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Glassware — Hydrolytic resistance of the interior surfaces of glass containers —

Part 1: Determination by titration method and classification

*Verrerie — Résistance hydrolytique des surfaces internes des
récipients en verre —*

Partie 1: Détermination par analyse titrimétrique et classification



Reference number
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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 document 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 fourth edition cancels and replaces the third edition (ISO 4802-1:2016), which has been technically revised.

The main changes are as follows:

- adding a complete description of the categories HC_T 1, HC_T 2, HC_T 3, HC_T B, HC_T D;
- aligning the autoclaving to the Ph. Eur.;
- including containers up to 0,5 ml filling volume.

A list of all parts in the ISO 4802 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.

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Introduction

This document is largely based on a test method approved by the International Commission on Glass (ICG), Technical Committee 2, *Chemical Durability and Analysis*, for measuring the hydrolytic resistance of the interior surfaces of glass containers.

The European Pharmacopoeia Commission has adopted the principle of the determination by titration and has set up a classification for glass containers for injectable preparations, which is included in this document. In addition, this document contains a classification of containers other than for injectable preparations.

According to international interlaboratory tests, this document specifies the test conditions in more detail than the European Pharmacopoeia in order to increase the reproducibility of the test results. In particular, the autoclaving cycle is described in detail.

The hydrolytic resistance of the inner glass surface is evaluated by determination of the released alkali reacting ions. According to their hydrolytic resistance, glass containers are classified in defined categories.

HC_T1 glass containers are suitable for most preparations whether or not for parenteral administration.

HC_T2 glass containers are suitable for most acidic and neutral, aqueous preparations whether or not for parenteral administration.

HC_T3 glass containers are in general suitable for non-aqueous preparations for parenteral administration, for powders for parenteral administration (except for freeze-dried preparations) and for preparations not for parenteral administration.

HC_TB glass containers are in general suitable for drinking ampoules (Container Class HGB 2 according to ISO 719).

HC_TD glass containers are in general suitable for lower demands on hydrolytic resistance (Container Class HGB 4 and HGB 5 according to ISO 719).

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Part 1: Determination by titration method and classification

1 Scope

This document specifies:

- a) a method for determining the hydrolytic resistance of the interior surfaces of glass containers when subjected to attack by water at $(121 \pm 1)^\circ\text{C}$ for (60 ± 1) min. The resistance is measured by titration of a known aliquot portion of the extraction solution produced with hydrochloric acid solution, in which case the resistance is inversely proportional to the volume of acid required;
- b) a classification of glass containers according to the hydrolytic resistance of the interior surfaces determined by the methods specified in this document.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 385, *Laboratory glassware — Burettes*

ISO 648, *Laboratory glassware — Single-volume pipettes*

ISO 719, *Glass — Hydrolytic resistance of glass grains at 98 °C — Method of test and classification*

ISO 720, *Glass — Hydrolytic resistance of glass grains at 121 °C — Method of test and classification*

ISO 1773, *Laboratory glassware — Narrow-necked boiling flasks*

ISO 3819, *Laboratory glassware — Beakers*

ISO 9187-1, *Injection equipment for medical use — Part 1: Ampoules for injectables*

3 Terms and definitions

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

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

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

3.1

ampoule

small, normally flat-bottomed container having stems in many different forms

Note 1 to entry: Ampoules are usually thin-walled and have a capacity normally up to 30 ml. They are intended to be closed, after filling, by flame sealing.