INTERNATIONAL STANDARD

ISO 9187-1

Second edition
2000-05-01

Injection equipment for medical use —

Part 1: Ampoules for injectables

Matériel d'injection à usage médical —

Partie 1: Ampoules pour produits injectables

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 3.

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 part of ISO 9187 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 9187-1 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 9187-1:1991), which has been technically revised.

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 must 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.

Four standardized forms of ampoule (forms A, B, C and D) have, in the past, 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 applies to ampoules with or without a colour break-ring.

If ampoules with a colour break-ring are requested by the user, this should be agreed between manufacturer and user, including a decision on break-ring colour.

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

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 9187. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 9187 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 720:1985, *Glass — Hydrolytic resistance of glass grains at 121 °C — Method of test and classification.*

ISO 1101:—[1)], *Geometrical product specifications (GPS) — Geometrical tolerancing — Tolerances of form, orientation, location and run-out.*

ISO 2859-1:1999, *Sampling procedures for inspection by attribute — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection.*

ISO 4802-1:1988, *Glassware — Hydrolytic resistance of the interior surfaces of glass containers — Part 1: Determination by titration method and classification.*

ISO 4802-2:1988, *Glassware — Hydrolytic resistance of the interior surfaces of glass containers — Part 2: Determination by flame spectrometry and classification.*

ISO 7500-1:1999, *Metallic materials — Verification of static uniaxial testing machine — Part 1: Tension/compression testing machine — Verification and calibration of the force-measuring system.*

1) To be published. (Revision of ISO 1101:1983)

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 a 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 ISO 720 - HGA 1 shall be used.

A change in the chemical composition of the glass material should be notified by the tube 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 ISO 4802 - HC 1.

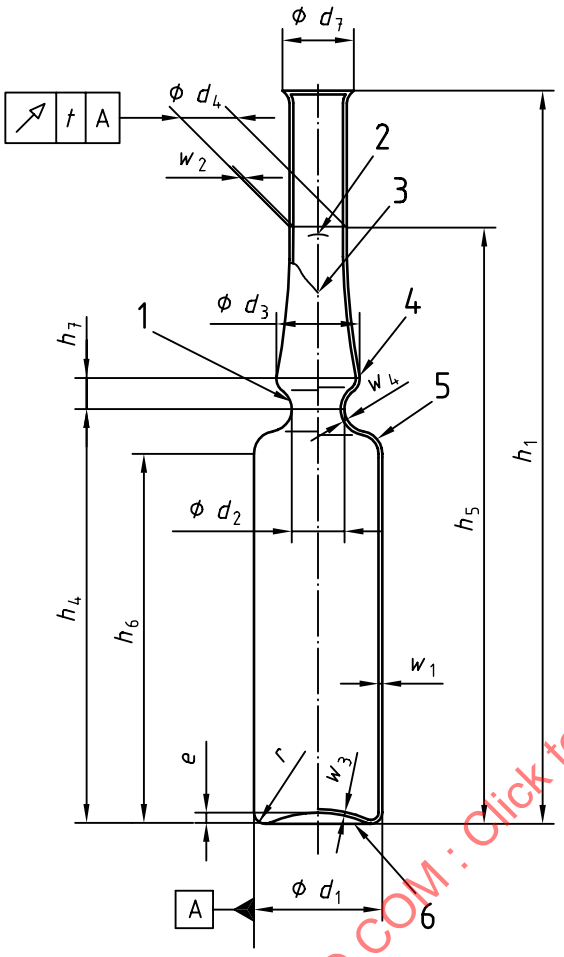
5.2 Annealing quality

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

5.3 Breaking force

It is presumed that the ampoules to be tested are provided 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.

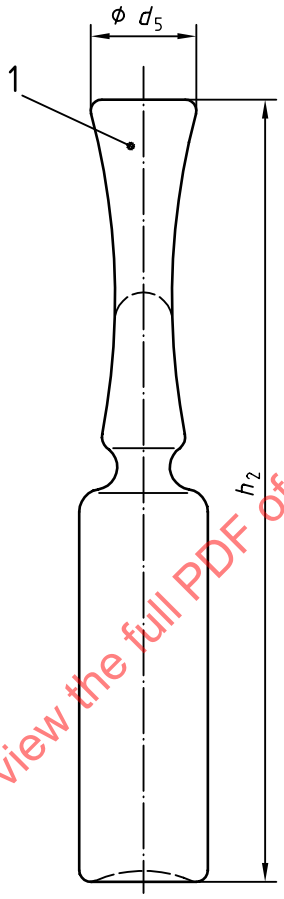


NOTE For other dimensions, see Figure 1.

Key

1 Constriction
2 Sealing point
3 Stem
4 Bulb
5 Shoulder
6 Base or bottom

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

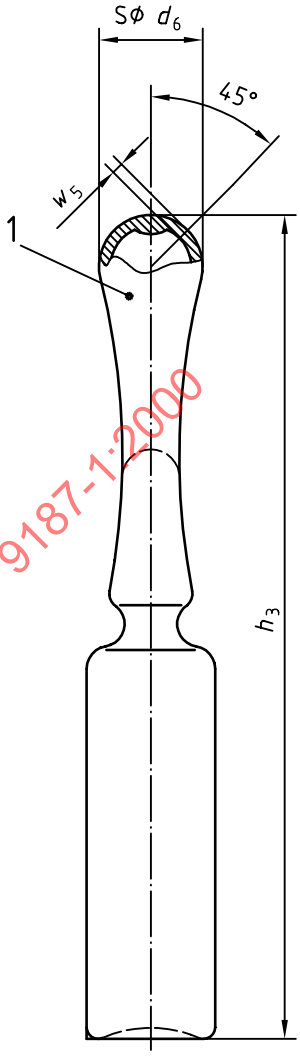


NOTE For other dimensions, see Figure 1.

Key

1 Funnel

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



NOTE For other dimensions, see Figure 1.

Key

1 Dome

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

Table 1 — Dimensions of ampoules

Dimensions in millimetres

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

Nominal volume	Base			Wall thickness							Volume to centre of constriction
	Radius	Depth of the base		Glass thickness of body		Glass thickness of stem at gauging	Glass thickness at base	Glass thickness of constriction		Glass thickness of dome	Circular run-out tolerance	
	r	e		w_1		w_2	w_3	w_4		w_5	t [c]	V
ml	± 0,5		tol.		tol.	± 0,05	min.		tol.			ml ≈
1	1	1	± 0,5	0,5	± 0,03	0,37	0,3	0,7	± 0,1	0,1 to 0,25	0,6	1,5
2				0,5	± 0,03	0,37	0,3				0,6	2,3
3	1,5			0,5	± 0,03	0,37	0,3				0,8	3,5
5				0,55	± 0,03	0,40	0,4	0,7	± 0,15		1	5,5
10	2	1,25	± 0,75	0,6	± 0,04	0,47	0,4	0,8	± 0,15		1	11,5
20	2,5	1,5	± 1	0,7	± 0,04	0,50	0,5	1	± 0,2	0,1 to 0,30	1,2	23,5
25				0,7	± 0,04	0,50	0,5				1,2	28,5
30				0,7	± 0,04	0,50	0,5				1,2	33,5

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

b No point of the funnel and the dome shall be outside the body diameter.

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

Table 2 — Breaking force

Nominal volume	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 Apparatus

6.2.1 Tensile testing machine in accordance with ISO 7500-1 and having the following characteristics:

— test speed, v: 10 mm/min;

— measuring range for force: 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 exerted 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.