



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

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**Packaging materials for final sterilized medical devices - Part 2:
Requirements and test methods for sterilized packaging
materials**

(English Translation)

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1 Scope

This document specifies requirements and test methods for materials of preformed barrier systems and packaging systems that are intended to maintain the sterility of terminally sterilized medical devices until use.

This document is applicable to the determination of the properties of flat paper wrapping materials, crepe paper wrapping materials, and nonwoven wrapping materials intended for single use, as well as textile wrapping materials intended for repeated use.

2 Normative references

The following documents contain the provisions which, through normative reference in this document, constitute the essential provisions of this document. For the dated referenced documents, only the versions with the indicated dates are applicable to this document; for the undated referenced documents, only the latest version (including all the amendments) is applicable to this document.

GB/T 451.2 Paper and board - Determination of grammage

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 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 1540 Paper and board - Determination of water absorption - Cobb method

GB/T 1545 Paper, board and pulp - Determination of acidity or alkalinity

GB/T3917.1 Textiles - Tear properties of fabrics - Part 1: Determination of tear force using ballistic pendulum method (Elmendorf)

GB/T 4744 Textiles - Testing and evaluation for water resistance - Hydrostatic pressure method

GB/T 5453 Textiles - Determination of the permeability of fabrics to air

GB/T 7408 Data Elements and interchange formats - Information interchange - Representation of dates and times

GB/T 7742.1 Textiles-Bursting properties of fabrics - Part 1: Hydraulic method for determination of bursting strength and bursting distension

GB/T 7974 Paper, board and pulps - Measurement of diffuse blue reflectance factor - D65 brightness (Diff/Geometry, Outdoor daylight conditions)

GB/T 10739 Paper, board and pulps - Standard atmosphere for conditioning and testing

GB/T 12914 Paper and board - Determination of tensile properties - Constant rate of elongation method (20 mm/min)

GB/T 19633.1-2015 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems

GB/T 24218.3 Textiles - Test methods for nonwovens - Part 3: Determination of tensile strength and elongation (Strip method)

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ISO 9197 Paper, board and pulps - Determination of water-soluble chlorides

ISO 9198 Paper, board and pulp - Determination of water-soluble sulfates

3 Terms and definitions

The terms and definitions defined in GB/T 19633.1 apply to this document.

4.1 General rule

For the materials for preformed sterile barrier systems and sterile barrier systems, the requirements of GB/T 19633.1 are applicable.

Only the operational performances and test methods of the materials included are provided in this document, the general requirements specified in GB/T 19633.1 are not as required.

Note: See Appendix B, GB/T 23329, ISO 9073-9, and GB/T 8942 for the test method.

4.2.2.1 Flat paper wrapping materials

4.2.2.1.1

When tested according to GB/T 455, the tearing strength of the wrapping material along the machine direction and in the transverse direction shall not be less than 500 mN. See GB/T 450 for the determination of machine direction and transverse direction.

4.2.2.1.2

When tested according to the Bendtsen method specified in GB/T 458, under the air pressure of 1.47 kPa, the air permeability of the wrapping material shall not be less than $1.7 \mu\text{m}/(\text{Pa} \cdot \text{s})$.

4.2.2.1.3

When tested according to GB/T 454, the bursting strength of the wrapping material shall not be less than 110 kPa.

4.2.2.1.4

When tested with an immersion of 10 min according to GB/T 465.1, the wet bursting strength of the wrapping material shall not be less than 35 kPa.

4.2.2.1.5

When tested according to Appendix A, the hydrophobicity of the wrapping material shall be such that the penetration time is not less than 20 s.

4.2.2.1.6

When tested according to Appendix C, the average pore diameter of 10 samples shall not exceed $35 \mu\text{m}$, and the maximum value shall not exceed $50 \mu\text{m}$.

4.2.2.1.7

When tested according to GB/T 12914, the tensile strength of the wrapping material shall not be less than 1.33 kN/m along the machine direction, and not less than 0.67 kN/m in the transverse direction.

4.2.2.1.8

When tested according to GB/T 465.2, the wet tensile strength of the wrapping material shall not be less than 0.33 kN/m along the machine direction, and not less than 0.27 kN/m in the transverse direction.

4.2.2.1.9

When tested with a test time of 60 s (Cobb method) according to GB/T 1540, the water absorption (Cobb value) of each side of the paper shall not exceed 20 g/m².

4.2.2.2 Crepe paper wrapping material

4.2.2.2.1

The wrapping material of crepe paper shall be wrinkled to improve its softness.

4.2.2.2.2

When tested according to GB/T 12914, the elongation at break of the wrapping material shall not be less than 10% along the machine direction and not less than 2% in the transverse direction.

4.2.2.2.3

When tested according to Appendix A, the hydrophobicity of the wrapping material shall be such that the penetration time is not less than 20 s.

4.2.2.2.4

When tested according to Appendix C, the average pore diameter of 10 samples shall not exceed 35 µm, and the maximum value shall not exceed 50 µm.

4.2.2.2.5

When tested according to GB/T 12914, the tensile strength of the wrapping material shall not be less than 1.33 kN/m along the machine direction, and not less than 0.67 kN/m in the transverse direction.

4.2.2.2.6

When tested according to GB/T 465.2, the wet tensile strength of the wrapping material shall not be less than 0.33 kN/m along the machine direction, and not less than 0.27 kN/m in the transverse direction.

4.2.2.3 Nonwoven wrapping materials

Note: The nonwovens used for sterile barrier systems mentioned in this section can be understood they are made of textile fibers and/or nonwoven fibers.

4.2.2.3.1

When tested according to GB/T 455, the intrinsic tearing strength of the nonwoven wrapping material shall not be less than 750 mN along the machine direction, and not less than 1000 mN in the transverse direction.