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Test Methods for Sterile Medical Device Package - Part 3: Internal Pressurization Failure Resistance of Unrestrained Packages

无菌医疗器械包装试验方法

第 3 部分：无约束包装抗内压破坏

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Foreword

The general title of YY/T 0681 is “Test methods for sterile medical device package”, which consists of the following parts:

- Part 1: Test guide for accelerated aging;
- Part 2: Seal strength of flexible battier materials;
- Part 3: Internal pressurization failure resistance of unrestrained packages;
- Part 4: Detecting seal leaks in porous packages by dye penetration;
- Part 5: Detecting gross leaks in medical packaging by internal pressurization (bubble test);
- Part 6: Evaluation of chemical resistance of printed inks and coatings on flexible packaging materials;
- Part 7: Evaluating inks or coating adhesion to flexible packaging materials using tape;
- Part 8: Coating/adhesive weight determination;
- Part 9: Burst testing of flexible package seals using internal air pressurization weight restraining plates;
- Part 10: Test for microbial barrier ranking of porous package material.

Other parts will be formulated continuously[1].

This Part is Part 3 of YY/T 0681.

This Part was drafted according to the rules given in GB/T 1.1-2009.

This Part of YY/T 0681 revises and adopts ASTM F 1140-07 “Internal Pressurization Failure Resistance of Unrestrained Packages”.

This Part shall be under jurisdiction of the National Standardization Technical Committee on Infusion Equipment for Medical Use.

Drafting organization of this Part: Shandong Quality Inspection Center for Medical Devices.

[1] Other parts will convert the relevant test method standards about packages for medical use in ASTM F.

Test Methods for Sterile Medical Device Package - Part 3: Internal Pressurization Failure Resistance of Unrestrained Packages

1 Scope

This Part of YY/T 0681 specifies the procedure for determining the ability of packages to withstand internal pressurization.

The burst test is to gradually pressurize the package until the package fails.

The creep test maintains a specified pressure for a specified time or until the package fails.

Note: Appendix A gives the relevant information of the precision and bias of the test methods specified in this Standard.

2 Normative references

The following documents are essential to the application of this document. For the dated documents, only the versions with the dates indicated are applicable to this document; for the undated documents, only the latest version (including all the amendments) are applicable to this document.

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

YY/T 0681.2 Test methods for sterile medical device package - Part 2: Seal strength of flexible battier materials

3 Terms and definitions

The following terms and definitions apply to this document.

3.1 Flexible

A material of the proper flexural strength and thickness to permit a turn back at an appropriate 180° angle. In order to fulfill all terms of the definition, at least one of the sealed materials must be flexible.

Appendix B

(Informative)

Testing packages with a large porous area

B.1 The testing of the seals of packages with porous barrier materials may be limited due to the inability to provide sufficient air volume. An example of this inability to provide sufficient air volume may be encountered when the package is so large that air leaks through the porous barrier faster than it can be applied. Because of this air leakage, inadequate force due to lower pressure will not allow either the bursting of the seals or reaching the desired holding pressure level.

B.2 Industry has typically responded to this effect by limiting the porous barrier area. There are two major classifications of barrier blocking agents, the first being labels or tape, and the second being non-solid agents that are spread across the porous barrier material. Caution must be used with any method of blocking to ensure that the porous barrier area is consistently and uniformly covered or coated. When using labels or tape as blocking agents, it is important that the blocking material does not reinforce the seal area being tested on the package. When using non-solid blocking agents that require spreading over the porous barrier material, caution must be used to ensure that the blocking agent does not affect the seal bonding area by penetrating the porous barrier material.

B.3 Regardless of the method used, consistency of the area blocked is necessary to provide minimum variability in the method. Validation of this method is necessary when used for regulated products.

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