tolerances are a function of manufacturing processes and materials. The currently practiced processes to achieve the required tolerances are Injection Blow Molding (IBM) and Injection Stretch Blow Molding (ISBM).

To achieve the specified dimensions and tolerances, it is recommended that the offset of the mould halve and insert for forming the neck finish are vertically max. 0,05 mm and horizontally max. 0,1 mm.

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.

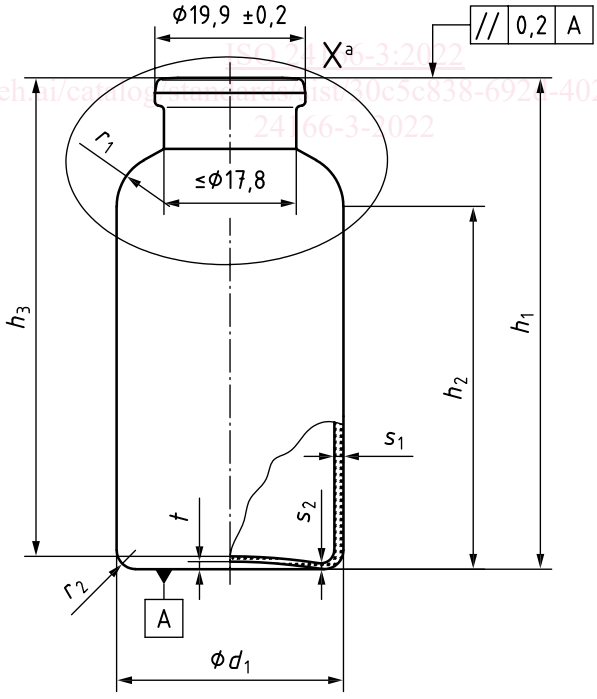
The material and wall thickness, s_1, shall meet the specified performance properties, e.g. oxygen and water vapour permeability and shall resist the vertical load as explained in 7.2.

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

5.2 Bottles without sealing ring

The dimensions of snap-on bottles made of plastic 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.

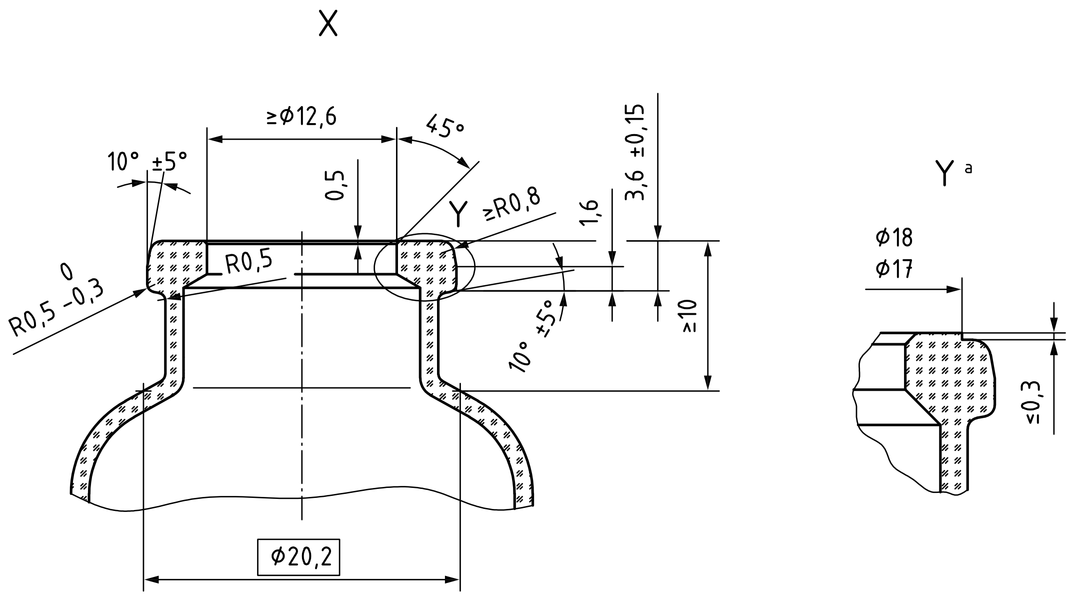
Dimensions in millimetres



[a] See Figure 2.

Figure 1 — Snap–on bottle without sealing ring

Dimensions in millimetres



[a] Flat neck finish (an offset 0,3 is alternatively also feasible).

Figure 2 — Neck finish without sealing ring

Table 1 — Brimful capacity and dimensions of snap-on bottles made of plastic without sealing ring

Dimensions in millimetres

<table>
<tr><th rowspan="2">Size of the bottle</th><th colspan="2">Brimful capacity ml</th><th colspan="2">d_1</th><th colspan="2">h_1</th><th>h_2</th><th colspan="2">h_3</th><th>r_1</th><th>r_2</th><th>s_1</th><th>s_2</th><th>t</th></tr>
<tr><th></th><th>Tol.</th><th></th><th>Tol.</th><th></th><th>Tol.</th><th></th><th></th><th>Tol.</th><th></th><th></th><th>min.</th><th>min.</th><th>min.</th></tr>
<tr><td>5P</td><td>9,2</td><td rowspan="3">±1,0</td><td>22,0</td><td rowspan="3">±0,3</td><td>40,0</td><td rowspan="2">±0,5</td><td>23,5</td><td>38,4</td><td rowspan="7">±0,5</td><td>4,0</td><td>2,5</td><td rowspan="4">0,6</td><td rowspan="4">0,4</td><td rowspan="7">1,0</td></tr>
<tr><td>10P</td><td>16,8</td><td rowspan="2">25,5</td><td>49,2</td><td>29,5</td><td>45,3</td><td>5,0</td><td>2,5</td></tr>
<tr><td>15P</td><td>19,7</td><td>55,3</td><td rowspan="2">±0,6</td><td>35,0</td><td>52,2</td><td>3,0</td><td>2,0</td></tr>
<tr><td>20P</td><td>25,5</td><td rowspan="3">±1,5</td><td rowspan="2">31,0</td><td rowspan="2">±0,4</td><td>50,7</td><td>27,5</td><td>48,0</td><td rowspan="2">6,0</td><td rowspan="2">3,0</td></tr>
<tr><td>30P</td><td>35,0</td><td>65,2</td><td>±0,7</td><td>42,0</td><td>61,8</td><td rowspan="3">0,8</td><td rowspan="3">0,5</td></tr>
<tr><td>50P</td><td>60,5</td><td>35,0</td><td rowspan="2">±0,5</td><td>85,6</td><td>±0,8</td><td>59,0</td><td>82,0</td><td rowspan="2">7,0</td><td>3,5</td></tr>
<tr><td>100P</td><td>118,0</td><td>±3,0</td><td>44,5</td><td>99,3</td><td>±1,0</td><td>75,0</td><td>95,0</td><td>4,5</td></tr>
<tr><td colspan="15">Wall thickness, s_1, shall be sufficient to resist the vertical force requirements.</td></tr>
</table>

5.3 Bottles with sealing ring

The dimensions of snap-on bottles made of plastic shall meet the requirements of Figure 3, Figure 4 and Table 2. The brimful capacity shall be as shown in Table 2.