

ICS 11.060.10
CCS C33

YY

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

YY 0717-2023

Replacing YY 0717-2009

Dentistry - Root canal sealing materials

牙科学 根管封闭材料

Issued on: September 5, 2023

Implemented on: September 15, 2026

Issued by: National Medical Products Administration

Table of Contents

1 Scope	1
2 Normative reference documents	1
3 Terms and Definitions	1
4 Requirements	2
5 Sampling	3
6 Test environment and sample preparation	3
7 Test method	3
7 Reference	9

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 0717-2009 "Dental Root Canal Sealing Materials". Compared with YY 0717-2009, except for structural adjustment and editing In addition to the modifications, the main technical changes are as follows:

--- "Non-curing dental root canal sealing materials are not applicable to this standard." has been deleted from the scope (see Chapter 1 of the.2009 edition);

---Added the terms "root canal sealing material" (see 3.1) and "root canal filling material" (see 3.2);

---The test procedures for fluidity, working time and solubility have been changed, and the limits have been redefined (see 4.3.1, 4.3.2, 4.3.5, 4.3.1, 4.3.2,

4.3.6 of the.2009 version);

---Change the liquidity indicator to " $\geq 17\text{mm}$ " (see 4.3.1,.2009 version of 4.3.1);

---Deleted the note about constant weight in the solubility step (see 7.7.3 of the.2009 version);

--- Move the description of biological hazards and ingredients claimed to have therapeutic effects from the requirements to the introduction (see Introduction,

4.2 of the.2009 version);

--- Added requirements for microbial limits (see 4.2.1);

---Changed the requirements for dimensional changes after curing (see 4.3.7, 4.3.5 of the 2009 version);

1 Scope

YY 0717 is the mandatory Chinese standard for root canal sealers, the cements that fill the space between the gutta-percha points and the canal wall in endodontic treatment. It sets the requirements such materials have to meet and the test methods that verify them, covering setting time, flow, film thickness, dimensional stability, solubility, radiopacity and the biological safety of a material placed in intimate contact with periapical tissue. The seal is what determines whether a root canal treatment lasts or the tooth reinfects, and the sealer is the part of that seal that has to remain stable for decades. Being a YY standard without the /T suffix, compliance is compulsory in China. The 2023 edition replaces YY 0717-2009 and takes effect in September 2026.

This document specifies the performance requirements and test methods for dental root canal sealing materials used to permanently seal tooth root canals. This document is applicable to the following root canal sealing materials, which can be cured in a humid or non-humid environment and can be used with or without root canal filling tips. A root canal sealing material used alone in conjunction with a root canal filling tip and for forward filling (i.e. root canal filling from the crown of the tooth).

2 Normative reference documents

The contents of the following documents constitute essential provisions of this document through normative references in the text. Among them, the dated quotations For undated referenced documents, only the version corresponding to that date applies to this document; for undated referenced documents, the latest version (including all amendments) applies to this document.

GB/T 6682 Analytical laboratory water specifications and test methods (GB/T 6682-2008, ISO 3696:1987, MOD)

GB/T 9937 Dental terminology (GB/T 9937-2020, ISO 1942:2009, MOD)

YY 0462 Dental plaster products (YY 0462-2018, ISO 6873:2013, MOD)

YY/T 1646 Test method for X-ray radiopacity of dental materials (YY/T 1646-2019, ISO 13116:2014, IDT)

ISO 8601 (all parts) Date and time format (Dateandtimeformat)

GB/T 7408-2005 Data element and exchange format information exchange date and time representation (

ISO 8601:2000, IDT) Pharmacopoeia of the People's Republic of China 2020 Edition Four

Parts

3 Terms and definitions

The terms and definitions defined in GB/T 9937 and the following apply to this document.

3.1 A root canal filling material used to permanently seal the pulp chamber of a tooth from which the pulp has been removed.

3.2 Root canal material used to permanently fill the pulp cavity occupied by the original pulp of a tooth.

3.3 mixing time mixing time During the working time, the time to mix the components evenly.

3.4 working time working time The time from the start of blending until the closure material can be handled without adversely affecting its properties.

3.5 Curing timesettingtime Timing starts from the end of mixing until the time required for the sealing material to solidify according to the indicators and conditions described in 7.5.

4.3.7 Dimensional changes after curing, and specified

7.9 test method, because this indicator measures the material filling into the root canal body The cumulative changes have an impact on the prognosis of treatment;

---Remove 4.4, 4.5, and

4.6 from the 4 requirements and change them to 5 and 6, and adjust the subsequent serial numbers accordingly, because 4.4, 4.5, and

4.6 are taken Samples, test conditions and specimen preparation are not performance requirements;

7.3.1.4 balance, accuracy 0.0001g;

7.7.4 add the description and expression of material disintegration to correspond to the requirements of 4.3.5;

---Change part of the

7.8 Judgment of results. Please note that some content in this document may be subject to patents. The publisher of this document assumes no responsibility for identifying patents. This document is proposed by the National Medical Products Administration. This document is under the jurisdiction of the National Standardization Technical Committee for Dental Materials and Equipment (SAC/TC99). The previous versions of the documents replaced by this document are as follows:

---First released in.2009 as YY 0717-2009;

---This is the first revision.

This document does not include qualitative and quantitative test methods used to demonstrate that materials do not present unacceptable biological risks, such as the assessment of such biological Risks can be referred to ISO 10993-1 and ISO 7405. If the manufacturer claims that the product has therapeutic effects, the purity and sterility of the relevant ingredients must comply with the Pharmacopoeia of the People's Republic of China or appropriate relevant laws and regulations. Dental root canal sealing materials