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

Part 2:
Determination by flame spectrometry and classification

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

Partie 2: Détermination par spectrométrie de flamme et classification

FDIS stage

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Field Code Changed

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 4802-2:2016), which has been technically revised.

The main changes are as follows:

— ——the explanation of the hydrolytic classes HC_F1, HC_F 2, HC_F 3, HC_FB, HC_F D for different glass types;

— ——clarification of needed properties of purified water and test water;

— ——harmonization of the samples cleaning and the autoclavation process with 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.

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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.

This document contains a classification which is related to but not equivalent to the classification set up in ISO 4802-1 for the titration method.

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_F1 glass containers are suitable for most preparations whether or not for parenteral administration.

HC_F2 glass containers are suitable for most acidic and neutral, aqueous preparations whether or not for parenteral administration.

HC_F3 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_FB glass containers are in general suitable for drinking ampoules (Container Class HGB 2 according to ISO 719).

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

Glassware — Hydrolytic resistance of the interior surfaces of glass containers

Part 2: Determination by flame spectrometry 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 ± 1) °C for (60 ± 1) min. The resistance is measured by determining the amount of sodium and other alkali metal or alkaline earth oxides in the extraction solution using flame atomic emission or absorption spectrometry (flame spectrometry);

b) ~~b)~~ a classification of glass containers according to the hydrolytic resistance of the interior surfaces determined by the methods specified in this document.

The test method specified in this document might not be applicable to containers whose surfaces have been treated for functional modifications, e.g. silicone (e.g. containers that are ready for direct filling).

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 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 1042, *Laboratory glassware — One-mark volumetric 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~~https://www.iso.org/obp

— IEC Electropedia: available at ~~https://www.electropedia.org/~~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 between 5 % and 13 %. This glass type may 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 according to ISO 720, it meets the requirements of class HGA 1. Containers properly made from this glass conform with hydrolytic resistance container class HC_F 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