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Test methods for sterile medical device package - Part 12: Flex durability of flexible barrier materials

无菌医疗器械包装试验方法

第 12 部分:软性屏障材料抗揉搓性

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Table of Contents

Test methods for sterile medical device package - Part 12: Flex durability of flexible barrier materials

1 Scope

This document describes test methods for the flex durability of flexible barrier materials.

This document applies to the testing of the flex durability of flexible barrier materials.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

GB/T 2918, *Plastics - Standard atmospheres for conditioning and testing*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1 pinhole

A small opening of no particular shape or size that passes completely through all layers of a flexible barrier material.

3.2 flexible

Easy to fold, bend, twist by hand.

4 Overview of test methods

4.1 Unless otherwise specified, the flexing test is performed on specimens of flexible barrier materials under standard atmospheric conditions. The flexing conditions, times and flexing degree vary with the structure type of the specimen. The flexing action consists of a twisting movement followed by a horizontal movement (in most cases). Repeatedly twist and compress the specimen in this way. The frequency is 45 times/min.

4.2 The degree of damage to the structural and/or mechanical properties of the material is judged by the flexing test. The properties to be evaluated in the flexing test determine

the appropriate level of test conditions. For flexible barrier film materials, the pinhole counting test and gas and/or water vapor transmission rate test methods can be used, see Annex A and Annex B. For the evaluation methods of breathable materials such as paper and polyolefin nonwovens, please refer to standards such as GB/T 19633.1 or YY/T 0698[1)].

4.3 The various test conditions are summarized as follows:

a) Condition A: full flexing for 1h (that is, 2700 cycles);

b) Condition B: full flexing for 20mins (that is, 900 cycles);

c) Condition C: full flexing for 6mins (that is, 270 cycles);

d) Condition D: 20 cycles of full flexing;

e) Condition E: 20 cycles of partial flexing.

5 Application

5.1 The various conditions described in this test are to prevent the occurrence of too many pinholes that are inconvenient to count and meaningless when testing a specimen structure, and the occurrence of too few pinholes is also meaningless. Generally, the number of pinholes on each sample shall be between 5~50. Material construction, purpose of the test, and agreement between interested parties are important factors to consider when selecting the level of test conditions.

5.2 This test method does not measure any part of wear associated with flux-to-break.

5.3 Failure of the integrity of one or more layers in a composite layer structure requires a different test than the need to check for pinholes that penetrate completely through the structure. Gas and/or water vapor transmission tests can be combined with the flexing test to measure loss of layer integrity. However, any penetration test requiring a differential pressure cannot measure the penetration coefficient in the presence of a pinhole.

6 Test instruments

6.1 Flexing tester: is designed to be set up according to the specifications listed in Chapter 9. The instrument shall mainly consist of a (90±1)mm diameter fixed shaft and a (90±1)mm diameter moving shaft. When the moving shaft is at the initial position of the stroke (that is, the maximum distance), the two shafts face to face are separated by (180±2)mm. Both shafts shall have vents to protect the sample from pressure. The width

[1)] Test methods such as tensile strength and/or air permeability.

7 Specimen preparation

7.1 The samples are cut into sheets of 200mm × 280mm. The 200mm dimension is the test direction. This is also the direction of the flexing tester shaft.

7.2 Four samples are flexed in each of their machine direction and cross direction. In addition, four flexed samples are taken from positions adjacent to the samples in two directions as control samples.

7.3 Leave open on both sides of the sample without sealing or taping it. Use a double-sided pressure-sensitive adhesive tape with a width not exceeding 13mm to bond the unsealed specimen into a cylindrical shape suitable for the shaft of the testing machine.

8 Conditioning

According to the provisions of GB/T 2918, the sample shall be conditioned for at least 24h under the conditions that the relative humidity is (50±5)% and the temperature is (23±2)°C (unless otherwise specified between the supplier and the purchaser).

9 Procedures

9.1 Test environment

Unless otherwise specified, the flexing test is carried out under the conditions described in Chapter 8.

9.2 Flexing conditions

9.2.1 Condition A

9.2.1.1 Setting of flexing tester

Set the flexing tester to maximum stroke. This setting gives the first 90mm of travel a 440° rotational movement. Then it is a 65mm horizontal linear motion. The frequency is 45 cycles/min. With this setting, when the moving shaft is at the initial position, the distance between the moving shaft and the end face of the fixed shaft is 180mm. When the moving shaft moves to the shortest distance, the end face is 25mm away from the fixed shaft.

9.2.1.2 Flexing test

Attach the flexible barrier samples that have been taped with double-sided pressure sensitive tape to the two shafts of the flexing tester. Or directly fix the sample on the testing machine. Turn on the flexing tester. Flex the sample for 1h at 45 cycles/min (that

is, a total of 2700 cycles).

9.2.2 Condition B

The test conditions are the same as Condition A. The samples are flexed for 20min at 45 cycles/min. (that is, a total of 900 cycles under full flexing and swirling action).

9.2.3 Condition C

The test conditions are the same as Condition A. The samples are flexed for 6min at 45 cycles/min. (that is, a total of 270 cycles under full flexing and swirling action).

9.2.4 Condition D

The test conditions are the same as Condition A. The samples are flexed for 20 times at 45 cycles/min. (that is, a total of 20 cycles under full flexing and swirling action).

9.2.5 Condition E

Set the flexing tester to the partial flexing described in 6.1. At this time, set the moving shaft so that the moving shaft only moves 80mm of the 180mm distance (the maximum distance between the two shafts or the initial position). Therefore, only about 90% of the swivel travel is used, giving a swivel motion of 400°. Horizontal travel is not used. The closest distance between the two shafts is 95mm. The partial flexing session at this short stroke will knead 20 cycles at 45 cycles/min.

9.3 Determination of flexing test results

9.3.1 Remove the flexible barrier material sample from the flexing tester. Mark a 150mm x 200mm area in the center. 150mm is the axial dimension of the tester. For samples after flex durability testing, whether for pinhole or layer integrity inspection, samples shall be taken in this area.

9.3.2 Perform a test to measure the properties of the samples after the flexing test. Continue to test the sample according to the relevant test method.

10 Report

10.1 The sample conditioning and test environment used.

10.2 Sample specifications (thickness/gram weight), structure (if appropriate).

10.3 Flexing test conditions.

10.4 Evaluation method of flex durability.

10.5 Test results.

Annex A

(informative)

Pinhole counting test

A.1 Test purpose

Whether the flexing test resulted in breakage is determined by measuring pinholes formed in the structure. Pinholes are determined by staining the white background with dyed turpentine through the pinholes.

In this test, the material is determined to be damaged only if the dyed turpentine penetrates the through-holes of the physical structure. A composite ply structure in which one layer remains intact will not be able to detect failure by the stained turpentine test.

A.2 Instruments and reagents

Large paint brush: width is 50mm~150mm.

Absorbent paper: paper that is absorbent.

White paper: uncoated paper, at least the same size as the specimen.

Turpentine (dyed, anhydrous): add 5g of anhydrous calcium chloride and 1.0g of oil-soluble red staining solution to 100mL of turpentine oil (chemically pure, with a specific gravity of 0.860~0.875 at 15°C). Stopper the container. Shake well. Leave it for at least 10h. Shake from time to time. Use dry filter paper to filter. Store in an airtight bottle.

NOTE: Pay attention that the use of these materials requires appropriate protection to avoid hazards due to skin contact, inhalation and flammability.

A.3 Test steps

A.3.1 Remove the flexible barrier sample from the flexing tester. Mark a 150mm×200mm area in the center of the white paper. The 150mm dimension is the axial dimension of the tester.

A.3.2 Tape the sample to the white paper.

A.3.3 Brush the stained turpentine solution onto the sample. Repeat as needed. Leave it for 1min.

A.3.4 After 1min, wipe off the dyed turpentine with absorbent paper. Apply pressure

Annex B

(informative)

Gas and/or water vapor transmission rate test

B.1 Test purpose

Whether the flexing test leads to breakage is determined by the change in the transmission rate of the sample gas and/or water vapor.

Gas transmission rate means, at constant temperature and unit pressure, the volume of gas that permeates a unit area of the specimen per unit time at steady transmission. It is expressed by the volume value under standard temperature and pressure, in $cm^3/(m^2 \cdot 24h \cdot 0.1MPa)$.

Water vapor transmission rate refers to the amount of water vapor permeated by a $1m^2$ specimen within 24h under the conditions of specified temperature, relative humidity, certain water vapor pressure difference and certain thickness. The unit is: $g/(m^2 \cdot 24h)$.

B.2 Instruments

Water vapor transmission rate tester, gas transmission rate tester.

B.3 Test methods

See GB/T 1037 and GB/T 26253 for the test method of water vapor transmission rate.

See GB/T 1038, GB/T 19789 and YY/T 1286.1 for the test method of gas transmission rate.

B.4 Test steps

B.4.1 Cut out a specimen of the central 150mm×200mm area of the flexible barrier material.

B.4.2 Measure the gas and/or water vapor transmission rate of the unflexed sample according to the relevant test method.

B.4.3 Measure the gas and/or water vapor transmission rate of the sample after the flexing test according to the relevant test method.

B.5 Result recording

Record the gas and/or water vapor transmission rate of the sample before and after the flexing test.

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