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Supervision Regulation on Safety Technology for Stationary Pressure Vessel (English Translation)

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Foreword

WS/T 326-2010 "toothpaste effect evaluation" is divided into 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 is part 4 of WS/T 326.

Clinical trials in this Part references to the clinical trial's design principle guidelines "American Dental Association Scientific Committee - Accreditation Program - Clinical Trial Program Guide, 2003" that was formulated by American Dental Association (ADA).

This Part was proposed by Chinese Stomatological Association.

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

Drafting organizations of this Part. Huaxi School of Stomatology of Sichuan University, School of Stomatology of Peking University, and School of Stomatology of Shanghai Jiaotong University.

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Efficacy evaluation of toothpaste -

Part 4.Guidelines for efficacy evaluation on dentin

hypersensitivity

1 Scope

This Part of WS/T 326 specifies the efficacy's classification, evaluation and clinical trial requirements for toothpaste products on anti-dentin hypersensitivity.

This Part applies to toothpaste products that claim having efficacy of anti-dentin hypersensitivity, and of which the physiochemical properties and health-safety indicators comply with relevant national standards.

2 Normative References

The following document is essential for the application of this document. For the documents cited with dates, only that edition applies to this document. For undated references, the latest edition (including any amendments) applies to this document.

WS/T 326.1 Efficacy evaluation of toothpaste - Part 1.General principles

3 Terms and Definitions

The terms and definitions defined in Part 1 of WS/T 326 apply to this document.

4.1 The evaluation shall be according to anti-dentin hypersensitivity's product

classification; in accordance with this Part to carry out the clinical trials at different times; depending on the situation of test sensitivity mean changes, before and after the use of subject product (experimental group) and control group product; and through statistical analysis.

4.2 During the test, the mean of dentin hypersensitivity indicators of the experimental

group shall be significantly lower, and have statistical significance compared with the negative control group.

5.1 Test Design Principles

It shall adopt randomized, blind-method, parallel or crossover experimental design's clinical trial methods. After conducting a baseline examination, it shall be balanced to

allocate the testees, including gender, age and the number of teeth of the testees.

5.2 Test duration

The trial period shall be from the time when the subject product claims effective, lasting for more than four weeks. Claiming that effectively reducing dentine hypersensitivity needs to determine the test period based on product characteristics.

5.3.1 Testees' requirements

Healthy adult male and female who meet the inclusion and exclusion criteria shall be determined based on the efficacy and principle of the product. And it shall meet a sufficient statistical power ($\beta = 0.80$) and 95% confidence level; generally, the number of people in each group to complete the whole process of the test shall be more than

5.3.3 Exclusion criteria

- a) Testee has severe oral diseases, chronic diseases or allergy to subject products.
- b) During the progress of periodontal disease, or in the past year there was an periodontal treatment received (including periodontal surgery).
- c) The loosening of sensitive teeth is greater than 1.
- d) there is a large area of dental filling body or crown, suspected pulpitis, caries, cracked enamel, removable partial denture abutment.
- e) Testee has allergies or idiosyncratic reactions to oral care products or its ingredients.
- f) Allergy to toothpaste and ingredients.

5.4.2 Probing sensitivity evaluation

- a) It may use an electronic pressure-sensitive probe (Yapple probe) that has been calibrated. This instrument can quantitatively measure the pressure applied to the tooth surface (g).
- b) When testing sensitivity, the probe shall contact the selected buccal exposed surface, located at the junction of dentinal and enamel essence; use the original-preset 10g force to probe; then increment the force 10g each time; the

maximum force is 80g; record the sensitivity threshold, that is, the pressure value when testee indicates that there is an uncomfortable feeling. Higher value of probing force indicates that the tooth sensitivity is at lower level, and vice versa.

5.4.3 Cold-air blown sensitivity evaluation

Use dental station's air-gun to blow the sensitive teeth for 1s, at 1cm away; compressor pressure is $413 \text{ kPa} \pm 35 \text{ kPa}$; blowing temperature is $19^{\circ}\text{C} \sim 21^{\circ}\text{C}$; when blowing, place the finger on the adjacent teeth to avoid the neighboring teeth's symptoms to affect the accuracy of the results. Use Schiff cold-air sensitive indicator for evaluation; scoring is as follows.

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