

ICS 55.020
CCS A 80



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

GB/T 45453-2025

**Packaging - Tamper verification features for medicinal product
packaging**

包装 药品包装的篡改验证特性

(English Translation)

Issued on: March 28, 2025

Implemented on: March 28, 2025

**Issued by: State Administration for Market Regulation, China National
Standardization Administration**

Table of Contents

Preface
1 Scope
2 Normative references
3 Terms and Definitions
4 General requirements
4.1 The role of tamper proof feature
4.2 Application and use of tamper proof features
4.3 Checking the Tamper Authentication Feature
5 Various tamper proof features
5.1 General
5.2 Adhesive-sealed folding cartons
5.3 Special structure folding carton
5.4 Seals and tapes
5.5 Film wrapping
5.6 Shrink film
5.7 Damaged or tear-off sealing caps
5.8 Sealing inside the container
5.9 Display blister packaging
5.10 Flexible packaging
5.11 Blow Fill Seal Containers
5.12 Others
Appendix A (informative) Additional information on tamper proof features
Reference

Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for standardization work Part 1: Structure and drafting rules for standardization documents" Drafting.

This document is modified to adopt ISO 21976:2018 "Tamper verification characteristics of packaged pharmaceutical products".

This document has the following structural adjustments compared to ISO 21976:2018.

--- 4.1 in ISO 21976:2018 has been deleted. 4.1~4.3 now correspond to 4.2~4.4 in ISO 21976:2018.

The technical differences between this document and ISO 21976:2018 and their reasons are as follows.

---Terms 3.1, 3.4, 3.5 and 3.6 in ISO 21976:2018 have been deleted because the Drug Administration Law of the People's Republic of China has stipulated the definition in ISO 21976:2018 is not completely consistent with that in the Drug Administration Law of the People's Republic of China;

--- The definitions of terms 3.3 and 3.7 in ISO 21976:2018 have been modified.

The content of the drug registration management regulations and other drug-related regulations such as the Pharmacopoeia of the People's Republic of China have been modified.

--- Added illustration of the plastic seal and threaded connection in the container as one-piece injection molding [see Figure 10 e) and f)].

1 Scope

This document specifies the requirements for tamper-proof features of pharmaceutical packaging.

This document applies to the use and verification of tamper verification features on pharmaceutical packaging and can be used as a reference for other product packaging.

2 Normative references

This document has no normative references.

3 Terms and definitions

The following terms and definitions apply to this document.

Finished product

An authorized medicinal product that has completed all stages of production, including packaging in its final container for distribution, sale or otherwise supply.

Immediate packaging and containers that come into direct contact with drugs Packaging materials and containers that are in direct contact with drugs used in drugs produced by pharmaceutical manufacturers and preparations prepared by medical institutions.

Outer packaging

Packaging other than packaging materials and containers that are in direct contact with the

drug.

Tampering

Unauthorized attempts to open, manipulate or reuse its packaging or components.

Features for verifying whether packaging and containers (3.2) or outer packaging (3.3) that are in direct contact with the drug have been opened or tampered with.

NOTE: Tamper proof features are often referred to as "tamper resistant design".

verification

Confirmation that specified requirements have been met by providing objective evidence.

[Source. GB/T 19000-2016, 3.8.12, modified]

4 General requirements

4.1

The role of tamper proof features Tamper-proof features should provide an indication of whether the finished product packaging has been opened or tampered with, indicating the presence of adulteration or unauthorized Attempts to open packaging or introduce counterfeit medicines into the legitimate supply chain. Tamper-proof features limit substitution of authentic packaging.