SVENSK STANDARD
SS-EN ISO 9187-1:2010

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Injektionsutrustning för medicinskt bruk – Del 1: Brytampuller av glas för injektionsvätskor (ISO 9187-1:2010)

Injection equipment for medical use – Part 1: Ampoules for injectables (ISO 9187-1:2010)

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Europastandarden EN ISO 9187-1:2010 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 9187-1:2010.

Denna standard ersätter SS-EN ISO 9187-1:2008, utgåva 2.

The European Standard EN ISO 9187-1:2010 has the status of a Swedish Standard. This document contains the official version of EN ISO 9187-1:2010.

This standard supersedes the Swedish Standard SS-EN ISO 9187-1:2008, edition 2.

Upplysningar om sakinnehållet i standarden lämnas av SIS, Swedish Standards Institute, telefon 08-555 520 00. Standarder kan beställas hos SIS Förlag AB som även lämnar allmänna upplysningar om svensk och utländsk standard.

Information about the content of the standard is available from the Swedish Standards Institute (SIS), telephone +46 8 555 520 00. Standards may be ordered from SIS Förlag AB, who can also provide general information about Swedish and foreign standards.

Denna standard är framtagen av kommittén för Förbrukningsmaterial inom sjukvården, SIS/TK 330.

Har du synpunkter på innehållet i den här standarden, vill du delta i ett kommande revideringsarbete eller vara med och ta fram andra standarder inom området? Gå in på www.sis.se - där hittar du mer information.

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 9187-1

October 2010

ICS 11.040.20

Supersedes EN ISO 9187-1:2008

English Version

Injection equipment for medical use - Part 1: Ampoules for injectables (ISO 9187-1:2010)

Matériel d'injection à usage médical - Partie 1: Ampoules pour produits injectables (ISO 9187-1:2010)

Injektionsgeräte zur medizinischen Verwendung - Teil 1: Ampullen für Injektionspräparate (ISO 9187-1:2010)

This European Standard was approved by CEN on 13 October 2010.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN Management Centre has the same status as the official versions.

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Ref. No. EN ISO 9187-1:2010: E

Foreword

The text of ISO 9187-1:2010 has been prepared by Technical Committee ISO/TC 76 “Transfusion, infusion and injection equipment for medical and pharmaceutical use” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 9187-1:2010 by Technical Committee CEN/TC S02 “Transfusion equipment” the secretariat of which is held by CCMC.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by April 2011, and conflicting national standards shall be withdrawn at the latest by April 2011.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 9187-1:2008.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 9187-1:2010 has been approved by CEN as a EN ISO 9187-1:2010 without any modification.

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

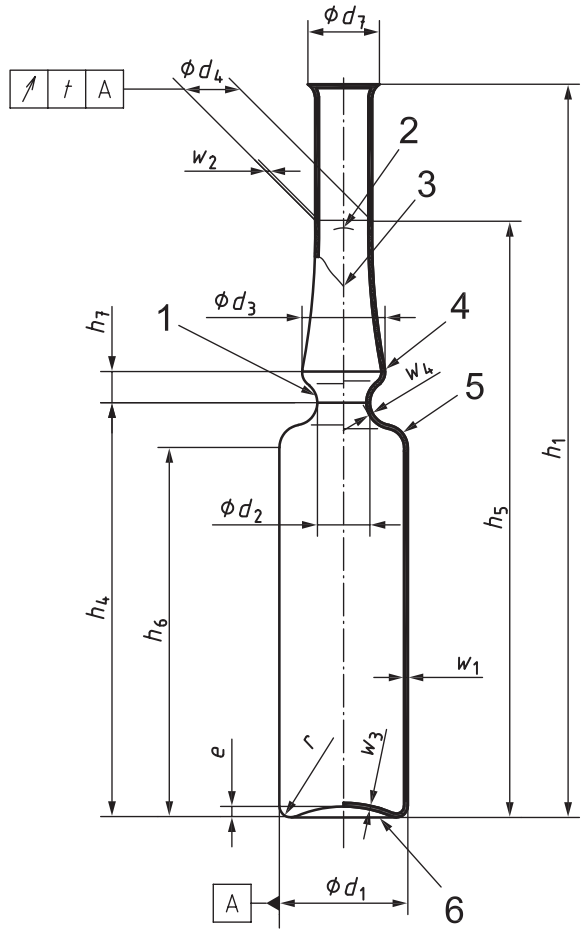
5.2 Annealing quality

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.

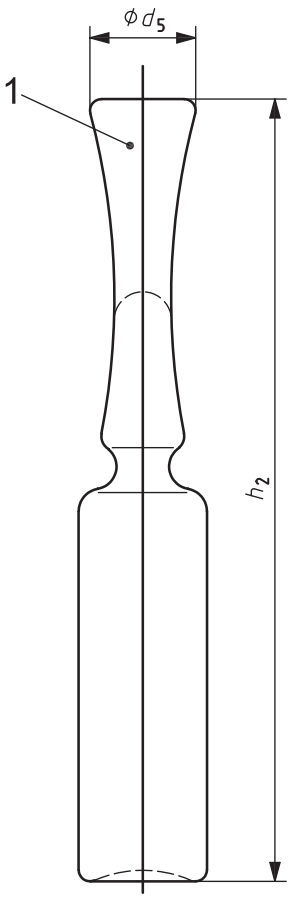


Key

1 constriction
2 sealing point
3 stem
4 bulb
5 shoulder
6 base or bottom

NOTE For dimensions of parameters, see Table 1.

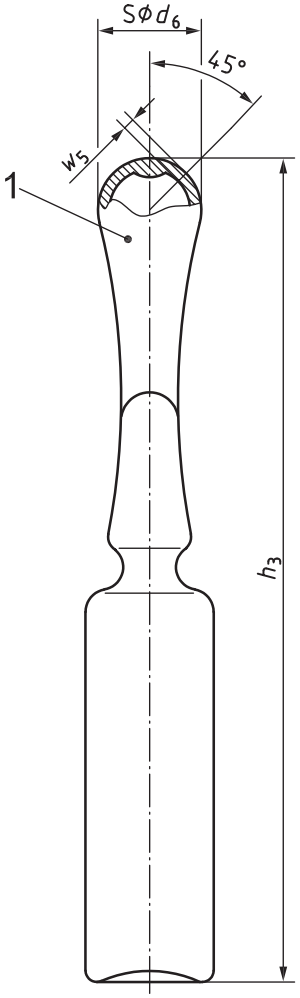
Figure 1 — Form B: stem, cut ampoule with constriction



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