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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

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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 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.

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).

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

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 ± 1) °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.

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. 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.

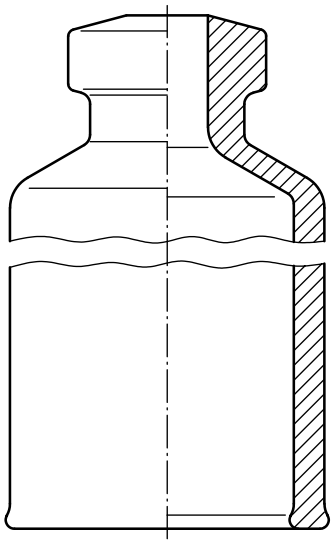
3.6
borosilicate glass
silicate glass having a very high hydrolytic resistance due to its composition, containing significant amounts of boric oxide

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.

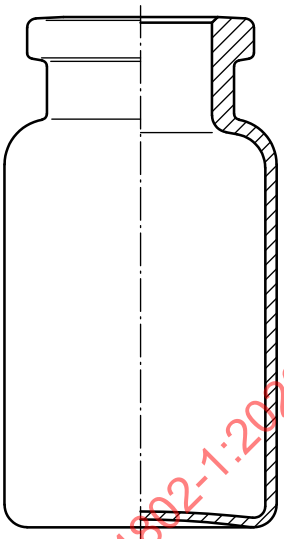
Note 2 to entry: Neutral glass is a borosilicate glass having a very high hydrolytic resistance and a high thermal shock resistance. When tested in accordance with ISO 720, it meets the requirements of class HGA 1. Containers properly made from this glass conform with hydrolytic resistance container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

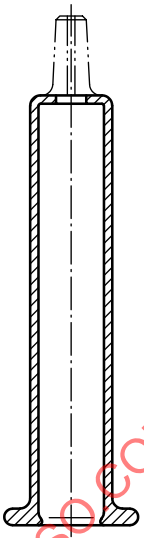
Note 1 to entry: Containers made from this glass have a moderate hydrolytic resistance due to the chemical composition of the glass, and conform with hydrolytic resistance container class HC_T 3.



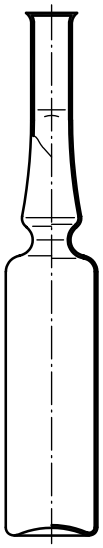
a) Example of a glass cylinder for a pen–injector / cartridge (see ISO 13926-1)



b) Example of an injection vial made of glass tubing (see ISO 8362-1)



c) Example of a syringe glass barrel (see ISO 11040-4)



d) Example of a stem cut ampoule with constriction (see ISO 9187-1)

Figure 1 — Examples of containers

3.8
surface treatment
treatment of the internal surface of glass containers with reagents in order to achieve a de-alkalized surface and to produce a significantly lower release of alkali metal ions (and alkali earth metal ions)

Note 1 to entry: Surface treatment is used, for example, in order to change a soda-lime-silica glass container of hydrolytic resistance class HC_T 3 to a container of hydrolytic resistance class HC_T 2 container. Treated containers are rinsed before use.

3.9
vial
small, flat-bottomed container, made from tubing or from moulded glass

Note 1 to entry: Vials are normally thick-walled and have a capacity up to 100 ml. They are normally sealed with a closure made from a material other than glass, and not by flame-sealing.

4 Principle

This test method is a surface test applied to glass containers as produced and/or as delivered.

The containers to be tested are filled with specified water to a specified capacity. They are loosely capped and then heated under specified conditions. The degree of the hydrolytic attack is measured by titration of the extraction solutions. The measurement data shall be classified according to the limits defined in appropriate container specific limit values in accordance with Table 2.

Dependent on different glass types, specific limit values are defined in the following:

The hydrolytic resistance is evaluated by determination of the released alkali reacting ions. According to their hydrolytic resistance, glass containers are classified as follows:

— HC_T1 glass containers: neutral glass, borosilicate glass with a high hydrolytic resistance due to the chemical composition of the glass itself;

NOTE 1 In the Ph.Eur. 3.2.1[12] and the USP <660>[15], the hydrolytic resistance classification are designated Type I.

— HC_T2 glass containers: usually of soda-lime-silica glass with a high hydrolytic resistance resulting from suitable treatment of the inner surface;

NOTE 2 In the Ph.Eur. 3.2.1[12] and the USP <660>[15] the hydrolytic resistance classification are designated Type II.

— HC_T3 glass containers: usually of soda-lime-silica glass with only moderate hydrolytic resistance;

NOTE 3 In the Ph.Eur. 3.2.1[12] and the USP <660>[15] the hydrolytic resistance classification are designated Type III.

— HC_TB glass containers: usually made of borosilicate or soda-lime-silica glass composition with higher hydrolytic resistance (container class: HGB 2 according to ISO 719);

— HC_TD glass containers: usually made of soda-lime-silica glass with low hydrolytic resistance (container class: HGB 4 or HGB 5 according to ISO 719).

The index “T” indicates that the measures for the classification are based on titration.

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 purified water (5.6) by multiple distillations. Remove the carbon dioxide by boiling for at least 15 min before use in a boiling flask (6.3) of fused silica or borosilicate glass, and cool.

NOTE 1 Any other suitable method can be used, e.g. preparation of carbon dioxide-free water according to Ph.Eur. 3.2.1[12] and USP 660[15].

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 (5.5) is added to 50 ml of the water to be examined.

This water may also be used as the reference solution (see 8.4).

The conductivity of the water shall not exceed 1 µS/cm, determined at 25 °C by an in-line conductivity meter.

Where the use of test water is specified in the following analytical procedures the requirements for bacterial endotoxins and microbial contamination are not relevant.

NOTE 2 This description is based on the Ph.Eur. 3.2.1[12]. In the Ph.Eur., water prepared as described above is designated water R1.

NOTE 3 Water of Grade 2 according to ISO 3696 [2] is suitable for this test.

5.2 Hydrochloric acid, standard volumetric solution, c(HCl) = 0,01 mol/l.

5.3 Hydrochloric acid, solution, c(HCl) ≈ 2 mol/l.

5.4 Hydrofluoric acid, c(HF) ≈ 22 mol/l (i.e. ≈400 g HF/l solution).

CAUTION — Hydrofluoric acid is very toxic and highly corrosive. Consider using a material safety data sheet!

5.5 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 test water (5.1).

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

Where the use of purified water is specified in the following analytical procedures the requirements for bacterial endotoxins and microbial contamination are not relevant.

NOTE 1 National or regional regulation on water intended for human consumption can apply.

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

NOTE 3 In the Ph.Eur. 3.2.1[12], water as described above is designated water R.

6 Apparatus

The usual laboratory apparatus and, in particular, the following shall be used.

6.1 Autoclave or **steam sterilizer**, capable of withstanding a pressure of at least 250 kPa and of carrying out the heating cycle specified in 8.3. It shall be capable of maintaining a temperature of (121 ± 1) °C, equipped with a calibrated thermometer or a calibrated thermocouple recorder, a pressure gauge and a vent cock.

When necessary and appropriate, the autoclave vessel and ancillary equipment shall be thoroughly cleaned before use using the purified water (5.6) in order to avoid contamination that can influence the test results.

Most recent autoclave models are not provided with a vent cock that can be operated manually. The operator is referred to the user instructions and/or technical description provided by the manufacturer of the autoclave with regard to the functioning of the venting operations. A time/temperature printout/recording can be used as evidence of a proper venting stage.

6.2 Burettes, having a suitable capacity of 50 ml, 25 ml, 10 ml or 2 ml, conforming with the requirements specified for class A burettes in ISO 385 and made of glass of hydrolytic resistance grain class HGA 1 as specified in ISO 719 or ISO 720 (Glass of hydrolytic resistance grain class ISO 719-HGB 1 adequately meets the requirements of class HGA 1 specified in ISO 720.).

The capacity of the burettes shall be chosen in accordance with the expected consumption of hydrochloric acid (5.2).

6.3 Conical flasks, having a capacity of 100 ml and 250 ml, and conforming with the requirements of ISO 1773.

Before its first use, each flask shall be pretreated by filling with purified water (5.6) and autoclaving at 121 °C for at least 1 h (see 8.3).

IMPORTANT — If it is intended to use these flasks for other purposes, before being re-used in accordance with this document, the flasks shall be properly cleaned (e.g. by treatment with hydrochloric acid and/or by autoclave cleaning).

6.4 Pipettes, having a suitable capacity and conforming with the requirements specified for class A pipettes described in ISO 648.

6.5 Water bath, capable of being heated to approximately 80 °C.

6.6 Beakers, having a suitable capacity and conforming with the requirements specified in ISO 3819.

Before its first use, each beaker shall be pretreated by filling with purified water (5.6) and autoclaving at 121 °C for at least 1 h (see 8.3).

6.7 Metal foil, e.g. made from aluminium or stainless steel.

7 Sample preparation

7.1 Sample size

The number of containers to be tested depends on the capacity of the container, the volume of extraction solution necessary for one titration and the number of titration results required. It shall be calculated according to the requirements given in Table 1.

Table 1 — Capacity of containers, volume of extraction solution and number of titrations/ containers

Capacity of container [volume corresponding to filling volume (see 7.2)] ml	**Volume of extraction solution for one titration** ml	**Number of titrations/ containers**
≤3	25,0	1
>3 ≤30	50,0	2
>30 ≤100	100,0	2
>100	100,0	3

7.2 Determination of the filling volume

7.2.1 Flat-bottomed containers ≤20 mm outer flange diameter (except ampoules, syringes and cartridges)

Select six containers (having a capacity ≤100 ml) or three containers (having a capacity >100 ml) at random from the sample lot and remove any debris or dust by shaking the containers. Allow the dry containers to reach room temperature. Weigh each of the empty containers to the nearest 0,01 g for containers having a nominal volume ≤30 ml, and to the nearest 0,1 g for containers having a nominal volume >30 ml. Place the containers on a horizontal surface and fill them nearly to the top with purified water (5.6), avoiding overflow and introduction of air bubbles. Adjust the liquid levels to the brimful line using purified water (5.6). The meniscus shall be equal to the upper edge of the bore.

Weigh the filled container to the nearest 0,01 g for containers having a nominal volume ≤30 ml, and to the nearest 0,1 g for containers having a nominal volume >30 ml. Calculate the mass of water, in grams, contained within the container.

Determine the mean value of the results from six containers and express the result in millilitres of water; this value is the mean brimful capacity of the containers.

Determine 90 % of this mean brimful capacity to one decimal place. This amount of water is used for the particular sample lot.

7.2.2 Flat-bottomed containers >20 mm outer flange diameter

Proceed as described in 7.2.1.

Determine 90 % of this mean brimful capacity to one decimal place. This volume is the filling volume for the particular sample lot.

7.2.3 Round-bottomed containers

Select six containers (having a capacity ≤100 ml) or three containers (having a capacity >100 ml) at random from the sample lot and remove any debris or dust. Allow the dry containers to reach room temperature. Fix each container vertically in an appropriate device and determine the brimful capacity in accordance with 7.2.1.

Then determine 90 % of the mean brimful capacity to one decimal place. This volume is the filling volume for the particular sample lot.

7.2.4 Lipped containers

Wrap adhesive plastic tape around the rim of the containers such that the tape around the lip is level with the rim. Weigh the container, then fill them with purified water (5.6) and reweigh as described in 7.2.1.

7.2.5 Ampoules

Place at least six dry ampoules on a flat, horizontal surface and fill them with purified water (5.6), at room temperature, from a burette (6.2), until the water level (meniscus) reaches h_6 of ISO 9187-1, where the body of the ampoules declines to the shoulder (see Figure 2). Read the capacities to two decimal places and calculate the mean value.

This volume, expressed to one decimal place, is the filling volume and shall be filled in all ampoules of the same lot.

NOTE The filling volume can also be determined by weighing.

7.2.6 Syringes and cartridges

Select six syringes or cartridges. Close the small opening (mouth of cartridges and needle and/or Luer cone of syringes) using an inert material (e.g. tip cap). Determine the mean brimful volume in accordance with 7.2.1.

Then determine 90 % of the mean brimful capacity to one decimal place. This volume is the filling volume.

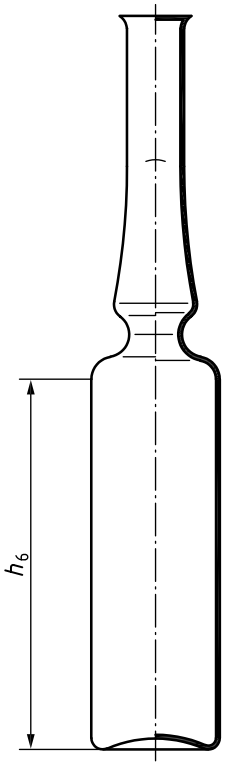


Figure 2 — Filling volume of ampoules (up to h_6)

8 Procedure

8.1 General

This procedure shall be completed within one working day.

8.2 Cleaning of samples

The following cleaning process for each container shall be completed within 20 min to 30 min.

Remove from all open samples any debris or dust that has collected during storage and transport. Shortly before the test, fill each container to the brim with the purified water (5.6) at ambient temperature and allow to stand for (20 ± 5) min. Immediately before testing, empty the samples, rinse twice with purified water (5.6), and then once with the test water (5.1) and allow to drain.

Closed ampoules shall not be rinsed before testing.

NOTE For opening by flame, closed ampoules can be warmed, e.g. in a water bath or air-oven at about 40 °C for approximately 2 min before opening, to avoid under pressure when opening, or cut and broken at the height of the sealing point.

8.3 Filling and heating

Fill each container, selected for the sample size in accordance with 7.1 and cleaned in accordance with 8.2, to the filling volume with the test water (5.1) by means of suitable volumetric measuring devices.

Cap each container, including ampoules, loosely with an inert material, for example with inverted beakers (6.6) of such a size that the bottoms of the beakers fit snugly down on the rims of the sample. Cap ampoules with a clean metal foil (6.7). Place syringes and cartridges in a beaker and cover the beaker with a clean metal foil (6.7).

Ensure that the metal foil (6.7) does not release measurable ions into the test water.

Containers of 2 ml or less, in which the water is not sufficiently retained during the autoclaving process, may be closed in a suitable way, e.g. with a stopper or plug of inert material, and fixed using a plunger or a stable fixing or clamping device.

Place the samples, gathered in groups in glass dishes or in the beaker, on the rack in the autoclave (6.1), containing purified water (5.6) at ambient temperature, and ensure that they are held above the level of the water in the vessel.

Insert the end of a calibrated thermal device in a filled container through a hole of approximately the diameter of the thermocouple and connect it to an external measuring device. If the container is too small to insert a thermocouple, apply a thermocouple in a suitable, similar container. Close the autoclave door or lid securely but leave the vent-cock open. Start automatic recording of the temperature versus time and heat the autoclave with the following characteristics: raise the temperature with a regular rate from room temperature to 100 °C within 20 min to 30 min, and maintain the temperature at (100 ± 1) °C for a further (10 ± 1) min. Raise the temperature from 100 °C to 121 °C within 20 min to 22 min. Maintain the temperature at (121 ± 1) °C for (60 ± 1) min from the time when the holding temperature is reached. Cool down to 100 °C, venting to prevent formation of a vacuum, within 40 min to 44 min.

CAUTION — For security reasons (boiling retardation), do not open the autoclave before the water in the containers has reached a temperature of 95 °C. Consider the safety instructions of the user manual.

NOTE Experience has shown that the rate of heating to 121 °C, the holding temperature of (121 ± 1) °C and the rate of cooling to 100 °C are critical. Deviations from the specified conditions can produce variable results to the extent of invalidating them.

Remove the hot samples from the autoclave and cool to room temperature within 30 min. Start the titration after cooling. Special care shall be taken in cooling down large capacity containers as thermal drops larger than 40 °C can cause the fracture of the glass by thermal shock.

8.4 Analysis of the extraction solutions

Carry out the titration within 1 h of removal of the containers from the autoclave. Combine the extraction solutions obtained from the containers to be tested (see Table 1) and mix. Introduce the volume according to the second column of Table 1 into a conical flask. When emptying small stemmed ampoules, the extraction solution can be partly neutralized by absorbing carbon dioxide (CO_2) from the atmosphere. To obviate this, invert the ampoules and heat the base gently with a flame. Ensure that no flame gases contaminate the test solution. In the case of combined extraction solutions from containers having a capacity ≤3 ml, pipette a volume of 25,0 ml (see the second column of Table 1) into a conical flask (6.3) having a capacity of 100 ml. In the case of combined extraction solutions from containers having larger capacities, pipette the required volumes (see the second column of Table 1) into separate conical flasks (6.3) of suitable capacity.

Prepare reference solutions (blank) by pipetting volumes of the test water (5.1), equivalent to those taken from the extraction solutions, into conical flasks (6.3) having a capacity commensurate with the size of the containers being tested. Add 0,05 ml of methyl red indicator solution (5.5) for each 25 ml of test water (5.1) and titrate the blank solution with hydrochloric acid (5.2) until a clearly visible colour change occurs.

Add 0,05 ml of methyl red indicator solution (5.5) to each flask for each 25 ml of extraction solution and titrate with hydrochloric acid (5.2) until the colour matches exactly that of the coloured reference solution.

Titration values of less than 1,0 ml shall be expressed to two decimal places, titration values greater than or equal to 1,0 ml to one decimal place.

NOTE Properly calibrated automatic titration equipment giving results with the same or better accuracy can also be used.

8.5 Test to determine whether the containers have been surface-treated

NOTE The hydrolytic resistance of the interior surface of vials and bottles made from soda-lime-silica glass can be considerably increased by treating these surfaces during the course of production.

If there are doubts whether surface treatment or not was performed on a container and/or to distinguish between type I and type II glass containers (according to Ph.Eur.), unused glass containers or the container samples previously tested shall be used.

Fill the samples with a mixture of one volume of hydrofluoric acid (5.4) and nine volumes of hydrochloric acid (5.3) to the brimful point. Allow the filled samples to stand at ambient temperature for 10 min, then empty the solution very carefully. Rinse the samples five times with purified water (5.6), then at least once again with purified water (5.6). Then test the samples as specified in 8.3 and 8.4.

CAUTION — Hydrofluoric acid is extremely aggressive. Even tiny quantities can cause life-threatening injuries. Consider using a material safety data sheet.

If the results are considerably higher than those obtained from the original surfaces (about five to ten times), the samples shall be considered to have been surface-treated.

9 Expression of results

9.1 Determination

Determine the mean value of the titration results and express it in millilitres of hydrochloric acid solution (5.2) per 100 ml of the extraction solution. The blank value (see 8.4) shall be used.

NOTE This hydrolytic resistance container class HC_T obtained by the titration method is comparable with the class HC_F obtained in according to ISO 4802-2, although the individual test values are not equivalent. Therefore, conversions of test results from this document and ISO 4802-2 are not possible.

9.2 Classification

The containers shall be classified as shown in Table 2, according to the consumption of hydrochloric acid solution (5.2), when tested as specified in 8.4 and determined according to 9.1.

9.3 Distinction between containers of hydrolytic resistance container class HC_T 1 and hydrolytic resistance container class HC_T 2

After etching and re-testing in accordance with 8.5, containers of hydrolytic resistance container class HC_T 1 shall satisfy the requirements for hydrolytic resistance container classes HC_T 1 and HC_T 2 in Table 2.

After etching and re-testing in accordance with 8.5, containers of hydrolytic resistance container class HC_T 2 shall produce values that are significantly greater than those given in the second column of Table 2 and which are much closer to those values for hydrolytic resistance container class HC_T 3 in Table 2.