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WS/T 326.4-2010

Efficacy evaluation of toothpaste - Part 4: Guidelines for efficacy evaluation on dentin hypersensitivity

牙膏功效评价 第4部分：抗牙本质敏感

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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.

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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 Efficacy Evaluation

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. And when one of the dentin-hypersensitivity indicators mean is reduced by 15% or more, it is deemed that the experimental group has efficacy on anti-dentine hypersensitivity.

- 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 Evaluation indicators

5.4.1 Evaluation method of dentin hypersensitivity

- a) Sensitive teeth have different reactions to different stimulation, so when using stimulation as the indicator of recording dentin hypersensitivity, these stimulations shall be proved to be measurable and repeatable. There shall have sufficient time to recover dentin reaction between stimulations, so as to avoid mutual interference.
- b) Evaluation shall use at least two kinds of stimulation (Yepple probe method and cold-air method); testees' reaction can be expressed with the following indicators:
 - 1) Changes of reaction to the standard level of stimulation;
 - 2) Continuously increase the level of stimulation, until that the reaction reaches intolerable degree;
 - 3) When using the electronic pressure-sensitive probe to count (it may also use the same-indicator's instrument) and Schiff cold-air sensitive indicator to measure and evaluate, attention shall be paid to the sequence and interval time of different stimulation methods.

5.4.2 Probing sensitivity evaluation

- a) It may use an electronic pressure-sensitive probe (Yepple 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

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