YY

PHARMACEUTICAL INDUSTRY STANDARD

OF THE PEOPLE'S REPUBLIC OF CHINA

ICS 11.040.01

C 30

YY/T 1759-2020

Guide for Design and Evaluation of Primary Flexible Packaging for Medical Devices

医疗器械软性初包装设计与评价指南

Issued on: September 27, 2020 **Implemented on: September 1, 2021**

Issued by: National Medical Products Administration

Table of Contents

Guide for Design and Evaluation of Primary Flexible Packaging for Medical Devices

1 Scope

This Standard provides a guide for design and evaluation of primary flexible packaging for medical devices. This Standard does not involve acceptability criteria.

NOTE: the acceptability criteria are jointly determined by the packaging manufacturer and the medical device manufacturer.

This Standard is applicable to the design and evaluation of primary flexible packaging of medical devices aseptically and non-aseptically provided.

2 Normative References

The following documents are indispensable to the application of this document. In terms of references with a specified date, only versions with a specified date are applicable to this document. In terms of references without a specified date, the latest version (including all the modifications) is applicable to this document.

GB/T 451.1 Paper and Board - Determination of Size and Deviation

GB/T 451.2 Paper and Board - Determination of Grammage

GB/T 451.3 Paper and Board - Determination of Thickness

GB/T 454 Paper - Determination of Bursting Strength

GB/T 455 Paper and Board - Determination of Tearing Resistance

GB/T 458 Paper and Board - Determination of Air Permeance

GB/T 464 Accelerated Aging (dry heat treatment) of Paper and Board

GB/T 465.1 Paper and Board - Determination of Bursting Strength after Immersion in Water

GB/T 465.2 Paper and Board - Determination of Tensile Strength after Immersion in Water

GB/T 1037 Test Method for Water Vapor Transmission of Plastic Film and Sheet - Cup Method

GB/T 7706 The Relief Prints for Decorating

GB/T 7742 (all parts) Textiles - Bursting Properties of Fabrics

GB/T 8807 Test Method for Specular Gloss of Plastics

GB/T 8809 Pendulum Impact Resistance of Plastic Film

GB/T 10006 Plastics - Film and Sheeting - Determination of the Coefficients of Friction

GB/T 12914 Paper and Board - Determination of Tensile Properties - Constant Rate of Elongation Method (20 mm/min)

GB/T 15171 Test Method for Leaks in Sealed Flexible Packages

GB/T 16578 (all parts) Plastics - Film and Sheeting - Determination of Tear Resistance

GB/T 16886 (all parts) Biological Evaluation of Medical Devices

GB/T 17593 (all parts) Textiles - Determination of Heavy Metals

GB/T 19633.1 Packaging for Terminally Sterilized Medical Devices - Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems

GB/T 19789 Packaging Materials - Test Method for Oxygen Gas Permeability Characteristics of Plastic Film and Sheeting - Coulometric Sensor

GB/T 21529 Determination of Water Vapor Transmission Rate for Plastic Film and Sheeting - Electrolytic Detection Sensor Method

GB/T 22819 High Permeable Paper - Determination of Air Permeability

GB/T 22895 Paper and Board - Determination of the Static and Kinetic Coefficients of Friction - Horizontal Plane Method

GB/T 22898 Paper and Board - Determination of Tensile Properties - Constant Rate of Elongation Method (100 mm/min)

GB/T 22901 Paper and Board - Determination of Air Permeance (medium range) - General Method

GB/T 22921 Paper and Board - Determination of Water Vapor Transmission Rate of Sheet Materials - Dynamic Sweep and Static Gas Methods

GB/T 24218.1 Textiles - Test Methods for Nonwovens - Part 1: Determination of Mass per Unit Area

GB/T 24218.2 Textiles - Test Methods for Nonwovens - Part 2: Determination of Thickness

YY/T 0698.6 Packaging Materials for Terminal Sterilized Medical Devices - Part 6: Paper for Manufacture of Sterile Barrier Systems Intended for Sterilization by Low Temperature Sterilization Processes or Irradiation - Requirements and Test Methods

YY/T 0698.7 Packaging Materials for Terminal Sterilized Medical Devices - Part 7: Adhesive Coated Paper for the Manufacture of Sealable Packs for Medical Use for Sterilization by Ethylene Oxide or Irradiation - Requirements and Test Methods

YY/T 1286.1 Platelets Storage Container Performances - Part 1: Determination of Gas Permeability of the Film - Differential-pressure Method

YY/T 1432 Test Method for Determination of Heat-sealability of Flexible Webs of Medical Devices as Measured by Seal Strength

YY/T 1433 Test Method of Hot Seal Strength (hot tack) of Flexible Webs of Medical Devices

ISO 6588 (all parts) Paper, Board and Pulps - Determination of pH of Aqueous Extracts

ISO 7765-1 Plastics Film and Sheeting - Determination of Impact Resistance by the Free-falling Dart Method - Part 1: Staircase Methods

ISO 9197 Paper, Board and Pulps - Determination of Water-soluble Chlorides

ISO 15105 (all parts) Plastics - Film and Sheeting - Determination of Gas-transmission Rate

3 Terms and Definitions

The following terms and definitions are applicable to this document.

3.1 Barrier Requirements

Barrier requirements refer to the demand to promote or restrict moisture, gas, light or combinations thereof to maintain the necessary level of sterility.

3.2 Durability Requirements

Durability requirements refer to the material characteristics related to the ability of the package to protect the product.

3.3 Integrity and Seal Requirements

Integrity and seal requirements refer to the ability of the package to prevent accidental dropping of the contents or entry of foreign substances when the package is not opened for use.

4.2 Method of Design and Evaluation

When a medical device is characterized and the sterilization method is determined, then, there are many specific requirements for its packaging. This Standard provides guidelines for the selection of test methods for the evaluation of these requirements, the packaging research and development stage and the routine control.

NOTE: product characterization includes quality or weight, geometric shape (length, width, height and shape) and product composition.

4.3 Description and Application of Test Methods

4.3.1 General principles

Table 1 provides the test methods available for various evaluations suitable for the research and development stage, and routine control. The provided test methods are not a test list. The appropriate test method needs to be selected in accordance with the specific packaging. Other test methods beyond Table 1 may also need to be selected.

NOTE: see Appendix A for information on some of the available test methods. Please refer to Appendix B for the description and application of the various test methods in Table 1.

4.3.2 Tests of packaging research and development stage

Tests of the packaging research and development stage are used to generate quantitative data on the properties of materials and components. Some test methods take a long time and are not suitable for process control that requires rapid response; some test methods are expensive and require special test instruments.

4.3.3 Tests of routine control

Tests of routine control need to be fast, low-cost and easy to carry out in a production environment. The purpose is not to develop design data, but to ensure that the design specifications are satisfied. These test methods are not necessarily used to directly measure the critical values; they may also be used to detect changes in materials, processes or key characteristics of the product.

4.3.4 Special consideration

The multiple test methods provided in this Standard are not necessarily applicable to a specific medical device packaging. The selection of a specific test method shall be based on the relevant characteristics of the medical device product and the purpose of the test (such as: the research and development stage, and routine control). The users of this Standard need to consider the applicability of various items and test methods.

This is an excerpt of the PDF (Some pages are marked off intentionally)

Full-copy PDF can be purchased from 1 of 3 websites:

1. https://www.ChineseStandard.us

- SEARCH the standard ID, such as GB 4943.1-2022.
- Select your country (currency), for example: USA (USD); Germany (Euro).
- Full-copy of PDF (text-editable, true-PDF) can be downloaded in 9 seconds.
- Tax invoice can be downloaded in 9 seconds.
- Receiving emails in 9 seconds (with download links).

2. https://www.ChineseStandard.net

- SEARCH the standard ID, such as GB 4943.1-2022.
- Add to cart. Only accept USD (other currencies - https://www.ChineseStandard.us).
- Full-copy of PDF (text-editable, true-PDF) can be downloaded in 9 seconds.
- Receiving emails in 9 seconds (with PDFs attached, invoice and download links).

3. https://www.google.com/search?tbm=bks&q=ChineseStandard.net

- SEARCH the standard ID, such as GB 4943.1-2022.
- Google Books -- Select your currency.
- Processed by Google (delivery, tax invoice etc.). Delivered in 9 seconds by Google.
- Tips: Download an unprotected True-PDF (text-editable) from Google-Books:
  1. https://play.google.com/books → 2. Sign in → Google account
  3. Find the BOOK you bought → 4. Click "3-dots" → Export
  5. Save as "*.pdf" (Save True-PDF to your local computer for offline reading/printing)

Translated by: Field Test Asia Pte. Ltd. (Incorporated & taxed in Singapore. Tax ID: 201302277C)

Accountable person and shareholder: Wayne Zheng

About Us (Goodwill, Policies, Fair Trading…): https://www.chinesestandard.net/AboutUs.aspx

Contact: Wayne Zheng, Sales@ChineseStandard.net

Linkin: https://www.linkedin.com/in/waynezhengwenrui/

------ The End ------