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**Screening Method for Erosion Potential of Oral Rinses on
Dental Hard Tissues**

口腔清洁护理液对牙齿硬组织潜在腐蚀性的评估方法

(ISO 28888:2013, Dentistry - Screening Method for Erosion Potential of Oral Rinses
on Dental Hard Tissues, MOD)

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Screening Method for Erosion Potential of Oral Rinses on Dental Hard Tissues

1 Scope

This document describes a method for evaluating the erosion potential of oral rinses on dental hard tissues using enamel and (or) dentine acid-etching models.

This document is applicable to the evaluation of erosion potential of oral rinses on dental hard tissues.

This document does not apply to the evaluation of oral rinses containing fluoride.

2 Normative References

The contents of the following documents constitute indispensable clauses of this document through the normative references in the text. In terms of references with a specified date, only versions with a specified date are applicable to this document. In terms of references without a specified date, the latest version (including all the modifications) is applicable to this document.

GB/T 6682 Water for Analytical Laboratory Use - Specification and Test Methods (GB/T 6682-2008, ISO 3696:1987, MOD)

GB/T 9937-2020 Dentistry - Vocabulary (ISO 1942:2009, MOD)

3 Terms and Definitions

What is defined in GB/T 9937-2020, and the following terms and definitions are applicable to this document.

3.1 tooth erosion; dental erosion

Tooth erosion / dental erosion refers to the progressive loss of calcified dental tissue by chemical processes that do not involve bacterial action.

[source: GB/T 9937-2020, 2.292]

4 Requirements

4.1 Overview

This document is a risk assessment of enamel and dentine acid-etching caused by oral rinses and a preliminary screening of the erosion potential of all fluoride-free oral rinses. If the product fails the screening, adopt a more complex and clinically relevant test method specified in the product standard for the testing.

4.2 Maximum pH Drop Value

The maximum pH drop value allowed in this document is 1.0.

If the pH drop value is greater than 1.0, then, the oral rinse fails the screening test. Under this circumstance, a more complex and clinically relevant test method should be selected, so as to determine the erosion effect of the oral rinse.

5 Reagents and Materials

5.1 Calcium chloride dihydrate ($\text{CaCl}_2 \bullet 2\text{H}_2\text{O}$), analytically pure.

5.2 Citric acid ($\text{C}_6\text{H}_8\text{O}_7$), analytically pure.

5.3 Potassium hydroxide (KOH), analytically pure.

5.4 Hydrochloric acid (HCl), analytically pure.

5.5 Trisodium citrate dihydrate ($\text{C}_6\text{H}_5\text{Na}_3\text{O}_7 \bullet 2\text{H}_2\text{O}$), analytically pure.

5.6 Potassium dihydrogen phosphate (KH_2PO_4), analytically pure.

5.7 Distilled water (H_2O), Grade-2 water in compliance with GB/T 6682.

5.8 For citric acid control buffer solution, in accordance with 7.2.3, prepare the following three standard citric acid buffer solutions:

---Solution 1: 1.0% citric acid solution, pH is 3.60 at 25 °C;

---Solution 2: 0.25% citric acid solution, pH is 3.68 at 25 °C;

---Solution 3: 0.07% citric acid solution, pH is 3.77 at 25 °C.

6 Instruments and Equipment

6.1 Beaker, 50 mL, made of borosilicate glass.

6.2 Beaker, 100 mL, made of borosilicate glass.

6.3 Pipette, with a measuring range of 0.01 mL ~ 1 mL.

6.4 Volumetric flask, 100 mL, 1 L.

6.5 Analytical balance, with an accuracy of 0.0001 g or higher.

6.6 Magnetic stirrer, equipped with a stirring magneton coated with polytetrafluoroethylene (PTFE).

6.7 Thermometer, with an accuracy of 0.1 °C or higher.

6.8 pH meter (pH electrode), calibrated, with an accuracy unit of ± 0.05 pH.

Use standard buffer solutions with pH of 2.0, 4.0 and 6.0 at 25 °C, or standard buffer solutions with pH of 1.68, 4.01 and 6.86, or pH buffer solutions prepared in accordance with national standards for the calibration. In addition, check the linear response, and the slope per pH unit shall be at least 58 mV.

NOTE: commercially available pH standard buffer solutions that comply with national standards and with attached certificates can be used.

7 Analytical Procedures

7.1 Sample Selection

From three different batches of oral rinses, take two representative samples from each batch (six samples in total).

7.2 Preparation of Solutions

7.2.1 Preparation of stock solutions

---Stock solution A (1 mol/L CaCl_2): add 147.01 g of $\text{CaCl}_2 \cdot 2\text{H}_2\text{O}$ (5.1) to 1 L of water (5.7);

---Stock solution B (1 mol/L KH_2PO_4): add 136.09 g of KH_2PO_4 (5.6) to 1 L of water (5.7).

NOTE: the two stock solutions need to be prepared immediately before use.

7.2.2 Preparation of screening solution

In accordance with the following steps, prepare the screening (calcium phosphate) solution:

- Add 500 mL of water (5.7), 1.266 mL of stock solution A (7.2.1) and 0.760 mL of stock solution B (7.2.1) to the 1 L volumetric flask;
- Use hydrochloric acid (5.4) to adjust pH to 5.05 ± 0.05 ;

NOTE 1: when pH is lower than 5.05 ± 0.05 , potassium hydroxide (5.3) can be used to adjust the pH.

- Use water (5.7) to dilute to 1 L.

7.3.3 Test duration

Stop after pH becomes stable.

7.3.4 Number of tests

For each test sample (six samples in total), repeat the test for four times.

7.3.5 Data recording and processing

For each test, record the pH of the test sample [i.e., the control buffer solution (5.8) or oral rinse], the initial pH of the screening (calcium phosphate) solution (7.2), the pH after adding the test sample, and the pH drop value (the initial pH minus the final pH).

Record the original data of each type of test material.

7.3.6 Result evaluation

Respectively calculate the average value of the pH drop values of four repeated tests for each sample (six samples in total) and the standard deviation of the pH drop value of the test sample. If the average pH drop value of each sample is equal to or less than 1.0, then, it passes the test.

8 Evaluation Report

In accordance with the test process, issue an evaluation report, which includes the following information:

- a) Complete identification of the oral rinse under test, including product name, manufacturer, batch No. and type of administration (such as: canned, pasty and syringe form);
- b) Storage conditions of oral rinse;
- c) Number of test samples;
- d) Whether the test result is PASS;
- e) Standard deviation of the tests described in this document (if applicable);
- f) Reference standard;
- g) Test date;
- h) Test personnel's signature and date.

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