INTERNATIONAL STANDARD

ISO 9187-2

Second edition
2010-10-15

Injection equipment for medical use —

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

Matériel d'injection à usage médical —

Partie 2: Ampoules à un seul point de cassure (OPC)

Reference number
ISO 9187-2:2010(E)

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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 9187-2 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 9187-2:1993), which has undergone a minor revision with the following modifications:

— the reference to ISO 9187-1 has been updated;

— the diameter of the point has been designated d_8 (instead of d_7) to be in line with the designation in ISO 9187-1.

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.

Injection equipment for medical use —

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

1 Scope

This part of ISO 9187 specifies materials, dimensions and requirements for forms of one-point-cut (OPC) ampoules (forms B, C and D) for injectables.

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 9187-1:2010, *Injection equipment for medical use — Part 1: Ampoules for injectables*

3 Dimensions and designation

3.1 Dimensions

The dimensions of OPC ampoules shall be as specified in ISO 9187-1 and as given in Table 1 and Figure 1 of this part of ISO 9187.

3.2 Designation

Designation of OPC 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 and the colour of the glass.

EXAMPLE Designation of a form B OPC ampoule with a nominal volume of 10 ml, made of colourless glass (cl) complying with the requirements of this part of ISO 9187:

Ampoule ISO 9187-2 – OPC – B – 10 – cl

4 Material

The material shall be in accordance with ISO 9187-1:2010, Clause 4.

Table 1 — Dimensions of OPC ampoules

Dimensions in millimetres

Nominal volume ml	Diameter of point d_8	Distance from bottom line to upper line of point h_9 max.	Wall thickness at constriction w_4
1	2 ± 0,5	32,5	0,7 ± 0,1
2		44,5	
3		46,5	
5		54,0	0,7 ± 0,15
10		70,0	0,8 ± 0,15
20		84,5	1 ± 0,20
25		99,5	
30		114,5	

5 Requirements

5.1 Hydrolytic resistance

The hydrolytic resistance shall be in accordance with ISO 9187-1:2010, 5.1.

5.2 Annealing quality

The annealing quality shall be in accordance with ISO 9187-1:2010, 5.2.

5.3 Breaking force

When tested in accordance with ISO 9187-1:2010, Clause 6, the breaking force shall comply with the values specified in Table 2.

In special cases, it may be possible to agree to a breaking force with a lower tolerance. This tolerance shall be agreed between manufacturer and user.

5.4 Position and stability of breaking point

5.4.1 The breaking point, consisting of colour pigments, shall be fixed in the centre above the cut. The maximum deviation from the centerline shall not exceed ±1 mm.

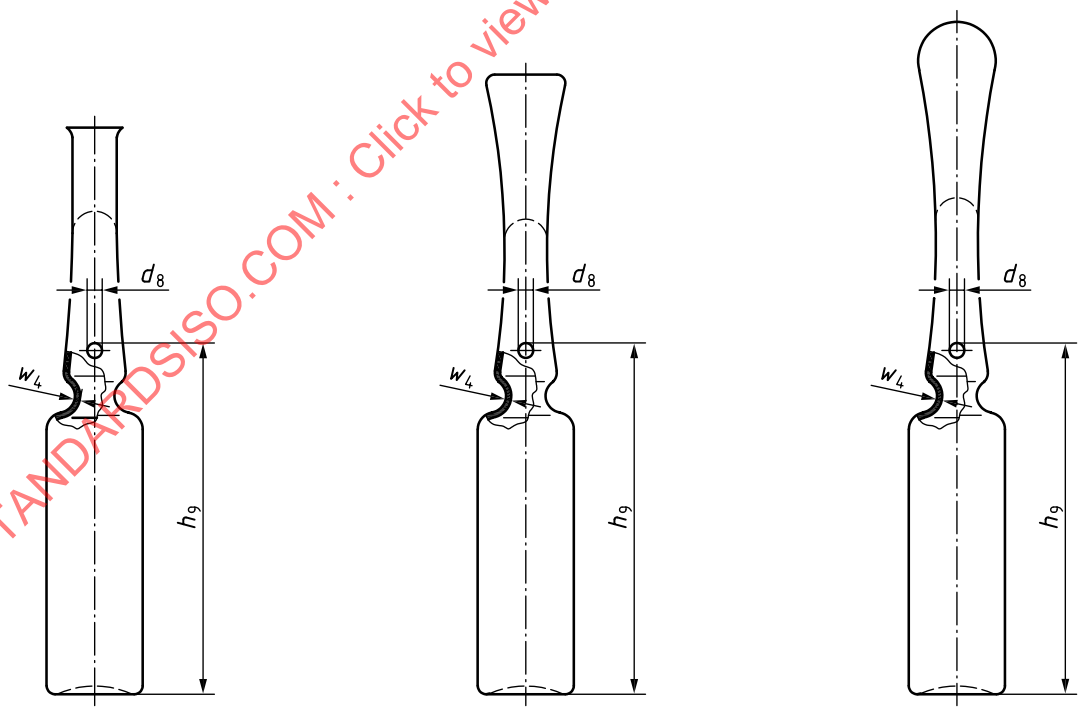
Table 2 — Breaking force

Nominal volume ml	Length l (= l_1 + l_2) mm	Breaking force $F_{min.}$ N	Breaking force $F_{max.}$ N
1	36 (= 18 + 18)	25	65
2			
3			
5		30	70
10	60 (= 22 + 38)		80
20			
25			
30			

When testing the breaking force, the equipment shall be positioned on the centre of the cut otherwise a considerable increase in breaking force will result.

5.4.2 The breaking point shall withstand a heating period of 30 min in a drying oven at a temperature of 120 °C, followed by dipping into water at 30 °C.

5.4.3 The breaking point shall withstand usual cleaning and sterilization conditions.



Form B **Form C** **Form D**

Figure 1 — Typical examples of OPC ampoules

6 Delivery

Delivery conditions shall be in accordance with ISO 9187-1:2010, Clause 7.

7 Packaging

Packaging shall be in accordance with ISO 9187-1:2010, Clause 8.

8 Marking

Marking shall be in accordance with ISO 9187-1:2010, Clause 9.