

ICS 55.020
CCS A 85



**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB/T 47937-2026

**Child-resistant packaging - Requirements and testing for
non-reclosable packaging for pharmaceutical products**

儿童防护包装 药品用不可再封口包装的要求与试验

(English Translation)

Issued on: July 30, 2026

Implemented on: November 1, 2026

Issued by: State Administration for Market Regulation

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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 is modified to adopt ISO 14375:2018 "Child-protected non-resealed pharmaceutical packaging - requirements and test methods".

Compared with ISO 14375:2018, this document has undergone the following structural adjustments.

---Sections 5.1.1 to 5.1.4 correspond to section 5.1 of ISO 14375:2018;

---5.3.1 corresponds to 5.3.2 of ISO 14375:2018, and 5.3.1 of ISO 14375:2018 has been deleted; among them, 5.3.1.2 and 5.3.2.1 5.3.2.2 corresponds to 5.3.2.2, 5.3.3.1, and 5.3.3.2 of ISO 14375:2018, respectively;

---5.4.1.1 corresponds to 5.4.1 of ISO 14375:2018, where 5.4.1.1.1 corresponds to 5.4.1.1 and 5.4.1.1 of ISO 14375:2018.

5.4.1.2 and 5.4.1.1.2 correspond to 5.4.1.3.1 of ISO 14375:2018;

---5.4.1.2 corresponds to 5.4.1.3.2 of ISO 14375:2018;

---Appendix B corresponds to Annex B and Annex C of ISO 14375:2018.

The technical differences between this document and ISO 14375:2018, and the reasons therefor, are as follows.

---The example of "alternative" adds the term "capsule" and its definition (see 3.3) to make the expression clearer;

---The test criteria have been revised (see 5.1), and content that overlaps with 5.3 has been removed, resulting in clearer logic and more concise statements;

---The general rules for test procedures (see 5.3.1 of ISO 14375:2018) have been removed to avoid repetition and make the logic clearer.

The following editorial changes have been made to this document.

---To align with existing standards, the standard title has been changed to "Requirements and Tests for Non-Resealable Packaging for Pharmaceuticals with Child-Protective Packaging";

---Added sources for the terms "child-protective packaging", "non-resealable child-protective packaging", "alternatives", and "type approval" (see...)

---The note regarding pediatric testing in the performance requirements has been amended

(see 4.2.1);

---Change the contents of Appendix C (informative) to the figure captions in Appendix B (see Appendix B).

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 and is under the jurisdiction of the National Packaging Standardization Technical Committee (SAC/TC49).

Introduction

The purpose of child-safe packaging is to create a physical barrier between children and potentially dangerous products. Do various types of packaging meet child-safe packaging standards?

The protective function needs to be certified through performance testing in accordance with relevant standards.

Since the adoption of child-protective packaging, the incidence of accidents involving children under 5 years old accidentally ingesting potentially dangerous products has decreased. This improvement...

It is questionable whether child-protective packaging has played a positive role in reducing such accidents.

Child-protective packaging is limited to products with potential hazards or products for which its use is mandated by laws and regulations. In other cases, its use is prohibited.

Using this product may lead consumers to misjudge its level of danger. Regardless, manufacturers providing standardized labeling and complete instructions is crucial for ensuring safety.

Ensuring the safety of medication use in households is of paramount importance.

When other protective measures fail, child-protective packaging becomes the last line of defense. The expectation is that functional packaging can completely prevent infection for up to 42 months.

It is impractical for children aged 51 months and older to open the package; child-protective packaging cannot replace other safety precautions. It should be noted that child protection...

Packaging is only the last link in many safety measures. Parents or guardians still have the responsibility to properly store medicines and prevent children from accessing them.

With the increasing popularity of child-protective packaging, it is necessary to standardize testing procedures to prevent problems in this crucial area of child safety.

Confusion and misunderstanding.

This document aims to minimize the number of children actually participating in the testing. Since performance testing began, there has been considerable progress in child protection...

We have accumulated extensive experience in packaging testing and continue to focus on how to reduce the number of children involved in testing. In the future, we need to establish a system based on mechanical testing...

The standardization of testing methods aims to reduce unnecessary child testing and support manufacturers in developing applicable packaging physical properties.

Non-resealable packaging for children's protective medicines Packaging Requirements and Tests

1 Scope

This document specifies the requirements for non-resealable packaging for pharmaceuticals with child-protective features and describes the corresponding test methods.

This document applies only to the type designation of non-resealable packaging for pharmaceuticals with child protection features.

2 Normative references

This document has no normative references.

The following terms and definitions apply to this document.

child-resistant packaging Packaging that is not easily opened (or its contents obtained) by children (under 52 months) but does not affect normal use by adults.

[Source. GB/T 4122.1-2008, 2.28, with modifications] 3.2 Non-reclosable child-resistant packaging Child-protective packaging that cannot be resealed properly after all or part of the contents have been removed.

[Source. GB/T 42089-2022, 3.2, with modifications] 3.3 substitute product Inert items similar to the actual contents.

Examples. powder, tablets, capsules, or liquid (uncolored water), etc.

Note: This product is sometimes referred to as a placebo product.

[Source. GB/T 42089-2022, 3.3, with modifications] 3.4 unit dose the smallest unit of product that can be taken intact from the initial packaging.

Procedures for demonstrating that a specific type of non-resealable packaging made from a