INTERNATIONAL STANDARD

ISO 9187-1

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Injection equipment for medical use —

Part 1 :
Ampoules for injectables

Matériel d'injection à usage médical —
Partie 1 : Ampoules pour produits injectables

INTERNATIONAL ISO

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Contents

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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.

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.

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

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

— *Part 1: Ampoules for injectables*

— *Part 2: OPC-ampoules*

Introduction

Ampoules are suitable primary 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 ampoules (forms A, B, C and D) have, in the past, been in widespread use; however, form A is no longer necessary for the pharmaceutical industry and, consequently, has not been included in this International Standard. To avoid any likelihood of confusion between manufacturers and users, it was decided to retain the same designation letters (i.e. B, C and D) for the forms of ampoule in current use and to disregard the letter A.

It is known that different dimensions of ampoules exist at present in various countries as standard versions. Many countries have already switched over to the dimensions laid down in this part of ISO 9187. All other countries whose ampoules do not yet comply with the dimensions laid down in this part of ISO 9187 should switch over within a period of three years after publication.

Injection equipment for medical use — Ampoules for injectables

1 Scope

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

It applies to ampoules with and without a colour break ring.

If ampoules with 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 standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 9187. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 9187 are encouraged to investigate the possibility of applying the most recent editions of the standards listed below. Members of IEC and ISO 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 2859-1 : 1989, *Sampling procedures for inspection by attributes — Part 1: Sampling plans indexed by acceptable quality level (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 7500-1 : 1986, *Metallic materials — Verification of static uniaxial testing machines — Part 1: Tensile testing machines.*

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.

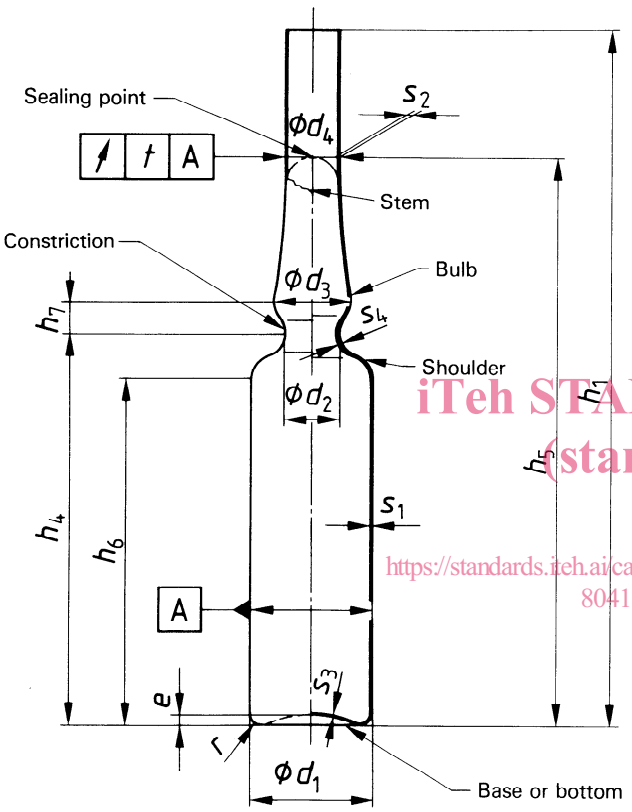
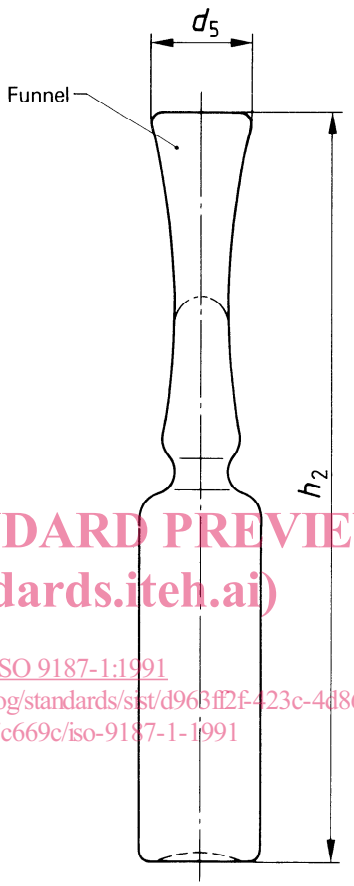
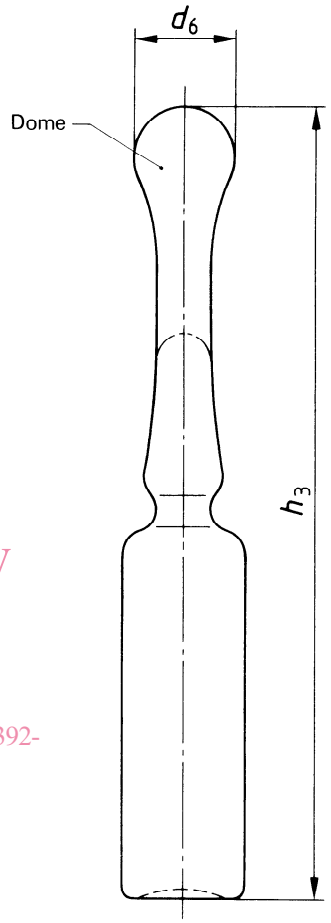


Figure 1 — Form B: stem, cut ampoule with constriction



NOTE — For other dimensions, see figure 1.

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



NOTE — For other dimensions, see figure 1.

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

3.2 Designation

3.2.1 Designation example 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

3.2.2 Designation example 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

Table 1 — Dimensions of ampoules

Dimensions in millimetres

Nominal volume	External diameter									Overall height						Height				Base			Wall thickness						Circular run-out tolerance	Volume to centre of constriction
	Body		Constriction	Bulb		Stem		Funnel		Dome	Form B		Form C		Form D	Height to constriction		Height to gauging point	Body height	Centre of constriction to bulb	Radius	Depth of the base		Glass thickness of body		Glass thickness of stem at gauging	Glass thickness at base	Glass thickness of constriction			
	d_1 [3]		d_2 [1]	d_3		d_4		d_5 [2]		d_6 [2]	h_1		h_2		h_3	h_4		h_5	h_6	h_7	r	e		s_1		s_2	s_3	s_4		t [4]	V
ml		tol.	±0,5		tol.		tol.		tol. [1]	±1 [3]		tol.		tol.	±1		tol.	+2	min.	max.	±0,5		tol.		tol.	±0,05	min.		tol.		ml ≈
1	10,75	±0,15	6,5	8,5	±0,5	6	±0,5	9	±0,8	10	60	±0,5	67	±1	70	25,5	±0,5	47	21	4,5	1	1	±0,5	0,5	±0,03	0,37	0,3			0,6	1,5
2	10,75	±0,15	6,5	8,5	±0,5	6	±0,5	9	±0,8	10	72	±0,5	79	±1	83	37,5	±0,5	57	33					0,5	±0,03	0,37	0,3	0,7	±0,1	0,6	2,3
3	12,75	±0,15	6,5	8,5	±0,5	6	±0,5	10,7	±0,8	10,5	75	±0,5	82	±1	89	39,5	±0,5	62	35	5	1,5			0,5	±0,03	0,37	0,3			0,8	3,5
5	14,75	±0,15	7	9	±0,5	7	±0,5	12,2	±1	12	83	±0,5	90	±1	95	46,5	±0,5	68	41	5,5				0,55	±0,03	0,42	0,4	0,7	±0,15	1	5,5
10	17,75	±0,20	7,5	9,5	±0,5	7,1	±0,6	13	±1	13,5	102	±0,5	109	±1	112	62	±1	87	55	6	2	1,25	±0,75	0,6	±0,04	0,47	0,4	0,8	±0,15	1	11,5
20	22,5	±0,25	8,5	12	±1	7,8	±0,8	14	±1	13,5	113	±1	120	±1,5	126	76	±1,3	100	65	6,5	2,5	1,5	±1	0,7	±0,04	0,55	0,5	1	±0,2	1,2	23,5
25	22,5	+0,25	8,5	12	±1	7,8	±0,8	14	±1	13,5	128	±1	135	±1,5	141	91	±1,3	115	80					0,7	±0,04	0,55	0,5			1,2	28,5
30	22,5	±0,25	8,5	12	±1	7,8	±0,8	14	±1	13,5	143	±1	150	±1,5	156	106	±1,3	130	95					0,7	+0,04	0,55	0,5			1,2	33,5

1) 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.

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

3) The tolerances are valid only with the following restriction: the actual dimensions of d_1 shall be bigger than the actual dimensions of $d_6 + t$.

4) The run-out tolerance shall be measured at the sealing point.

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, 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.

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	70
2			
3			
5			75
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

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.

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) shall be carried out.

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 in 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.

6.5 Expression of results

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 Delivery

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

Dimensions in millimetres

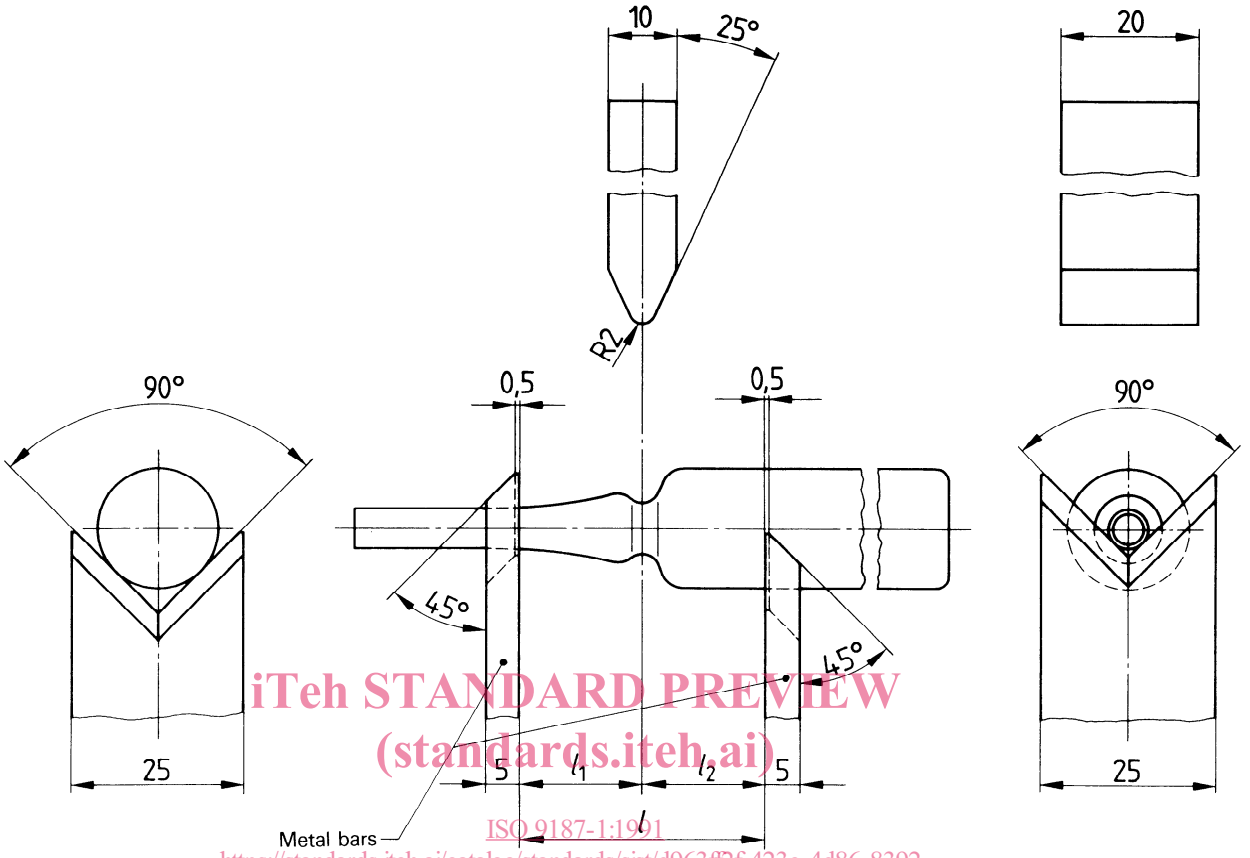


Figure 4 — Example of test set-up for determining the breaking force of ampoules

7.2 Secondary sorting of ampoules according to the stem diameter, d_4, in the measuring axis, if desired, 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: height of the appropriate type of ampoule + 2 mm

NOTE — Packaging units with other dimensions as laid down in 8.1 should be agreed between manufacturer and user.

8.2 The immediate packaging of all ampoules shall, as far as possible, 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 user.