INTERNATIONAL STANDARD

**ISO 9187-1**

Fourth edition
2010-10-15

# Injection equipment for medical use —

## Part 1: Ampoules for injectables

*Matériel d'injection à usage médical —*

*Partie 1: Ampoules pour produits injectables*

Reference number
ISO 9187-1:2010(E)



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Published in Switzerland

# Foreword

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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 9187-1 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical and pharmaceutical use*.

This fourth edition cancels and replaces the third edition (ISO 9187-1:2006), which has undergone a minor revision with the following modifications in Table 1.

— The base radius, $r$, has been modified for the 10 ml, 20 ml, 25 ml and 30 ml glass.

ISO 9187 consists of the following parts, under the general title *Injection equipment for medical use*:

— *Part 1: Ampoules for injectables*

— *Part 2: One-point-cut (OPC) ampoules*

# Introduction

Ampoules are suitable packaging materials for storing pharmaceutical products until they are administered to the patient. Owing to the direct contact between injectables and the primary container over extended storage periods, possible interactions are to be avoided in order to guarantee patient safety. Adequate means to achieve this objective include proper selection of primary packaging materials, the choice of suitable package design and the availability of specific requirements and methods for testing individual container systems.

In the past, four standardized forms of ampoule (forms A, B, C and D) have been in widespread use. However, form A is no longer used in the pharmaceutical industry and consequently has not been included in this part of ISO 9187. To avoid any confusion among manufacturers and users, it was decided to retain the same designation letters (i.e. B, C and D) for the forms of ampoules in current use and to disregard the letter A.

# Injection equipment for medical use —

# Part 1:
# Ampoules for injectables

## 1 Scope

This part of ISO 9187 specifies materials, dimensions, capacities, performance and packaging requirements for three forms of glass ampoule (forms B, C and D) for injectable pharmaceutical products.

It is applicable to ampoules with and without a colour break-ring; the provision of ampoules with a colour break-ring, and the choice of colour of the break-ring, is subject to agreement between the manufacturer and user.

Ampoules complying with this part of ISO 9187 are intended for single use only.

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

ISO 2859-1, *Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection*

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*

ISO 7500-1, *Metallic materials — Verification of static uniaxial testing machines — Part 1: Tension/ compression testing machines — Verification and calibration of the force-measuring system*

## 3 Dimensions and designation

### 3.1 Dimensions

The dimensions of ampoules shall be as shown in Figures 1, 2 and 3 (forms B, C and D respectively) and as given in Table 1.

### 3.2 Designation

Designation of ampoules shall consist of the descriptor word “ampoule”, followed by a reference to this part of ISO 9187, followed by the ampoule form, the nominal volume, the colour of the glass and, if applicable, mention of a colour break-ring.

EXAMPLE 1 Designation of a form B ampoule without colour break-ring with a nominal volume of 10 ml, made of colourless glass (cl) complying with the requirements of this part of ISO 9187:

**Ampoule ISO 9187-1 – B – 10 – cl**

EXAMPLE 2 Designation of a form B ampoule with a colour break-ring (cbr) with a nominal volume of 10 ml, made of colourless glass (cl) complying with the requirements of this part of ISO 9187:

**Ampoule ISO 9187-1 – B – 10 – cl – cbr**

## 4 Material

Colourless (cl) or amber (br) glass of hydrolytic resistance grain class HGA 1, in accordance with ISO 720, shall be used.

A change in the chemical composition of the glass material should be notified by the ampoule manufacturer to the user at least nine months in advance.

## 5 Requirements

### 5.1 Hydrolytic resistance

When tested in accordance with ISO 4802-1 and ISO 4802-2, the hydrolytic resistance of the internal surface of ampoules shall comply with the requirements specified for hydrolytic resistance container class $HC_T$ 1 and $HC_F$ 1 respectively

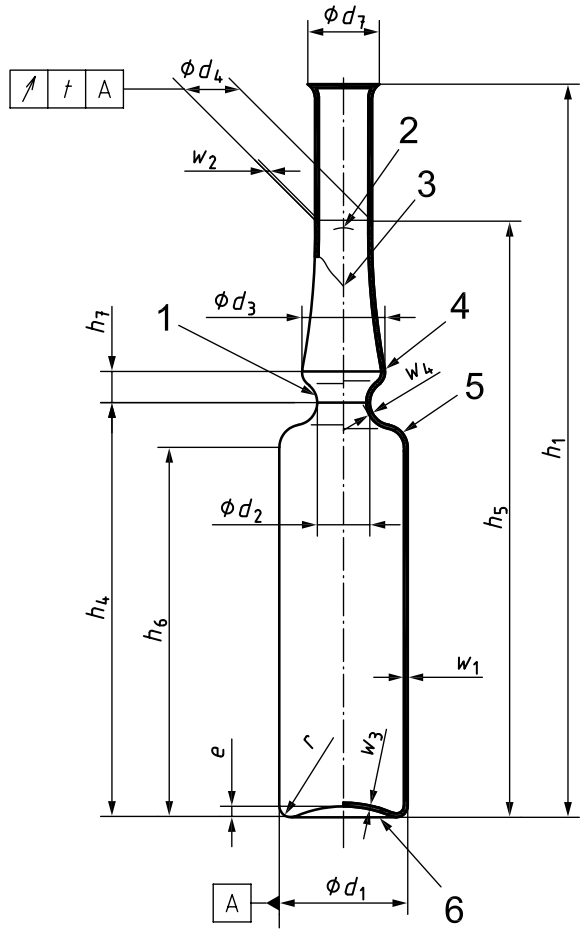
### 5.2 Annealing quality

Ampoules shall be annealed; the maximum residual stress of uncoloured ampoules after annealing shall not produce an optical retardation exceeding 50 nm/mm of glass thickness.

### 5.3 Breaking force

The breaking test shall be carried out on ampoules with a predetermined breaking point, such as a ceramic ring, at the constriction.

When tested in accordance with Clause 6, the breaking force shall be as specified in Table 2.

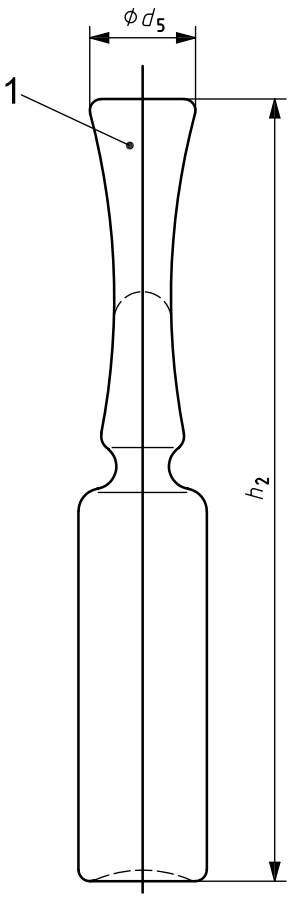



**Key**

1 constriction
2 sealing point
3 stem
4 bulb
5 shoulder
6 base or bottom

NOTE For dimensions of parameters, see Table 1.

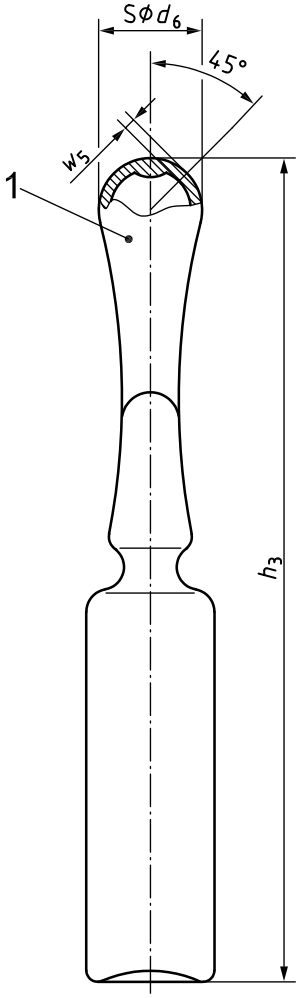
**Figure 1 — Form B: stem, cut ampoule with constriction**




**Key**

1 funnel

**Figure 2 — Form C: stem, open-funnel ampoule with constriction**




**Key**

1 dome

**Figure 3 — Form D: stem, sealed ampoule with constriction**

**Table 1 — Dimensions of ampoules**

Dimensions in millimetres

| Dimension | | | Nominal volume ml | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | 1 | 2 | 3 | 5 | 10 | 20 | 25 | 30 |
| External diameter | Body $d_1$[a] | | 10,75 | 10,75 | 12,75 | 14,75 | 17,75 | 22,5 | 22,5 | 22,5 |
| | | tol. | ±0,15 | ±0,15 | ±0,15 | ±0,15 | ±0,20 | ±0,25 | ±0,25 | ±0,25 |
| | Constriction $d_2$[b] | | 6,5 | 6,5 | 6,5 | 7 | 7,5 | 8,5 | 8,5 | 8,5 |
| | | tol. | ±0,5 | ±0,5 | ±0,5 | ±0,5 | ±0,5 | ±0,5 | ±0,5 | ±0,5 |
| | Bulb $d_3$ | | 8,5 | 8,5 | 8,5 | 9 | 9,5 | 12 | 12 | 12 |
| | | tol. | ±0,5 | ±0,5 | ±0,5 | ±0,5 | ±0,5 | ±1 | ±1 | ±1 |
| | Stem $d_4$ | | 6 | 6 | 6 | 7 | 7,1 | 7,8 | 7,8 | 7,8 |
| | | tol. | ±0,35 | ±0,35 | ±0,35 | ±0,35 | ±0,35 | ±0,5 | ±0,5 | ±0,5 |
| | Funnel $d_5$[c] | | 9 | 9 | 10,7 | 12,2 | 13 | 14 | 14 | 14 |
| | | tol. | ±0,8 | ±0,8 | ±0,8 | ±1 | ±1 | ±1 | ±1 | ±1 |
| | Dome $d_6$[c] | | 10 | 10 | 10,5 | 12 | 13,5 | 13,5 | 13,5 | 13,5 |
| | | tol. | ±1 | ±1 | ±1 | ±1 | ±1 | ±1 | ±1 | ±1 |
| | Flared end $d_7$ | | 8 | 8 | 8 | 9 | 9,5 | 11 | 11 | 11 |
| | | tol. | ±1 | ±1 | ±1 | ±1 | ±1 | ±1 | ±1 | ±1 |
| Overall height | Form B $h_1$ | | 60 | 72 | 75 | 83 | 102 | 113 | 128 | 143 |
| | | tol. | ±1 | ±1 | ±1 | ±1 | ±1 | ±1 | ±1 | ±1 |
| | Form C $h_2$ | | 67 | 79 | 82 | 90 | 109 | 120 | 135 | 150 |
| | | tol. | ±1 | ±1 | ±1 | ±1 | ±1 | ±1,5 | ±1,5 | ±1,5 |
| | Form D $h_3$ | | 70 | 83 | 89 | 95 | 112 | 126 | 141 | 156 |
| | | tol. | ±1 | ±1 | ±1 | ±1 | ±1 | ±1 | ±1 | ±1 |
| Height | Height to constriction $h_4$ | | 25,5 | 37,5 | 39,5 | 46,5 | 62 | 76 | 91 | 106 |
| | | tol. | ±0,5 | ±0,5 | ±0,5 | ±0,5 | ±1 | ±1,3 | ±1,3 | ±1,3 |
| | Height to gauging point $h_5$ | | 47 | 57 | 62 | 68 | 87 | 100 | 115 | 130 |
| | | tol. | ±2 | ±2 | ±2 | ±2 | ±2 | ±2 | ±2 | ±2 |
| | Body height $h_6$ | min. | 21 | 33 | 35 | 41 | 55 | 65 | 80 | 95 |
| | Height measured from centre of constriction to bulb $h_7$ | max. | 4,5 | 4,5 | 5 | 5,5 | 6 | 6,5 | 6,5 | 6,5 |
| Base | Radius $r$ | | 1 | 1 | 1,5 | 1,5 | 1,5 | 2,0 | 2,0 | 2,0 |
| | | tol. | ±0,5 | ±0,5 | ±0,5 | ±0,5 | ±0,5 | ±0,5 | ±0,5 | ±0,5 |
| | Depth of the base $e$ | | 1 | 1 | 1 | 1 | 1,25 | 1,5 | 1,5 | 1,5 |
| | | tol. | ±0,5 | ±0,5 | ±0,5 | ±0,5 | ±0,75 | ±1 | ±1 | ±1 |

**Table 1** (*continued*)

Dimensions in millimetres

| Dimension | | | Nominal volume ml | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | 1 | 2 | 3 | 5 | 10 | 20 | 25 | 30 |
| Wall thickness | Glass thickness of body $w_1$ | | 0,5 | 0,5 | 0,5 | 0,55 | 0,6 | 0,7 | 0,7 | 0,7 |
| | | tol. | ±0,03 | ±0,03 | ±0,03 | ±0,03 | ±0,04 | ±0,04 | ±0,04 | ±0,04 |
| | Glass thickness of stem at gauging $w_2$ | | 0,37 | 0,37 | 0,37 | 0,40 | 0,47 | 0,50 | 0,50 | 0,50 |
| | | tol. | ±0,05 | ±0,05 | ±0,05 | ±0,05 | ±0,05 | ±0,05 | ±0,05 | ±0,05 |
| | Glass thickness at base $w_3$ | min. | 0,3 | 0,3 | 0,3 | 0,4 | 0,4 | 0,5 | 0,5 | 0,5 |
| | Glass thickness at constriction $w_4$ | | 0,7 | 0,7 | 0,7 | 0,7 | 0,8 | 1 | 1 | 1 |
| | | tol. | ±0,1 | ±0,1 | ±0,1 | ±0,15 | ±0,15 | ±0,2 | ±0,2 | ±0,2 |
| | Glass thickness of dome $w_5$ | | 0,1 to 0,25 | | | | | 0,1 to 0,30 | | |
| | Circular run-out tolerance $t^d$ | | 0,6 | 0,6 | 0,8 | 1 | 1 | 1,2 | 1,2 | 1,2 |
| | Volume to centre of constriction $V$ | ml ≈ | 1,5 | 2,3 | 3,5 | 5,5 | 11,5 | 23,5 | 28,5 | 33,5 |

[a] The deviation from the perpendicularity between bottom and length axis at the body outside diameter shall not exceed an angle of 2°.

[b] If there is a need to reduce the constriction diameter, e.g. due to a reduction of particles, it shall be agreed between the manufacturer and purchaser.

[c] No point of the funnel and the dome shall be outside the body diameter.

[d] The run-out tolerance shall be measured at the sealing point (according to ISO 1101).

**Table 2 — Breaking force**

| Nominal volume ml | Length $l$ (= $l_1$ + $l_2$) mm | Breaking force $F_{min.}$ N | Breaking force $F_{max.}$ N |
|---|---|---|---|
| 1 | 36 (= 18 + 18) | 30 | 80 |
| 2 | | | |
| 3 | | | |
| 5 | | | |
| 10 | 60 (= 22 + 38) | | 90 |
| 20 | | | 100 |
| 25 | | | |
| 30 | | | |

# 6 Test for breaking force

## 6.1 Principle

The test is suitable for determining the force required to separate the ampoule stem from the body and for assessing whether a clean break is obtained.

## 6.2 Tensile testing machine

The tensile testing machine shall be in accordance with ISO 7500-1 and have the following characteristics:

— a test speed, $v$, of 10 mm/min;

— a measuring range for force of 200 N.

NOTE Other test procedures, e.g. with a power increase of 20 N/s, are admissible if equivalent results can be obtained.

An example of the test set-up is illustrated in Figure 4.

## 6.3 Sampling

### 6.3.1 Number of samples

Random sampling in accordance with ISO 2859-1 (inspection level S-4) is recommended.

### 6.3.2 Conditioning of samples

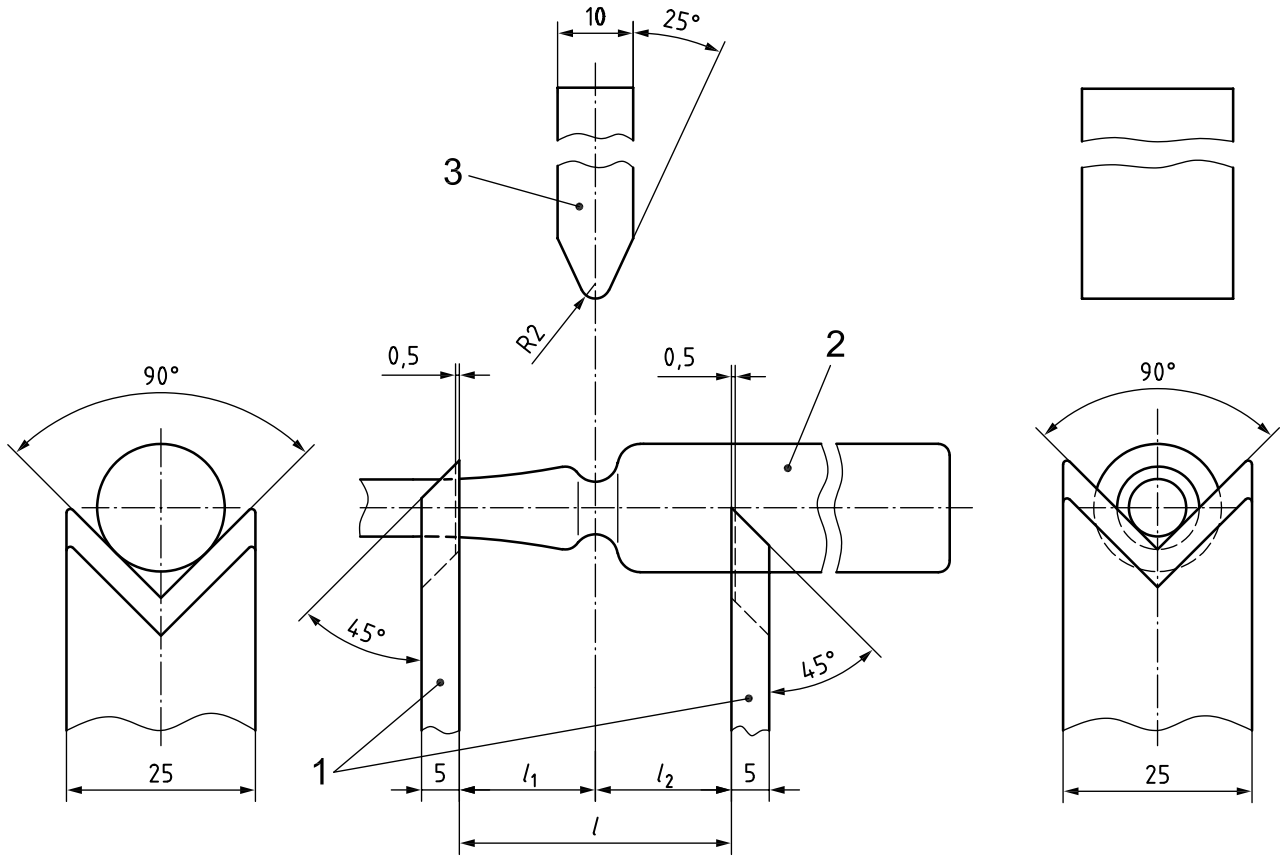
The temperature of the samples shall be 20 °C ± 5 °C.

## 6.4 Procedure

Set the distance between the metal bars, as shown in Figure 4 so that the force is imparted on the middle of the bars at an angle of 90° to the axis of the ampoule.

Apply the force using the tensile testing machine to rupture. Record the breaking force.

Dimensions in millimetres




**Key**

1 metal bars

2 ampoule

3 punch of the tensile testing machine

NOTE For dimensions of parameters, see Table 2.

**Figure 4 — Example of test set-up for determining the force for breaking ampoules**

## 6.5 Expression of results

In order for the ampoule to comply with this part of ISO 9187, all single test results shall comply with the relevant values specified in Table 2.

## 6.6 Test report

The following information shall be specified in the test report:

a) a description of the test set-up, including the tensile testing machine;

b) a description of the sample;

c) the number of samples;

d) the test results, including the arithmetic mean, $\bar{x}$, and the standard deviation, $s$, of the sample;

e) the place and date of the tests;

f) the name and signature of the person who carried out the tests.



7

## 7 Delivery

**7.1** Ampoules shall be sorted according to their design and nominal volumes, and shall be delivered in packaging units (see Clause 8).

**7.2** If desired, secondary sorting of ampoules according to stem diameter, $d_4$, in the measuring axis shall be subject to agreement between the manufacturer and user.

## 8 Packaging

**8.1** The packaging unit shall have the following dimensions:

— length (internal): 384 mm;

— width (internal): 143 mm;

— height of the appropriate type of ampoule +2 mm.

Packaging units whose dimensions differ from those stated above are subject to agreement between the manufacturer and user.

**8.2** As far as possible, all packaging immediately surrounding the ampoules shall be made from materials that do not shed particles.

## 9 Marking

The following information shall be marked on the packaging:

— the manufacturer's name and address;

— the designation in accordance with 3.2.

Further marking shall be subject to agreement between the manufacturer and the user.

# Bibliography

[1] ISO 1101, *Geometrical Product Specifications (GPS) — Geometrical tolerancing — Tolerances of form, orientation, location and run-out*

**ICS 11.040.20**

Price based on 9 pages