

International Standard



4802

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Glass — Hydrolytic resistance of the interior surfaces of glass containers — Methods of test

Verre — Résistance hydrolytique des surfaces internes des récipients en verre — Méthodes d'essai

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Foreword

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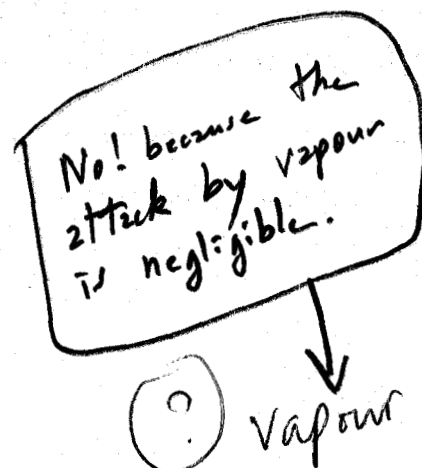
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International Standard ISO 4802 was developed by Technical Committee ISO/TC 48, *Laboratory glassware and related apparatus*, and was circulated to the member bodies in August 1980.

It has been approved by the member bodies of the following countries :

Australia	Hungary	Spain
Brazil	Italy	United Kingdom
Canada	Korea, Rep. of	USA
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France	Romania	
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No member body expressed disapproval of the document.



Glass — Hydrolytic resistance of the interior surfaces of glass containers — Methods of test

0 Introduction

This International Standard is based largely on methods of test approved by the International Commission on Glass, Subcommittee A 2, *Chemical Durability*, for measuring the hydrolytic resistance of the interior surfaces of glass containers. The European Pharmacopoeia Commission has adopted the determination by titration and set up a classification for glass containers for injectable preparations.

1 Scope

This International Standard specifies methods 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 either by titration of a known aliquot of the extract produced under the conditions of test (in which case the resistance is inversely proportional to the volume of acid required) or, and particularly for smaller containers, by the determination of the amount of sodium and other alkali or alkaline earth oxides in the extraction solution, using the flame emission or the atomic absorption spectrometric method (flame spectrometric methods).

NOTE — It should be noted that the values obtained by titration and those obtained using the flame emission or atomic absorption spectrometer are not directly comparable.

Details of a dithizone limit test for heavy metals are given in the annex.

2 Field of application

The methods are applicable to all containers for laboratory and pharmaceutical use which are capable of being subjected to the conditions of the tests.

They are applicable to articles made from soda-lime-silicate glass or borosilicate glass (including neutral glass), either in the original or in the surface-treated condition.

3 References

ISO 385/2, *Laboratory glassware — Burettes — Part 2: Burettes for which no waiting time is specified.*¹⁾

ISO 648, *Laboratory glassware — One-mark pipettes.*

ISO 1773, *Laboratory glassware — Boiling flasks (narrow-necked).*

ISO 3819, *Laboratory glassware — Beakers.*²⁾

ISO 6955, *Analytical flame emission, atomic absorption and atomic fluorescence spectroscopy — Vocabulary.*²⁾

4 Principle

The methods of test are surface tests normally applied on glass containers as delivered.

The containers to be tested are filled with specially pure water to a specified capacity and heated under specified conditions. The degree of the hydrolytic attack is measured by analysis of the extraction solutions.

5 Reagents

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

5.1 Specially pure water.

Water which is free from heavy metals, particularly copper, as shown by a dithizone test (see the annex)³⁾, having a specific

1) At present at the stage of draft. (Revision, in part, of ISO/R 385.)

2) At present at the stage of draft.

3) For testing heavy metals with dithizone see Iwantscheff, G.: *Das Dithizon und seine Anwendung in der Mikro- und Spurenanalyse* [Dithizone and its application in micro- and trace analysis]. Weinheim: Verlag Chemie 1972.