YY

PHARMACEUTICAL INDUSTRY STANDARD

OF THE PEOPLE'S REPUBLIC OF CHINA

ICS 11.120.20
C 48

YY/T 0471.5-2017

Replacing YY/T 0471.5-2004

Test Methods for Primary Wound Dressings -

Part 5: Bacterial Barrier Properties

接触性创面敷料试验方法

第 5 部分：阻菌性

Issued on: February 28, 2017 **Implemented on: January 1, 2018**

Issued by: China Food and Drug Administration

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Test Methods for Primary Wound Dressings -

Part 5: Bacterial Barrier Properties

1 Scope

This Part of YY/T 0471 specifies test methods[1] of evaluating bacterial barrier properties of primary wound dressings that claim to have bacterial barrier properties.

In this Part, test methods involve microbial detection, which shall be conducted by trained personnel in biosafety laboratories.

2 Terms and Definitions

The following terms and definitions are applicable to this Standard.

2.1 Low-moisture Condition

Under low-moisture condition, 2 sides of dressings are not wet. Under this condition, dressings shall manifest no or minimal exudate on the wound; the external surface of dressings shall be under low-moisture condition.

NOTE: dressings that do not claim to be water resistant shall be deemed to have a dry external surface.

2.2 Semi-wet Condition

Under semi-wet condition, 1 side of dressings is wet. Under this condition, there is exudate on the wound, but the external surface of dressings shall be under low-moisture condition, namely, “dry outside, wet inside”; or there is no or minimal exudate on the wound, and the external surface of dressings is expected to be under wet condition, namely, “wet outside, dry inside”.

NOTE: dressings that do not claim to be water resistant shall be deemed to have a dry external surface; dressings that claim to be water resistant shall be deemed to have a wet external surface.

2.3 Wet Condition

Under wet condition, 2 sides of dressings are wet. Under this condition, there is exudate on the wound, and the external surface of dressings is expected to be under wet condition.

[1] Antibacterial ingredients in dressings might exert influence on the test result in this Part. Please refer to Appendix A for an instruction for application of this Part.

Respectively take 3 samples, turn the internal surface of the samples towards the sampling room. Clamp the samples to the area between the challenge room and the sampling room. The mode of clamping shall be confirmed; guarantee that there is no leakage of challenge microorganism. In terms of relatively large sample, cut off the remaining part or wrap it around the test device; in terms of relatively small sample, raw materials of large samples can be adopted for testing, or an appropriate mode can be adopted to fill up the missing part for testing.

5.2.2 Add challenge microorganism

Use sterile swab to wipe-take challenge inoculum; inoculate it on the external surface of the samples through the mouth of the challenge room; smear as even as possible.

5.2.3 Sample challenge

Take an appropriate mode to seal the mouth of the challenge room and the sampling room of the test device; guarantee that no external contamination will be generated. Place the test device into an incubator at 26 °C and maintain for 24 h.

5.2.4 Penetrating microbiological examination

After the stipulated time, pre-moisturize sterile swab in sterile saline solution and squeeze out surplus water. Try to wipe all the internal surfaces of the samples through the mouth of the sampling room. Then, inoculate in the mode of wiping the plate surface of nutrient agar. Use 3 sterile swabs to wipe each sample; respectively inoculate on the plate of 3 nutrient agars; during this process, swabs shall be rotated for several times. Place the plate of nutrient agar at 26 °C and start culture for 24 h.

5.2.5 Challenge microbiological vitality examination

After the stipulated time, operate in accordance with 5.2.4. Wipe the external surface of the samples through the mouth of the challenge room to examine challenge microbiological vitality.

5.3 Result Judgment

On the plate of nutrient agar medium that is adopted for vitality examination, there shall be the growth of Serratia marcescens; otherwise, the test shall be deemed as invalid. If there is no growth of microorganism on the plate of nutrient agar that is adopted for the sampling analysis of the internal surface of the sample, it shall be deemed that the sample complies with the requirement of bacterial barrier properties under low-moisture condition. If there is growth of microorganism on the plate of nutrient agar that is adopted for the sampling analysis of the internal surface of the sample, appropriate microbiological methods shall be adopted to examine whether it is Serratia marcescens. If it is Serratia marcescens, it shall be deemed that the sample does not comply with the requirement of bacterial barrier properties under low-moisture condition; if it is not Serratia marcescens, it signifies that there is external

2---Glass elbow;

3---Challenge bacterial solution;

4---Sample to be tested;

5---Glass test device;

6---Sterile swab;

7---Fixing screw;

8---Support.

Figure 3 -- Sketch Map of Test Device - Semi-wet Condition (wet outside, dry inside)

7.2 Test Method

7.2.1 Sample clamping

Operate in accordance with 5.2.1.

7.2.2 Add challenge microorganism

Fill up the challenge room with challenge bacterial solution.

7.2.3 Sample challenge

Operate in accordance with 5.2.3.

7.2.4 Penetrating microbiological examination

Operate in accordance with 5.2.4.

7.2.5 Challenge microbiological vitality examination

After the stipulated time, use sterile swab to take challenge bacterial solution to wipe the plate of nutrient agar medium to examine challenge microbiological vitality. Use 3 sterile swabs to take bacterial solution on each sample; respectively smear it on 3 nutrient agar plates for inoculation. Place the plate at 26 °C and start culture for 24 h.

7.3 Result Judgment

On the plate of nutrient agar medium that is adopted for vitality examination, there shall be the growth of Serratia marcescens; otherwise, the test shall be deemed as invalid. If there is no growth of microorganism on the plate of nutrient agar that is adopted for the sampling analysis of the internal surface of the sample, it shall be deemed that the sample complies with the requirement of bacterial barrier properties under semi-wet

Appendix A

(informative appendix)

Instruction for Standard Application

A.1 Applicable Object

Clinically speaking, infection is an important complication of wound. Primary wound dressings play a role as a mechanical barrier of wound. The bacterial barrier properties of primary wound dressings are tremendously important to the control of wound infection. However, this does not mean all the primary wound dressings are requested to manifest bacterial barrier properties. Certain types of wound with extremely low risks of infection might not need primary wound dressings with bacterial barrier properties. Furthermore, the bacterial barrier properties of some primary wound dressings that need to be matched with secondary dressings are jointly provided by the two types of dressing, and merely conducting evaluation on the bacterial barrier properties of primary wound dressings might also lead to unilateral information. The evaluation of whether a specific primary wound dressing has the bacterial barrier properties depends on intensive study of risks of infection of different types of wound.

A.2 Method Selection

The condition of the internal surface of dressings depends on the amount of exudate, which correspondingly manifests the wet or low-moisture condition. Under the normal environment, the external surface of dressings would be under low-moisture condition. If the external surface is under wet condition, it is not a normal condition of dressings. However, in terms of certain dressings, for example, dressings that claim to be water resistant, the external surface might be under wet condition. During the evaluation of the bacterial barrier properties of dressings, test methods shall be selected in accordance with the different expected conditions of the dressings.

If dressings are expected to be applied to wound with minimal exudate, at least the test method of low-moisture condition shall be the first option. On this basis, if the external surface of dressings is expected to be under wet condition, for example, dressings that claim to be water resistant, the test method of semi-wet condition (wet outside, dry inside) shall be selected.

If dressings are expected to be applied to wound with a great deal of exudate, at least the test method of semi-wet condition (dry outside, wet inside) shall be the first option. On this basis, if the external surface of dressings is expected to be under wet condition, for example, dressings that claim to be water resistant, the test method of wet condition shall be selected.

At present, there is no adequate proof that verifies which test method is more rigorous.

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