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Deli iz elastomera za parenteralne farmacevtske oblike - 2. del: Identifikacija in opredelitev (ISO/DIS 8871-2:2019)

Elastomeric parts for parenterals and for devices for pharmaceutical use - Part 2: Identification and characterization (ISO/DIS 8871-2:2019)

Elastomere Teile für Parenteralia und für Geräte zur pharmazeutischen Verwendung - Identifizierung und Charakterisierung (ISO/DIS 8871-2:2019)

Éléments en élastomère pour administration parentérale et dispositifs à usage pharmaceutique - Partie 2: dentification et caractérisation (ISO/DIS 8871-2:2019)

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Part 2: Identification and characterization

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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).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*.

This second edition cancels and replaces the first edition (ISO 8871-2:2003), which has been technically revised.

The main changes compared to the previous edition are as follows:

- expand the scope about including coated stoppers,
- addition of terms and definitions,
- addition of [clause H.6](#) Interpretation of results for ATR.

A list of all parts in the ISO 8871- series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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).

Polymer coatings or films are often applied to either entire or partial surface(s) of a rubber component to impart certain physical or chemical properties. The methods in this document enable determination of the presence and coverage/continuity of such surface treatments on a rubber component. Evaluation of the actual properties intended to be provided by these surface treatments is beyond the scope and covered elsewhere, in 8871 or other ISO documents.

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Elastomeric parts for parenterals and for devices for pharmaceutical use —

Part 2: Identification and characterization

1 Scope

This document specifies evaluation procedures applicable to elastomeric parts including coated stoppers used for drug containers and medical devices in order to guarantee the product identity. The physical and chemical test procedures specified in this document permit the determination of the typical characteristics of elastomeric parts, and can serve as a basis for agreements between manufacturer and user regarding the product consistency in subsequent supplies. An appropriate set of tests is selected, depending upon the type of elastomer and its application.

This document does not specify other requirements for elastomeric parts. These are laid down in the relevant product standards.

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 48, *Rubber, vulcanized or thermoplastic — Determination of hardness (hardness between 10 IRHD and 100 IRHD)*

ISO 247:2006, *Rubber — Determination of ash*

ISO 2781:2018, *Rubber, vulcanized or thermoplastic — Determination of density*

ISO 8871-1, *Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 1: Extractables in aqueous autoclavates*

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <http://www.iso.org/obp>

3.1

barrier coating

layer of a different polymer completely or partly covering the elastomeric part to reduce migration, permeation, interactions of substances of rubber component to rubber product and vice versa

Note 1 to entry: The coating can be applied by different techniques, e.g. spraying, tumbling, or vapor-depositing a liquid or vapor onto the rubber component or laminating a film onto the elastomeric surface during the moulding process.

Note 2 to entry: The presence of the coating can be verified by using the test method described in [Annex H](#).

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**3.2
elastomer**

material with elastic properties

**3.3
lubrication coating**

layer of a different polymer completely or partly covering the elastomeric part to support functionality in the final container system

Note 1 to entry: Certain lubrication coatings can also be used to eliminate the need of silicone oil in the container closure system and/or enhancing other functionalities e.g. gliding force, break loose force, removal force.

Note 2 to entry: The coating can be applied by different techniques, e.g. spraying, tumbling, or vapor-depositing a liquid or vapor onto the rubber component or laminating a film onto the elastomeric surface.

**3.4
rubber**

elastic substance obtained by crosslinking of polyisoprene or synthetic unsaturated polymers

**3.5
surface treatment**

any extraneous material placed on any portion of the external surface of the elastomer to produce the desired properties.

Note 1 to entry: Surface treatments (e.g. siliconization) are applied to avoid sticking together and enhance machineability on processing lines.

4 Tests**4.1 General**

Rubber is a complex material and not generally definable. The only property which all elastomeric materials have in common is a special type of resilience or elasticity. When a strip of rubber is stretched, it will extend by up to many times its original length without breaking. On release of the stretching force, it snaps back to its original size and shape virtually unaltered. Similarly, one can squeeze it, twist it or distort it in any direction comparatively easily, and it will spring back again to its original shape unchanged.

Owing to its three-dimensional network, achieved by chemical cross-linking of the polymer chains during vulcanization, rubber is practically insoluble in solvents such as tetrahydrofuran, although considerable reversible swelling may occur; this characteristic differentiates rubber from pseudo-elastic materials, such as poly(vinyl chloride) and certain thermoplastic elastomers.

In view of the complexity of rubber, the identity of a given elastomeric material cannot be verified just by applying a single physical or chemical test, and a set of tests is needed for reliable identification.

The manufacturer shall guarantee that all elastomeric parts of current supplies have been produced from the same formulation and that they exhibit the same characteristics as the samples which have been given to the user first and the suitability of which has been proved.

4.2 Hardness

Hardness shall be determined in accordance with ISO 48.

4.3 Density

Density shall be determined in accordance with the procedure described in ISO 2781:2018, Clause 4, method A.

4.4 Ash

The inorganic residue after combustion shall be determined as described in ISO 247:2006, 3.1, method A.

4.5 Infra-red spectrum

4.5.1 Material

A very simple method to create a fingerprint of a rubber material is to record an infrared (IR) spectrum. The two common methods for obtaining an IR spectrum of a rubber material are pyrolysis IR and surface IR/ATR (attenuated total reflectance)-technique.

The pyrolysis IR can be obtained as described in [Annex A](#). The surface IR/ATR can be obtained as described in [Annex H](#). The spectra should be compared to a spectrum obtained by the same IR-method on a reference sample of the material.

In practice, pyrolysis IR requires a time-consuming sample preparation and in addition needs the cautious handling of hazardous vapours and oils.

In contrast to this, the surface IR/ATR offers the possibility to obtain a fingerprint from an elastomeric part with minimum or no sample preparation.

4.5.2 Coating

The presence of a coating can be verified by comparing FTIR spectra of the surface and the material (see [Annex H](#)). For measuring the coating the samples do not need to be cut.

4.6 Compression set

The compression set indicates the degree of permanent deformation remaining after compression at a constant deformation and defined temperature for a defined time. The compression set shall be determined in accordance with [Annex B](#).

4.7 Swelling

Elastomeric materials are subject to varying degrees of swelling when exposed to organic solvents; the degree of volume and/or mass increase is primarily influenced by the type of elastomer. Swelling requires special care when the rubber components are in contact with emulsions or oily vehicles.

The relevant procedure is specified in [Annex C](#).

4.8 Development of a fingerprint by gas chromatography

The elastomeric materials under examination are extracted in a solvent, which does not dissolve but might swell the rubber. The extract is injected into a gas chromatograph. The chromatogram obtained exhibits a typical profile and can be used as a fingerprint for identification purposes. Furthermore, GC-coupling techniques, e.g. GC-MS, may provide additional information about the composition of the extract.

The relevant procedure is specified in [Annex D](#).

4.9 Detection of volatile substances by gas chromatography

Elastomeric materials may release volatile substances. These may originate from one of the following categories of material:

- oligomers or process aids present in the base polymer;
- stabilizers or antioxidants;

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— softeners.

The relevant procedure is specified in [Annex E](#).

4.10 Determination of residual moisture

During treatments typical for the pharmaceutical industry, elastomeric parts can absorb moisture in considerable quantities. During storage of the drug unit, the trapped moisture may be released and absorbed by the drug product, thus reducing the effectiveness of the drug (critical case: lyophilized drugs). The nature of the absorption and desorption processes is affected by the composition of the rubber, the type of treatment (e.g. steam autoclaving) and the efficiency of any subsequent drying process.

The relevant procedure is specified in [Annex F](#).

4.11 Determination of fingerprint by thermogravimetric analysis (TGA)

Elastomeric parts are composed of components which can be classified relative to their performance under thermal treatment, as follows:

- base polymers;
- inorganic fillers;
- substances volatile at elevated temperatures;
- carbon black.

The relevant procedure is specified in [Annex G](#).

4.12 Determination of extractables in aqueous autoclavates

Elastomeric materials may release substances of undetermined nature in water. For the general assessment of the chemical cleanliness of closures, the determination of overall parameters such as oxidizable materials and electrical conductivity can be used.

The relevant test procedures are specified in ISO 8871-1.

5 Preparation of samples for testing

5.1 Treatment before testing

Since the various test procedures may require different pretreatments, such treatment is specified in each annex.

It is generally assumed that samples of rubber parts will be provided in a clean state in accordance with the state of the art. In order to avoid recontamination, they shall be contained in protective packaging. Any particular treatment or method of packaging to be carried out by the manufacturer shall be subject to agreement between the manufacturer and the customer.

5.2 Number of samples needed for the tests

Due to the large number of tests in this part of ISO 8871 and their complexity, usually not all of the tests are performed in each investigation. For this reason, the number of samples needed shall be agreed on between the manufacturer and the test laboratory. Each annex specifies the number of samples which are necessary to perform that specific test.