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Glass — Hydrolytic resistance of glass grains at 121 °C — Method of test and classification

Verre — Résistance hydrolytique du verre en grains à 121 °C — Méthode d'essai et classification

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Contents

Page

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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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 third edition cancels and replaces the second edition (ISO 720:1985), which has been technically revised.

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

— a more precise definition of the field of application by means of glass types was added;

— wherever possible a harmonization with the identical paragraphs in the European Pharmacopoeia, chapter 3.2.1, and the USP, chapter 660, was established to simplify the application in the laboratories globally. This concerns, e.g. sample size, mesh size;

— the process of autoclaving was adapted to the requirements of the European Pharmacopoeia, chapter 3.2.1, which will ease the application of this document;

— the usage of acetone was restricted to always fresh, new acetone, since re-usage might lead to deviating test results;

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.

Glass — Hydrolytic resistance of glass grains at 121 °C — Method of test and classification

1 Scope

This document specifies

a) a method for determining the hydrolytic resistance of glass grains at 121 °C. The resistance is measured and expressed by the volume of acid required for titration of the alkali extracted from the unit mass of glass, and can also be expressed by the amount of sodium oxide equivalent to this volume of acid, and

b) a classification of glass according to the hydrolytic resistance determined by the method of this document.

This document is intended for use on the more resistant types of glass, e.g. borosilicate glass.

NOTE 1 For the less resistant glasses, e.g. soda-lime, the method specified in ISO 719 is more suited.

NOTE 2 It is emphasized that there is no exact correlation between the classification laid down in this document and that laid down in ISO 719, and it is, therefore, essential to identify which classification is being used.

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 565, *Test sieves — Metal wire cloth, perforated metal plate and electroformed sheet — Nominal sizes of openings*

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

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

ISO 3696, *Water for analytical laboratory use — Specification and test methods*

ISO 3819, *Laboratory glassware — Beakers*

ISO 13130, *Laboratory glassware — Desiccators*

3 Terms and definitions

No terms and definitions are listed in this document.

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

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

4 Principle

The method of testing is a test for glass as a material applied on glass grains. Extraction of 10 g of grains, of particle size between 300 µm and 425 µm, with grade 2 water for 30 min at 121 °C. Measurement of the degree of the hydrolytic attack by analysis of the extraction solutions.

The test method shall not be applied to glasses with extreme low alkaline contents or that are essentially free of alkaline species as this method measures only the alkaline release as the indication for chemical durability.

The density of the glass to be tested should, preferably, be 2,4 g/cm^3 ± 0,2 g/cm^3 at 20 °C.

5 Reagents

During the test, unless otherwise stated, use only reagents of recognized analytical grade.

5.1 Test water, to be prepared as follows: prepare the test water from distilled water (5.5) by multiple distillations. Any other suitable method can be used, e.g. preparation of carbon dioxide-free water according to USP 660[4].

When tested immediately before use, water prepared as described above shall produce an orange-red (not violet-red or yellow) colour corresponding to the neutral point of methyl red indicator of pH 5,5 ± 0,1 when 0,05 ml of methyl red indicator solution (5.3) is added to 50 ml of the water to be examined. This water may also be used as the reference solution (see Clause 8). The conductivity of the water shall not exceed 1 µS/cm, determined at 25 °C by an in-line conductivity meter.

NOTE 1 This description is based on the European Pharmacopoeia 3.2.1[3]. In the European Pharmacopoeia, water prepared as described above is designated water R1.

NOTE 2 Water of Grade 2 according to ISO 3696 is suitable for this test.

5.2 Hydrochloric acid, standard volumetric solution, *c*(HCl) = 0,02 mol/l.

5.3 Methyl red, indicator solution.

Dissolve 25 mg of the sodium salt of methyl red ($C_{15}H_{14}N_3NaO_2$) in 100 ml of the grade 2 water (5.1). Alternatively, the indicator solution can be prepared as described, in e.g. USP 42 [6.60] or Ph.Eur. 10 [3.2.1] (this method is based on dissolution of methyl red in 0.1 M sodium hydroxide, ethanol and distilled water).

5.4 Acetone (CH_3COCH_3).

5.5 Purified water, prepared by distillation, by ion exchange, by reverse osmosis or by any other suitable method from water having drinking water quality.

NOTE 1 See national or regional regulation for information on water intended for human consumption.

NOTE 2 Water that corresponds to Grade 3 according to ISO 3696 is suitable.

NOTE 3 In the European Pharmacopoeia 3.2.1[3], water as described above is designated water R.

6 Apparatus

Ordinary laboratory apparatus and, in particular, the following.

6.1 Balance, capable of weighing up to 500 g, accurate to ±5 mg or better.