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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 0681.1-2018

Test methods for sterile medical device packages - Part 1: Guide for accelerated aging

无菌医疗器械包装试验方法 第1部分：加速老化试验指南

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Foreword

YY/T 0681 "Test methods for sterile medical device package" consists of the following 16 parts. - Part

1 Scope

YY/T 0681.1 is the accelerated ageing guide for sterile medical device packaging, and it is the document behind almost every shelf life claim in the industry. A manufacturer cannot wait five years to find out whether a pouch still holds a sterile barrier after five years, so packages are aged at elevated temperature and the elapsed time converted to real time by a defined relationship. The guide sets out how that is done and what its limits are, including the requirement that accelerated results eventually be confirmed by real-time ageing. It is Part 1 of the Chinese sterile packaging test method series. For any manufacturer of sterile devices seeking Chinese registration, this is the standard the expiry date on the label is justified by.

This Part of YY/T 0681 specifies the guide for designed accelerated aging solutions. This Part applies to the rapid determination of the sterile integrity of the sterile barrier system specified in GB/T 19633.1-2015 and the effects that physical properties of its packaging material components are affected by the elapsed time. NOTE

1.Use the information in this Part of YY/T 0681 to support the expiration date of the medical device sterile barrier system (i.e. shelf life). This Part is not applicable to real-time aging solution. NOTE

2.Accelerated aging test involves sterile barrier system with or without instruments. This Part does not address the compatibility of sterile barrier system materials with instrument interactions required during new product development or evaluation. NOTE

3.Real-time aging test is a basic aging study used to determine the results of accelerated aging tests. NOTE

4.This Part does not address methods for confirmation of sterile barrier system, including effects on mechanical processing, sterilization processes, circulation, handling and transport. The ability of the sterile barrier system to resist transport challenges is given in YY/T 0681.15. NOTE

5.This Part does not address the effects of extreme weather conditions that may be experienced in a simulated transport environment. For the climatic strain capacity test of the sterile barrier system, see YY/T 0681.16.

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 4857.2, Packaging - Transport packages - Temperature and humidity conditioning

GB/T 19633.1-2015, Packaging for terminally sterilized medical devices - Part

3 Terms and definitions

For the purposes of this document, the terms and definitions defined in GB/t 19633.1-2015 as well as the followings apply.

3.1 accelerated aging store samples at a higher temperature to reduce time to simulate real-time aging

3.2 accelerated aging factor an estimated or calculated time ratio of physical performance changes to the same level as the package stored in real-time conditions NOTE. The aging factor (Q10) at which the temperature increases or decreases by 10°C is a conservatively estimated accelerated aging factor.

3.3 accelerated aging temperature a higher temperature that enters aging study; it is calculated based on the estimated storage temperature, the estimated operating temperature, or both

3.4 accelerated aging time duration of accelerated aging test

3.5 ambient temperature storage temperature of the sample representing the actual aging time of the storage conditions

3.6 sterile barrier system shelf life the expected storage time of the sterile barrier system to maintain its key performance parameters under ambient conditions or under specified storage conditions

4 Meaning and application

4.1 Degradation of physical properties of materials over time and degradation of materials at bonding or heat sealing over time and dynamic events during subsequent transport and handling, may lead to loss of integrity of the sterile barrier system.

4.2 The packaging system shall provide protection and maintain the integrity of the sterile barrier system.

4.3 Real-time aging procedures provide the best data to ensure that sterile barrier system materials and sterile barrier system integrity do not degrade over time.

4.4 If there is a lack of understanding of the material of the sterile barrier system being evaluated, a conservative accelerated aging factor shall be used. More realistic accelerated aging factors can be used.

4.5 When accelerating the aging process to establish a nominal shelf life, it shall be recognized that the data obtained from the study is based on a simulation of the aging effect of the material.

5 Instruments

5.1 A room (or box). its size may allow the sample to be independently exposed to the selected temperature and relative humidity of the circulating air.

5.2 Control instrument. keep the room (box) within the limits of the required atmospheric conditions.

5.4 Thermometer. a measuring device capable of recording and displaying temperature with an accuracy of 0.1°C can be used.

6 Accelerated aging theory

6.1 Accelerated aging of materials refers to accelerated changes in material properties

associated with the safety and functionality of materials or sterile barrier system over time.

6.2 In aging study, material or sterile barrier system are subjected to harsher or more frequent external strains than usual in a relatively short period of time.

6.3 Accelerated aging technology is based on this assumption.

6.4 The determination method for Q10 is to test each material at various temperatures and define the difference in reaction rate between materials for every 10°C change in temperature.

6.5 The accelerated aging time in the accelerated aging scheme does not use the humidity factor. However, extreme temperature and humidity conditions that are inconsistent with actual conditions may affect the performance of the entire sterile barrier system.

7 Accelerated aging plan

7.1 Material characterization Accelerated aging theory and its application are directly related to the composition of packaging materials. Material properties that may affect the results of accelerated aging study include.

7.2 Design guide for accelerated aging plan

7.2.3 Select accelerated aging temperature based on material characterization. The higher the accelerated aging temperature, the greater the accelerated aging factor, and the shorter the time to accelerate aging. It shall be noted that the accelerated aging temperature cannot be reduced in an uncontrolled manner to shorten the time for accelerated aging.

7.4 Accelerated aging plan steps

7.4.1 Select Q10 value.

7.4.2 Determine the shelf life of the desired sterile barrier system based on market demand, product demand, etc.

7.4.3 Determine the time interval for the aging test, including zero time.

7.4.4 Determine test conditions, ambient temperature and accelerated aging temperature.

7.4.5 Determine whether humidity conditions are used in aging studies. If used, determine the relative humidity (RH) target value and allowable deviation.

7.4.6 Use Q10, TRT, and TAA to calculate test duration time.

7.4.10 Evaluate whether the sterile barrier system meets its original design requirements after real-time aging.

8 Post-aging test guide