INTERNATIONAL STANDARD

ISO 8871-1

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Elastomeric parts for parenterals and for devices for pharmaceutical use —

Part 1: Extractables in aqueous autoclavates

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

Partie 1: Substances extractibles par autoclavage en milieu aqueux

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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 8871-1 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical and pharmaceutical use*.

Together with the other parts (see below), this part of ISO 8871 cancels and replaces ISO 8871:1990, 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

The elastomeric parts specified in the various parts of this International Standard are produced from a material which is usually called “rubber”. However, rubber is not a unique entity, since the composition of rubber materials may vary considerably. The base elastomer and the type of vulcanization have a major influence on the principle characteristics of an individual rubber material, as do additives such as fillers, softeners and pigments. These may have a significant effect on the overall properties. The effectiveness, purity, stability and safe handling of a drug preparation may be affected adversely during manufacture, storage and administration if the rubber part used has not been properly selected and validated (approved).

Elastomeric parts for parenterals and for devices for pharmaceutical use —

Part 1:
Extractables in aqueous autoclavates

1 Scope

1.1 This part of ISO 8871 defines procedures for classifying elastomeric parts for primary packs and medical devices used in direct contact with preparations for parenteral use, including both aqueous preparations and dry preparations which have to be dissolved before use.

It specifies a series of comparative test methods for chemical evaluation by the determination of extractables in aqueous autoclavates (see Clause 4) and describes the various fields of application for elastomeric parts. Dimensions and functional characteristics are specified in the relevant International Standards. Required properties as specified in this part of ISO 8871 are regarded as minimum requirements.

1.2 This part of ISO 8871 is applicable for the categories of elastomeric parts given in Clause 3; specific requirements, however, are laid down in the relevant International Standards dealing with the items or devices listed in Clause 3.

Elastomeric parts for empty syringes for single use are excluded from the scope of this part of ISO 8871 as they are not in contact with the injected preparation for a significant length of time.

1.3 Compatibility studies with the intended preparation have to be performed before the approval for final use can be given; however, this part of ISO 8871 does not specify procedures for carrying out compatibility studies.

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 8362-2:1988, *Injection containers for injectables and accessories — Part 2: Closures for injection vials*

ISO 8362-5:1995, *Injection containers for injectables and accessories — Part 5: Freeze drying closures for injection vials*

ISO 8536-2:2001, *Infusion equipment for medical use — Part 2: Closures for infusion bottles*

ISO 8536-6:1995, *Infusion equipment for medical use — Part 6: Freeze drying closures for infusion bottles*

ISO 11040-2:1994, *Prefilled syringes — Part 2: Plungers and discs for dental local anaesthetic cartridges*

ISO 11040-5:2001, *Prefilled syringes — Part 5: Plungers for injectables*