INTERNATIONAL STANDARD

ISO 9187-1

Fourth edition
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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

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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

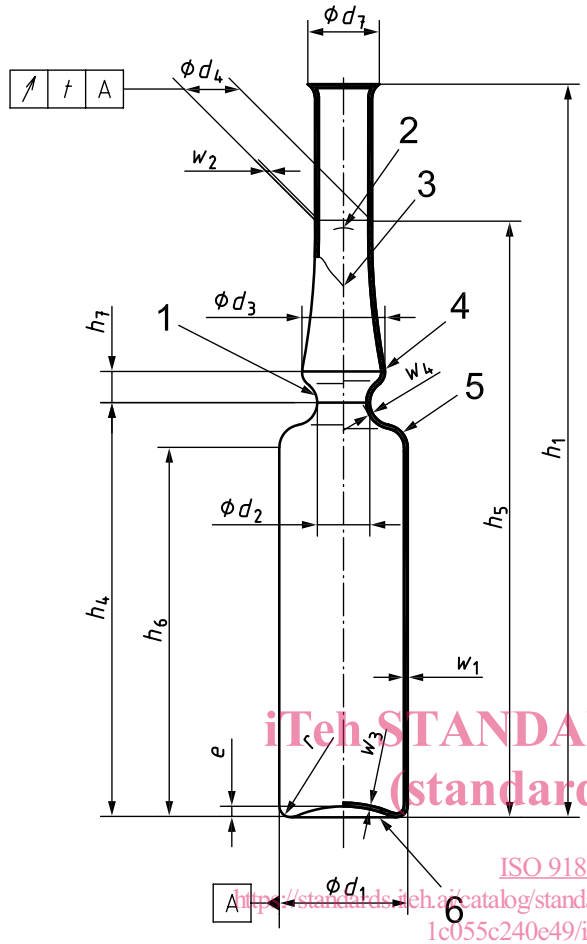
5.2 Annealing quality

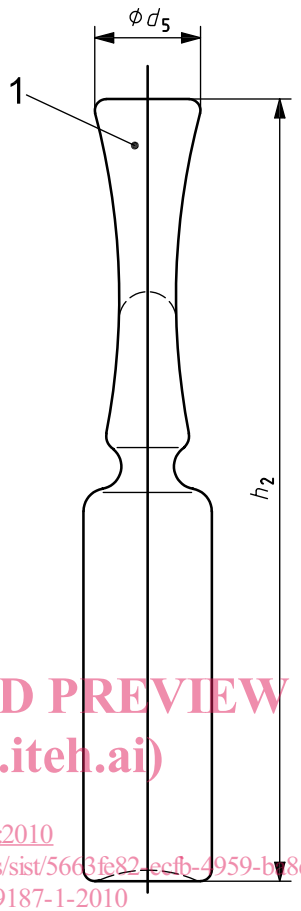
Ampoules shall be annealed; the maximum residual stress of uncoloured ampoules after annealing shall not produce an optical retardation exceeding 50 nm/mm of glass thickness.

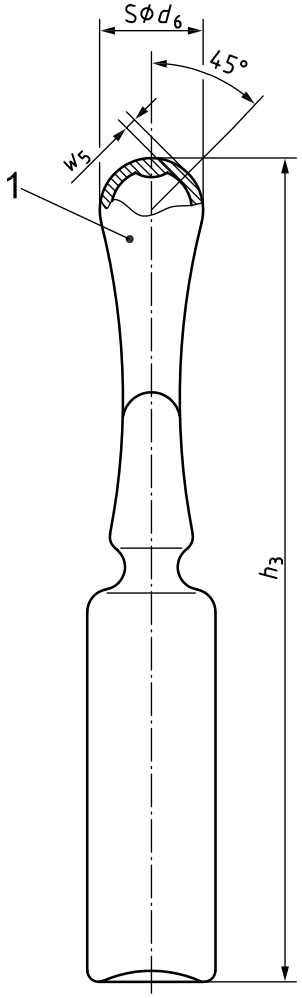
5.3 Breaking force

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			