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QB

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

QB/T 2966-2014

Functional toothpastes

功效型牙膏

(English Translation)

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1 Scope

This Standard specifies the terms and definitions, requirements, test methods, inspection rules and marks of functional toothpastes.

This Standard is applicable to the toothpaste products in which by adding functional ingredients to toothpaste, the toothpaste has the functions of auxiliary prevention, alleviation of oral problems or a certain improvement of the dental condition, and promotes its efficacy, marks its effect on the packaging.

Toothpastes that implement this Standard shall first meet the requirements of GB 8372.

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/T 601, Chemical Reagent - Preparations of Standard Volumetric Solutions

GB/T 603, Chemical reagent - Preparations of reagent solutions for use in test methods

GB/T 6682, Water for analytical laboratory use - Specification and test methods

GB 6819, Dissolved acetylene

GB 8372, Toothpaste

GB/T 15337, General rules for atomic absorption spectrometric analysis

GB 22115, General requirements on raw materials of toothpastes

QB/T 2968, Determination of strontium chloride in toothpastes

WS/T 326, Efficacy evaluation of toothpaste

Order of the General Administration of Quality Supervision, Inspection and

Quarantine [2005] No. 75, Measures for Measurement Supervision and

Administration of Quantitative Packaging Commodities

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

functional toothpastes

The toothpaste that by adding functional components, in addition to the basic function of toothpaste, it can also help prevent or reduce certain oral problems and promote oral health. Its basic functions include: cleaning the mouth, reducing dental stains, reducing soft dirt, whitening teeth, reducing plaque, refreshing breath, refreshing taste, maintaining the health of teeth and periodontal tissues (including gums), and protecting oral health.

3.2

functional components

Ingredients that help functional toothpaste achieve one or more functions in addition to its basic functions. The efficacy of the functional toothpaste mainly includes: preventing caries, inhibiting plaque, anti-dentin sensitivity, reducing gum-related problems, removing stains and whitening, anti-calculus, reducing bad breath, and other functions that have been verified to improve the efficacy of oral problems.

4.1 Raw material

The raw materials used in the production of functional toothpaste shall meet the requirements of GB 22115.

4.2 Hygiene indicators

The hygiene indicators shall be in accordance with GB 8372.

4.3 Sensory, physical and chemical indicators

Sensory, physical and chemical indicators are in accordance with GB 8372.

4.4 Efficacy evaluation and safety requirements

a) The efficacy evaluation study shall be conducted on the basis of the safety evaluation of the functional components;

b) The efficacy involved in WS/T 326 is performed according to the evaluation method of WS/T 326;

c) Toothpaste products that claim to have same efficacy, use the same functional components, and have an added amount not less than the proved, do not need efficacy evaluation;

d) For the efficacy evaluation report (including clinical evaluation report and laboratory evaluation report), at least one shall be issued by the institution that meets one of the following qualifications:

1) Grade III Class A oral medical institutions (including the School of

Stomatology, Stomatological Specialty Hospitals and General Hospital

Stomatological Departments) with the qualification of "Pharmaceutical

Clinical Trial Institute" of the State Food and Drug Administration (SFDA). If it is a stomatology department of a general hospital, it must have had the stomatology qualification certificate of "Drug Clinical Trial

Agency";

2) School of stomatology / specialized hospital, awarded by the Ministry of Health as a key clinical specialty (stomatology);

3) Provincial stomatological hospital (the project leader must have passed the national drug clinical trial technical training and passed the assessment, and obtained the GCP certificate).

e) The laboratory evaluation report can also be issued by a national or provincial third-party laboratory organization whose qualification is qualified.

5.4 Safety

In order to ensure the safety of the product, the components added in the functional toothpaste shall meet the requirements of GB 22115.

5.5 Qualitative or quantitative determination of functional components

The enterprise tests the functional components according to the measurement method (recommended but not limited to) described in the annex of this

Standard. It can also issue a report after being detected by a domestic third- party testing agency. If there are other functional components and their determination methods, they shall be supplemented and perfected in the in accordance with WS/T 326. There is currently no prescribed method for efficacy evaluation, which shall be conducted in accordance with the principles prescribed in this Standard.

Annex B (informative)

Determination of paeonol content

B.1 Instrument

High performance liquid chromatography.

B.2 Reagents

B.2.1 Paeonol reference substance (China National Institute for the Control of Pharmaceutical and Biological Products).

B.2.2 Methanol: chromatographically pure.

B.3 Preparation of reference substance solution

Weigh 0.01g of paeonol reference substance (to the nearest of 0.0001g) in a volumetric flask. Add methanol to dissolve and make 0.032mg/mL paeonol solution.

B.4 Preparation of sample solution

Weigh 0.2g of sample (to the nearest of 0.0001g) in a stoppered test tube.

Accurately add 10mL of methanol. Use a glass rod to stir the toothpaste sample.

Conduct ultrasonic extraction 30min. Place still. Pour the supernatant into a centrifuge tube. Centrifuge at 2000r/min for 5min. Use a 0.45µm filterable membrane to filter and the solution shall be obtained.

B.5 Determination

B.5.1 Chromatographic conditions

Chromatographic column: C 18 250mmx4.6mm, 5µm.