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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

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Foreword

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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 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 ~~many results of~~ 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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Glassware — Hydrolytic resistance of the interior surfaces of glass containers — ~~Part 1: Determination by titration method and classification~~

Part 1: Determination by titration method and classification

1 Scope

This document specifies:

- a) ~~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) ~~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.

3.2

bottle

flat-bottomed container, made from moulded glass

Note 1-to-entry:- Bottles are normally thick-walled and have a capacity usually of more than 5 ml. They may be of circular or other geometric cross-section. Bottles are sealed with a closure made from a material other than glass, and not by flame-sealing.

3.3

brimful capacity

volume of water required to fill a container, placed on a flat, horizontal surface

3.4

container

article made from glass to be used as primary packaging material intended to come into direct contact with a pharmaceutical preparation

EXAMPLE Bottles, vials, syringes, ampoules and cartridges. See also [Figure 1](#).

Note 1-to-entry:- These containers are made from borosilicate or soda-lime-silica glass.

3.5

filling volume

defined volume of water to fill the test specimen

Note 1-to-entry:- For the determination of the filling volume, see [7.2.7.2](#). The filling volume is a test-specific quantity that is used to compare container sets from different sources or lots. It has no relation to the nominal product volume.

3.6

borosilicate glass

silicate glass having a very high hydrolytic resistance due to its composition, containing significant amounts of boric oxide

Note 1-to-entry:- Borosilicate glass contains a mass fraction of boric oxide usually between 5 % and 13 %. This glass type can also contain aluminium oxide and/or alkaline earth oxides.

Note 2-to-entry:- Neutral glass is a borosilicate glass having a very high hydrolytic resistance and a high thermal shock resistance. When tested in accordance with ISO 720, it meets the requirements of class HGA 1. Containers properly made from this glass conform with hydrolytic resistance container class HC_T 1 of this document.

3.7

soda-lime-silica glass

silicate glass containing a mass fraction up to approximately 15 % of alkali metal oxides – mainly sodium oxide – and a mass fraction up to about 15 % of alkaline earth oxides, mainly calcium oxide