INTERNATIONAL STANDARD

ISO 9187-2

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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 9187-2:1993(E)

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 9187-2 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical use.*

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 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.

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 reference

The following standard contains provisions which, through reference in this text, constitute provisions of this part of ISO 9187. At the time of publication, the edition indicated was 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 edition of the standard indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 9187-1:1991, *Injection equipment for medical use — Part 1: Ampoules for injectables.*

3 Dimensions and designation

3.1 Dimensions

The dimensions for OPC ampoules shall be as laid down in ISO 9187-1 and as given in table 1. See figure 1 for typical examples.

3.2 Designation

Designation example 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 9187-1:1991, clause 4.

Table 1 — Dimensions of OPC ampoules

Dimensions in millimetres

Nominal volume ml	Diameter of point d_7	Distance from bottom line to upper line of point h_9 max.	Wall thickness at constriction s_4
1	2 ± 0,5	32,5	0,7 ± 0,10
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	

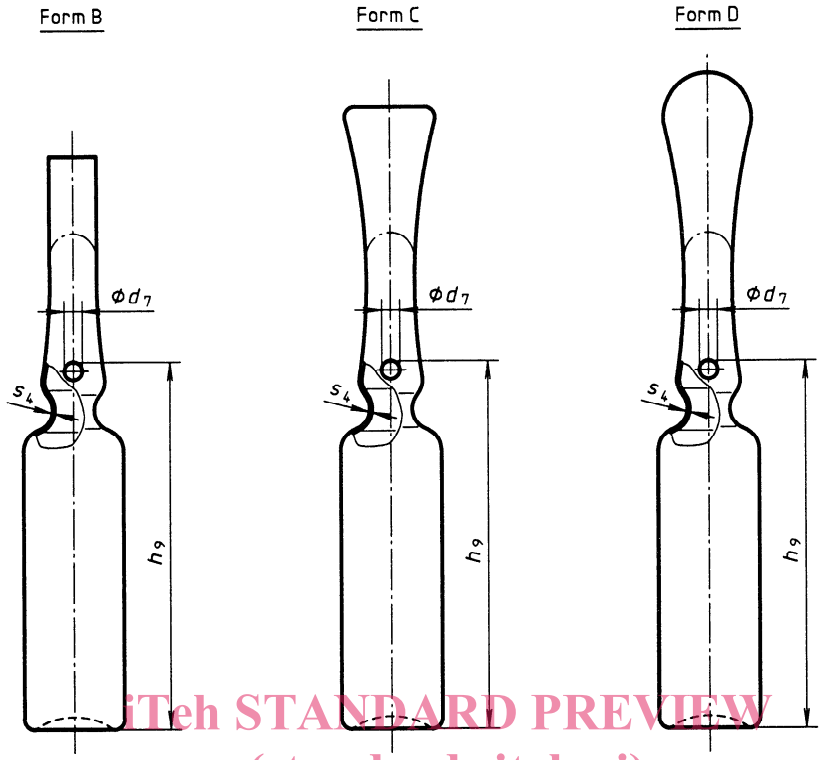

Figure 1 — Typical examples of OPC ampoules

5 Requirements

5.1 Hydrolytic resistance

The hydrolytic resistance shall be in accordance with ISO 9187-1:1991, subclause 5.1.

5.2 Annealing quality

The annealing quality shall be in accordance with ISO 9187-1:1991, subclause 5.2.

5.3 Breaking force

When tested in accordance with ISO 9187-1:1991, clause 6, the breaking force shall comply with the values laid down 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 point

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

Table 2 — Breaking force

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

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

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

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

6 Delivery

Delivery conditions shall be in accordance with ISO 9187-1:1991, clause 7.

7 Packaging

Packaging shall be in accordance with ISO 9187-1:1991, clause 8.

8 Marking

Marking shall be in accordance with ISO 9187-1:1991, clause 9.

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Descriptors: medical equipment, parenteral infusion equipment, ampoules, glass, specifications, dimensions, tests, designation, marking, packaging.

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