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

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.

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.