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WS

**INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

WS/T 326.2-2010

**Efficacy evaluation of toothpaste. Part 2: Guidelines for
anti-caries efficacy evaluation
(English Translation)**

Issued on: December 3, 2010

Implemented on: December 3, 2012

Issued by: Ministry of Health of the People 's Republic of China

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Foreword

WS/T 326-2010 Efficacy evaluation of toothpaste consists of the following parts.

- Part 1.General principles;
- Part 2.Guidelines for anti-caries efficacy evaluation;
- Part 3.Guidelines for efficacy evaluation on the control of dental plaque or gingivitis;
- Part 4.Guidelines for efficacy evaluation on dentin hypersensitivity.

This Part is the second part of WS/T 326.

This Part refers to the American Dental Association (ADA) Guidelines for the Validation of Fluoride Toothpaste in the Guidelines for the Safety and Efficacy of Oral Health Products - " Guidance on Acknowledgment of Fluoride Toothpaste by the American Dental Association Scientific Committee, November 2005".

This Part was proposed by Chinese Journal of Stomatology.

This Part was approved by the Ministry of Health of the People's Republic of China.

The drafting organizations of this Part. West China College of Stomatology of Sichuan University, Peking University School of Stomatology and Sun Yat-sen University Guanghua School of Stomatology.

Main drafters of this Part. Hu Deyu, Wang Xiaoling, Wang Qin, Lin Huancai,

Zhang Boxue.

Efficacy evaluation of toothpaste -

Part 2.Guidelines for anti-caries efficacy evaluation

1 Scope

This Part of WS/T 326 specifies efficacy evaluation and evaluation method of anti-caries of toothpaste.

This Part applies to toothpaste products that claim to have anti-caries efficacy and physical and chemical properties, health and safety indicators in line with the corresponding national standards.

2 Normative references

The following referenced documents are indispensable for the application 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.

GB 8372 Toothpaste

3 Terms and definitions

For the purposes of this document, the terms and definitions specified in WS/T

4.2.1 According to 5.1 laboratory evaluation method of anti-caries efficacy,

after the experiment, when free fluorine or soluble fluorine content of fluoride toothpaste is ≥ 500 mg/kg, the product shall have anti-caries efficacy.

4.2.2 According to clinical trial requirements of 5.2 anti-caries efficacy, at

baseline, mid-trial, and at the end of the trial, respectively KEEP statistics on the increase in the value of the indicators after the test for the experimental group and the positive control group (fluoride toothpaste of total fluorine of 1100 mg/kg ~ 1450 mg/kg in accordance with this Standard, excluding other active ingredients) and CARRY OUT the statistical analysis on the changes of each

index at any period between the two groups.

5.1.1 Determination of free fluoride or soluble fluorine content after fluoride-

containing toothpaste product aging test shall be carried out according to the fluoride determination method specified in GB 8372.

5.2.1 Principles for test design

Randomized, controlled, and blinded clinical trial methods should be used. The test should be equipped with a positive control.

5.2.2 Duration of test

The test should be continued for at least 2 years. Caries status shall be checked and recorded at baseline, at mid-trial, and at the end of the trial.

5.2.4 Index checking or using

Crown caries. the use of decayed-missing-filled tooth (DMFT), distant metastasis-free survival (DMFS), decayed-missing-filled tooth (dmft) and distant metastasis-free survival (dmfs).

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