भारतीय मानक

Indian Standard

IS 15537 (Part 2) : 2023
ISO 9187-2 : 2010

चिकित्सा उपयोग के लिए इंजेक्शन उपकरण

भाग 2 वन-पॉइंट-कट (ओ पी सी) अम्पूल्स

Injection Equipment for Medical Use

Part 2 One-Point-Cut (OPC) Ampoules

ICS 11.040.20

भारतीय मानक ब्यूरो
BUREAU OF INDIAN STANDARDS
मानक भवन, 9 बहादुर शाह ज़फर मार्ग, नई दिल्ली - 110002
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI - 110002
www.bis.gov.in www.standardsbis.in

December 2023 **Price Group 5**

Hospital Equipment and Surgical Disposal Sectional Committee, MHD 12

NATIONAL FOREWORD

This Indian Standard (Part 2) which is identical with ISO 9187-2 : 2010 ‘Injection equipment for medical use — Part 2: One-point-cut (OPC) ampoules’ issued by the International Organization for Standardization (ISO) was adopted by Bureau of Indian Standards on the recommendation of the Hospital Equipment and Surgical Disposal Sectional Committee and after approval of the Medical Equipment and Hospital Planning Division Council.

The text of ISO Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are however not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words ‘International Standard’ appear referring to this standard, they should be read as ‘Indian Standard’; and
b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards which are to be substituted in their respective places are listed below along with their degree of equivalence for the editions indicated:

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
ISO 9187-1 : 2010 Injection equipment for medical use — Part 1: Ampoules for injectable	IS 15537 : 2021/ISO 9187-1 : 2010 Injection equipment for medical use: Part 1 Ampoules for injectable (*first revision*)	Identical

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated, expressing the result of a test or analysis shall be rounded off in accordance with IS 2 : 2022 ‘Rules for rounding off numerical values (*second revision*). The number of significant places retained in the rounded off value should be same as that of the specified value in this standard.

This standard also makes a reference to the BIS Certification Marking of the product. Details of which is given in National Annex A.

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.

Indian Standard

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.

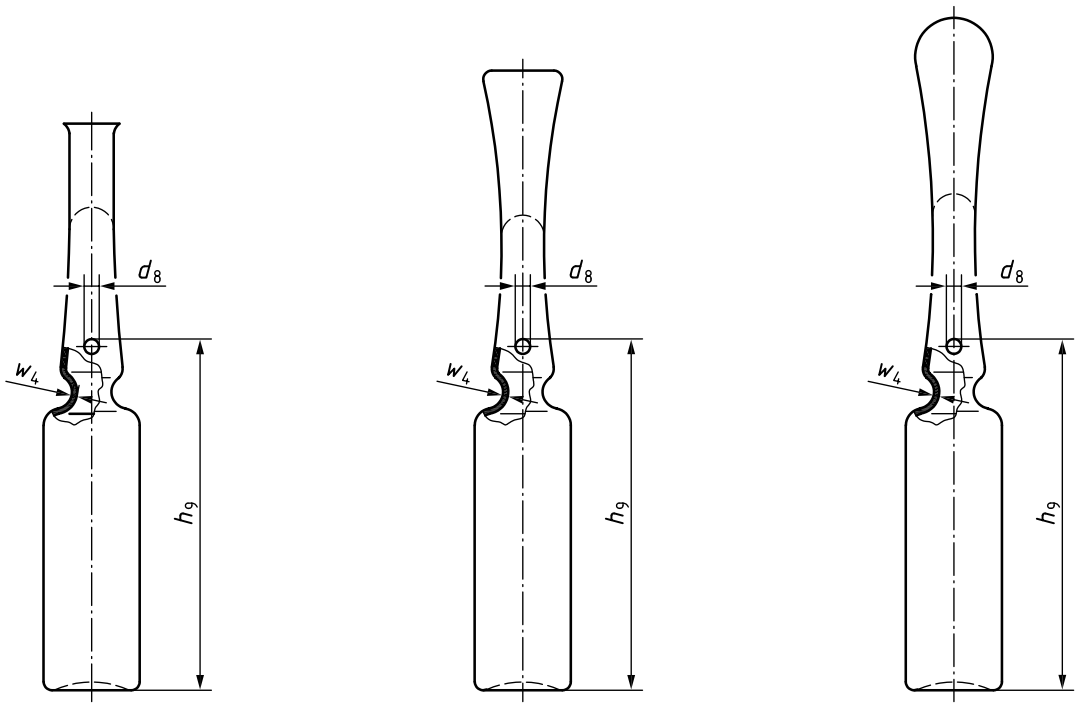
Table 2 — Breaking force

Nominal volume ml	Length l (= l_1 + l_2) mm	Breaking force	
		$F_{min.}$ N	$F_{max.}$ 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.

NATIONAL ANNEX A

(*National Foreword*)

A-1 BIS CERTIFICATION MARKING

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act,* 2016 and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.

Bureau of Indian Standards

BIS is a statutory institution established under the *Bureau of Indian Standards Act*, 2016 to promote harmonious development of the activities of standardization, marking and quality certification of goods and attending to connected matters in the country.

Copyright

Review of Indian Standards

Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard along with amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition by referring to the website-www.bis.gov.in or www.standardsbis.in

This Indian Standard has been developed from Doc No.: MHD 12 (20819).

Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

BUREAU OF INDIAN STANDARDS

Headquarters:

Manak Bhavan, 9 Bahadur Shah Zafar Marg, New Delhi 110002
Telephones: 2323 0131, 2323 3375, 2323 9402 *Website*: www.bis.gov.in

Regional Offices:		*Telephones*
Central	: 601/A, Konnectus Tower -1, 6th Floor, DMRC Building, Bhavbhuti Marg, New Delhi 110002	2323 7617
Eastern	: 8th Floor, Plot No 7/7 & 7/8, CP Block, Sector V, Salt Lake, Kolkata, West Bengal 700091	2367 0012 2320 9474
Northern	: Plot No. 4-A, Sector 27-B, Madhya Marg, Chandigarh 160019	265 9930
Southern	: C.I.T. Campus, IV Cross Road, Taramani, Chennai 600113	2254 1442 2254 1216
Western	: Plot No. E-9, Road No.-8, MIDC, Andheri (East), Mumbai 400093	2821 8093

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