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Elastomeric parts for parenterals and for devices for pharmaceutical use —

Part 5:
Functional requirements and testing

Éléments en élastomère pour administration parentérale et dispositifs à usage pharmaceutique —

Partie 5: Exigences fonctionnelles et essais

ICS: 11.040.20

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

ISO 8871-5 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical and pharmaceutical use*.

This second edition of ISO 8871-5 cancels and replaces the first edition, which has been technically revised.

ISO 8871 consists of the following parts, under the general title *Elastomeric parts for parenterals and for devices for pharmaceutical use*:

— *Part 1: Extractables in aqueous autoclavates*

— *Part 2: Identification and characterization*

— *Part 3: Determination of released-particle count*

— *Part 4: Biological requirements and test methods*

— Part 5: Functional requirements and testing

Introduction

Elastomeric or rubber closures for pharmaceutical use are used in combination with vials and many times in conjunction with piercing devices. There are three functional parameters which are important to the piercing process. These are: penetrability, fragmentation and self-sealing. The three functional tests described in this part of ISO 8871 can be used as a reference method for testing elastomeric closures that are pierced using injection needles made from metal. In addition, the aqueous solution tightness test can be used to verify the effectiveness of the sealing of a specific closure/vial combination.

Elastomeric parts for parenterals and for devices for pharmaceutical use —

Part 5:
Functional requirements and testing

1 Scope

This part of ISO 8871 specifies requirements and test methods for functional parameters of elastomeric closures used in combination with vials and when pierced by an injection needle.

NOTE Functional testing with spikes is specified in ISO 8536-2 and in ISO 8536-6.

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 7864, *Sterile hypodermic needles for single use*

ISO 8362-1, *Injection containers and accessories — Part 1: Injection vials made of glass tubing*

ISO 8362-3, *Injection containers and accessories — Part 3: Aluminium caps for injection vials*

ISO 8362-4, *Injection containers and accessories — Part 4: Injection vials made of moulded glass*

ISO 8362-6, *Injection containers and accessories — Part 6: Caps made of aluminium-plastics combinations for injection vials*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
penetrability
force required for piercing an elastomeric closure

3.2
fragmentation
measure of the number of elastomeric particles which are generated by the piercing process

3.3
self-sealing
measure of the resealing efficiency of elastomeric closures following penetration and withdrawal of a needle

3.4
container closure seal integrity
measure for the effective sealing of a specific elastomeric closure/vial combination

4 Requirements

4.1 Penetrability

When tested in accordance with Annex A, the force required for piercing shall not be greater than 10 N for each closure.

4.2 Fragmentation

When tested in accordance with Annex B, the number of elastomeric fragments per 48 piercings visible with the naked eye shall not be greater than 5.

4.3 Self-sealing and aqueous solution tightness

When tested in accordance with Annex C, none of the vials shall contain any trace of coloured solution when observed with the naked eye. This requirement applies to multidose containers only, i.e. containers which utilize elastomeric closures that are pierced multiple times.

Materials that meet the requirements are not required to undergo further testing in accordance with 4.4.

4.4 Aqueous solution tightness

When tested in accordance with Annex D, none of the vials shall contain any trace of coloured solution when observed with the naked eye.

5 Preparation of elastomeric closures for testing

5.1 Sampling

The number of closures required for each test is:

— penetrability 10

— fragmentation 12

— self-sealing and aqueous solution tightness 10

— aqueous solution tightness 10

In practice, it is recommended that more than the minimum required number of closures be prepared for testing.

5.2 Cleaning

Closures shall be sterilized in the as-delivered condition. If samples from regular production cleaning processes are not available, the stoppers shall be cleaned in accordance with the following procedure.

Introduce an appropriate number of rubber closures in a suitable glass container, cover with particle-free water, boil for 5 min, then rinse five times with cold particle-free water.

5.3 Sterilization

The closures shall be tested after having been subjected to the sterilization method actually used.

Annex A
(normative)

Test for penetrability

A.1 General

Many elastomerics or elastomeric closures for pharmaceutical use are used in conjunction with injection needles. The force necessary to penetrate or pierce a rubber closure is an important parameter in evaluating the suitability of the closure for its intended use.

A.2 Principle

The force necessary to completely pierce an elastomeric closure is measured using a suitable apparatus.

A.3 Apparatus, equipment and reagents

A.3.1 **10 closures**, prepared in accordance with Clause 5.

A.3.2 **10 clean vials**, in accordance with ISO 8362-1 or ISO 8362-4, finish sized to match the size of closures (e.g. 13 mm, 20 mm).

A.3.3 **10 aluminium or plastic/aluminium crimp seals**, in accordance with ISO 8362-3 or ISO 8362-6, sized to match the size of closures (e.g. 13 mm, 20 mm), and crimping apparatus.

A.3.4 **10 lubricated long-bevel** [bevel angle (11 ± 2)°] **metal hypodermic needles**, external diameter of 0,8 mm in accordance with ISO 7864.

A.3.5 **Apparatus**, capable of measuring a force of 10 N with an accuracy of ± 0,25 N.

A.4 Procedure

A.4.1 Close the vials with the closures to be tested and secure with a crimp seal.

A.4.2 Fit the force-measuring apparatus (A.3.5) with a hypodermic needle (A.3.4) and pierce a closure perpendicular to the surface. Record the maximum force. Use a new needle for each of the 9 remaining closures and repeat the procedure.

A.5 Expression of results

Record the force required for piercing each closure and compare the test results with the requirements in 4.1.