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

YY/T 0825-2026

Replacing YY/T 0825-2011

**Dental science - External dental bleaching products
(English Translation)**

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Reference

Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part 1: Structure and Drafting Rules of Standardization Documents".

Drafting.

This document replaces YY/T 0825-2011 "Dentistry - External Bleaching Products for Teeth". Compared with YY/T 0825-2011, the only changes are structural adjustments.

Aside from editorial changes, the main technical changes are as follows.

- The scope has been changed (see Chapter 1, Chapter 1 of the 2011 edition);
 - Added the term and definition of "corrosion" (see 3.3);
 - The classification has been changed (see Chapter 4, 4.3 of the 2011 edition).
 - Changed from "Concentration of bleaching active ingredient - peroxide" to "Concentration of bleaching active ingredient (equivalent to hydrogen peroxide)", and added...
- The phrase "can be tested using Appendix A or other equivalent methods" has been added (see 5.1, 2011 edition 5.1).
- The "Surface Corrosion" section has been changed (see 5.3, 2011 version of 5.3).
 - The "concentration of bleaching active ingredients" has been removed (see 6.1 in the 2011 edition);
 - The preparation of dental specimens has been amended (see 6.2, 2011 edition of 6.2).

--The preparation and use of teeth whitening products has been amended (see 6.3, 2011 edition of 6.3).

--The phrase "Calculate the change in microhardness of the enamel surface according to the following formula" has been deleted (see 6.4.1 in the 2011 edition).

--The "Result Determination" section has been removed (see section 6.4.2 in the 2011 version).

--The labeling and instruction manual requirements have been changed (see Chapter 7, Chapter 7 of the 2011 edition).

This document is modified to adopt ISO 28399:2021 "Dentistry - External bleaching products for teeth".

The technical differences between this document and ISO 28399:2021, and the reasons therefor, are as follows.

--Added a calculation formula for the surface microhardness reduction rate (see 6.3.1), clarifying the calculation method for the hardness reduction rate;

--An improved method for determining the surface microhardness reduction rate (see 6.3.2) has been added to enhance the operability of the determination.

Please note that some content in this document may involve patents. The issuing organization of this document assumes no responsibility for identifying patents.

This document was proposed by the National Medical Products Administration.

This document is under the jurisdiction of the National Technical Committee on Standardization of Dental Materials and Instruments (SAC/TC 99).

Introduction

Dental bleaching products are used to lighten or whiten the color of natural teeth. These products are applied directly to the teeth inside the mouth.

Outer surface.

This document does not include specific qualitative and quantitative testing methods to demonstrate the absence of unacceptable biohazards, but recommends them when assessing potential biological hazards.

For information on harmful substances, please refer to ISO 10993-1 and ISO 7405.

Dental external teeth whitening products

1 Scope

This document specifies the requirements and testing methods for external dental bleaching products. These products are for oral use and may be used by professionals (clinics).

Teeth whitening products for indoor use (or professional or non-professional home use) or for consumer use (or both), applied in the oral cavity.

This document also specifies requirements for product packaging, labeling, and instructions for use.

This document does not apply to the following teeth whitening products.

--The content specified in ISO 11609;

--The color of natural teeth can be altered through mechanical methods (e.g., removing stains) or restorative methods such as veneers or crowns.

--Auxiliary or additional materials (such as tray materials) and appliances or devices (such as lamps) used with bleaching products.

This document does not address the biosafety of teeth whitening products.

Note: The maximum concentration of bleach for professional or non-professional use depends on the regulations of each country's regulatory body.

2 Normative references

The contents of the following documents, through normative references within the text, constitute essential provisions of this document. Dated citations are listed below.

For references to documents, only the version corresponding to that date applies to this document; for undated references, the latest version (including all amendments) applies.

document.

ISO 1942 Dentistry Vocabulary Note. GB/T 9937-2020 Dental Terminology (ISO 1942:2009, MOD) ISO 3696 Water for analytical laboratory use - Specification and test methods and test methods) Note. GB/T 6682-2008 Specifications and test methods for water used in analytical laboratories (ISO 3696:1987, MOD) ISO 6344-1 Grain size analysis of coated abrasives - Part 1: Grain size composition Part 1: Grain size distribution test) Note. GB/T 9258.1-2000 Abrasives for coated abrasives - Grain size analysis - Part 1: Grain size composition (idt ISO 6344-1:1998) ISO 8601-1 Date and time-representations - Part 1: Fundamental principles for information interchange-Part 1: Basic rules) Note. GB/T 7408.1-2023 Representation for the Interchange of Date and Time Information - Part 1: Fundamental Principles (ISO 8601-1:2019, IDT) ISO 8601-2 Date and time-representations