**Age testing Report**

**Prepared by: Date:**

**Reviewed by: Date:**

**Approved by: Date:**

|  |  |  |
| --- | --- | --- |
| **Version** | **Date** | **Description of change** |
| A/0 | ***{填写批准日期 }*** | Initial version |
|  |  |  |

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**1 Purpose**

To evaluate the performance of ***{填写申报产品名称 }*** is still valid in 3 years shelf life.

**2 Reference**

2.1 ASTM F1980-16 [Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/detail.cfm?standard__identification_no=34580)

***2.2 {填写器械涉及标准}***

**3 Responsibility**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| SN | Department | Title | Name | Responsibility |
| 1 | ***{根据实际情况填写}*** | ***{根据实际情况填写}*** | ***{根据实际情况填写}*** | Prepare Aging testing protocol and aging testing report; |
| 2 | ***{根据实际情况填写}*** | ***{根据实际情况填写}*** | ***{根据实际情况填写}*** | Responsible for conducting the aging testing, including sampling, accelerated aging test, product testing. |
| 3 | ***{根据实际情况填写}*** | ***{根据实际情况填写}*** | ***{根据实际情况填写}*** | Responsible for data collection and analysis. |
| 4 | ***{根据实际情况填写}*** | ***{根据实际情况填写}*** | ***{根据实际情况填写}*** | Responsible for approval of aging testing protocol and aging testing report |

**4 Requirement**

The product meets the requirement of ***{填写器械涉及标准}***

***【如果标准中没有给出具体的标准，需要在该部分给出具体的接受准则】***

**5 Test Method**

***{填写器械涉及标准}***

***【如果标准中没有给出具体的测试方法，需要在该部分给出具体的测试方法】***

**6 Testing before aging**

6.1 Make sample plan

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Sample** | **Product Name** | **Manufacturer** | **Model** | **Product Lot** | **Product Date** | **Sample size at each time** |
| Sample 1 | ***{填写器械名称}*** | ***{填写制造商名称}*** | ***{填写器械型号}*** | ***{填写器械批号}*** | ***{填写器械生产日期}*** | T0  Size: ***{填写试验样品数量}*** |
| Sample 2 | ***{填写器械名称}*** | ***{填写制造商名称}*** | ***{填写器械型号}*** | ***{填写器械批号}*** | ***{填写器械生产日期}*** | T0  Size: ***{填写试验样品数量}*** |
| ....... | ....... | ....... | ....... | ....... | ....... | ....... |

6.2 Test procedure

6.2.1 Take samples as the sample plan. Store them in the warehouse for ***{填写前处理的时间}*** day***【前处理的时间可以能是根据产品需要来的，也可能是测试规范，也可能是测试表标准】*** before testing and record the storage environment.

6.2.2 Conduct testing according to ***{填写器械涉及标准}*** at the ***{填写老化前样品测试的时间}*** and the record the testing result. The testing time is ***{填写老化前样品测试的时间}【可以是时间段】。***

6.3 The record of storage environment

Setting Temperature: ***(25℃)***  Setting Humidity: ***(15%RH)***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Date | Record Time | Temperature and humidity | Date | Record Time | Temperature and humidity |
| ***{根据实际情况填写具体信息}*** | ***{根据实际情况填写具体信息}*** | ***{根据实际情况填写具体信息}*** | ***{根据实际情况填写具体信息}*** | ***{根据实际情况填写具体信息}*** | ***{根据实际情况填写具体信息}*** |
| ....... | ....... | ....... | ....... | ....... | ....... |

6.4 Test Results

The summary of the test result is as below. The details of the test result can refer to ***{老化前的测试报告}【该报告中需要按照Guidance for Industry and Food and Drug Administration Staff：Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions指南中的要求进行拟制，其中检测涉及的设备，试验过程等均需要清楚明了】.***

|  |  |  |
| --- | --- | --- |
| **Model** | **Test Result** | **Conclusion** |
| ***{填写器械型号}*** | ***{填写测试结果}*** | Pass |
| ***{填写器械型号}*** | ***{填写测试结果}*** | Pass |
| ...... |  |  |

**7 Accelerated aging testing**

**7.1 Principle of accelerated aging testing**

7.1.1 Basic Principle

Accelerated aging techniques are based on the assumption that the chemical reactions involved in the deterioration of materials follow the Arrhenius reaction rate function. This function states that a 10℃ increase or decrease in temperature of a homogeneous process results in, approximately, a two times or 1/2-time change in the reate of chemical reaction (Q10).

When the temperature increases, the aging factor increases and the aging time decreases. However, the risk of increasing the temperature and shortening the aging time on the performance of the product should be equivalent to that at room temperature. High or low relative humidity level may aggravate the aging damage of many materials, but the calculation of accelerated aging time is based on the temperature rather than the increase of humidity.

7.1.2 Accelerated aging factor and time

|  |  |
| --- | --- |
| **Formulation** | **Calculation** |
| **AAF= Q10 [TAA -TRT] /10** | Q10=2.0, TRT=\*25°C |
| Note: | TAA=60°C |
| AAF: accelerated aging factor | AAF=2.0 (60-25)/10 |
| TAA= accelerated aging temperature (°C) | AAF=2.0 3.5, AAF=11.31 |
| TRT= ambient temperature (°C) | AAT=365 days/11.31 |
| AAT(accelerated aging time) = RT / AAF | AAT=32.27 day |
| The storage temperature is regarded as 25 ° C. | |

7.1.3 Determination of accelerated aging conditions and testing time

The accelerated aging is set as 60°C. Q10=2.0, TRT=25°C.

So, the AAF=AAF=2.0 (60-25)/10=11.31.

The shelf life of product is set as 2 years. The testing time is set as below.

|  |  |  |
| --- | --- | --- |
|  | AAT(accelerated aging time) | Test Time |
| T1(Time that conduct accelerated aging test for 33days) | AAT=365 days/11.31  =32.27days | ***{填写具体的测试日期 }*** |
| T2(Time that conduct accelerated aging test for 65 days) | AAT=365\*2days/11.31  =64.54days | ***{填写具体的测试日期 }*** |
| T3(Time that conduct accelerated aging test for 97 days) | AAT=365\*3days/11.31  =96.82days | ***{填写具体的测试日期 }*** |

**7.2 Accelerated aging testing**

7.2.1 Make sample plan

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Sample** | **Product Name** | **Manufacturer** | **Model** | **Product Lot** | **Product Date** | **Sample size at each time** |
| Sample 1 | ***{填写器械名称}*** | ***{填写制造商名称}*** | ***{填写器械型号}*** | ***{填写器械批号}*** | ***{填写器械生产日期}*** | T1, T2, T3  Size: ***{填写试验样品数量}*** |
| Sample 2 | ***{填写器械名称}*** | ***{填写制造商名称}*** | ***{填写器械型号}*** | ***{填写器械批号}*** | ***{填写器械生产日期}*** | T1, T2, T3  Size: ***{填写试验样品数量}*** |
| ....... | ....... | ....... | ....... | ....... | ....... | ....... |

7.2.2 Test procedure

7.1.2.1 Take samples as the sample plan. Put samples in the constant temperature machine at ***{填写开始进行加速老化的时间}***. The temperature of the constant temperature machine is set as 60℃.

7.1.2.2 Take sample as the sample plan at ***{填写对应实时老化1年的时间}***.

Maintain samples at each test condition as below for ***{填写前处理的时间}*** day***【前处理的时间可以能是根据产品需要来的，也可能是测试规范，也可能是测试表标准】*** and record the storage environment.

Setting Temperature: ***（25℃）*** Setting Humidity:  ***（15%RH）***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Date | Record Time | Temperature and humidity | Date | Record Time | Temperature and humidity |
| ***{根据实际情况填写具体信息}*** | ***{根据实际情况填写具体信息}*** | ***{根据实际情况填写具体信息}*** | ***{根据实际情况填写具体信息}*** | ***{根据实际情况填写具体信息}*** | ***{根据实际情况填写具体信息}*** |
| ....... | ....... | ....... | ....... | ....... | ....... |

7.1.2.3 Conduct testing according to ***{填写器械涉及标准}*** at the ***{填写对应实时老化1年后样品测试的时间}*** and the record the testing result. The testing time is ***{填写老化前样品测试的时间}【可以是时间段】***.

The summary of the test result of sample from T1 is as below. The details of the test result can refer to ***{对应实时老化1年的测试报告}【该报告中需要按照Guidance for Industry and Food and Drug Administration Staff：Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions指南中的要求进行拟制，其中检测涉及的设备，试验过程等均需要清楚明了】.***

|  |  |  |
| --- | --- | --- |
| **Model** | **Test Result** | **Conclusion** |
| ***{填写器械型号}*** | ***{填写测试结果}*** | Pass |
| ***{填写器械型号}*** | ***{填写测试结果}*** | Pass |
| ...... |  |  |

7.1.2.4 Take sample as the sample plan at ***{填写对应实时老化2年的时间}***.

Maintain samples at each test condition as below for ***{填写前处理的时间}*** day***【前处理的时间可以能是根据产品需要来的，也可能是测试规范，也可能是测试表标准】*** and record the storage environment.

Setting Temperature: ***（25℃）*** Setting Humidity:  ***（15%RH）***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Date | Record Time | Temperature and humidity | Date | Record Time | Temperature and humidity |
| ***{根据实际情况填写具体信息}*** | ***{根据实际情况填写具体信息}*** | ***{根据实际情况填写具体信息}*** | ***{根据实际情况填写具体信息}*** | ***{根据实际情况填写具体信息}*** | ***{根据实际情况填写具体信息}*** |
| ....... | ....... | ....... | ....... | ....... | ....... |

7.1.2.5 Conduct testing according to ***{填写器械涉及标准}*** at the ***{填写对应实时老化2年后样品测试的时间}*** and the record the testing result. The testing time is ***{填写老化前样品测试的时间}【可以是时间段】***.

The summary of the test result of sample from T2 is as below. The details of the test result can refer to ***{对应实时老化2年的测试报告}【该报告中需要按照Guidance for Industry and Food and Drug Administration Staff：Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions指南中的要求进行拟制，其中检测涉及的设备，试验过程等均需要清楚明了】.***

|  |  |  |
| --- | --- | --- |
| **Model** | **Test Result** | **Conclusion** |
| ***{填写器械型号}*** | ***{填写测试结果}*** | Pass |
| ***{填写器械型号}*** | ***{填写测试结果}*** | Pass |
| ...... |  |  |

7.1.2.6 Take sample as the sample plan at ***{填写对应实时老化3年的时间}***.

Maintain samples at each test condition as below for ***{填写前处理的时间}*** day***【前处理的时间可以能是根据产品需要来的，也可能是测试规范，也可能是测试表标准】*** and record the storage environment.

Setting Temperature: ***（25℃）*** Setting Humidity:  ***（15%RH）***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Date | Record Time | Temperature and humidity | Date | Record Time | Temperature and humidity |
| ***{根据实际情况填写具体信息}*** | ***{根据实际情况填写具体信息}*** | ***{根据实际情况填写具体信息}*** | ***{根据实际情况填写具体信息}*** | ***{根据实际情况填写具体信息}*** | ***{根据实际情况填写具体信息}*** |
| ....... | ....... | ....... | ....... | ....... | ....... |

7.1.2.7 Conduct testing according to ***{填写器械涉及标准}*** at the ***{填写对应实时老化3年后样品测试的时间}*** and the record the testing result. The testing time is ***{填写老化前样品测试的时间}【可以是时间段】***.

The summary of the test result of sample from T2 is as below. The details of the test result can refer to ***{对应实时老化2年的测试报告}【该报告中需要按照Guidance for Industry and Food and Drug Administration Staff：Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions指南中的要求进行拟制，其中检测涉及的设备，试验过程等均需要清楚明了】.***

|  |  |  |
| --- | --- | --- |
| **Model** | **Test Result** | **Conclusion** |
| ***{填写器械型号}*** | ***{填写测试结果}*** | Pass |
| ***{填写器械型号}*** | ***{填写测试结果}*** | Pass |
| ...... |  |  |

**8 Real-time aging testing**

**8.1 Principle of real-time aging testing**

The real-time aging is that the product is put in the real storage condition for the time of shelf life. The shelf life is 3 year. The product is stored in the warehouse for 3 years.

|  |  |  |
| --- | --- | --- |
|  | Real aging time | Test Time |
| T’1(Time that conduct real-time aging test for 3 years) | Real aging time  ≥3 years=365days\*2 | ***{填写实时老化3年的时间}*** |

**8.2 Real-time aging testing**

8.2.1 Make sample plan

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Sample** | **Product Name** | **Manufacturer** | **Model** | **Product Lot** | **Product Date** | **Sample size at each time** |
| Sample 1 | ***{填写器械名称}*** | ***{填写制造商名称}*** | ***{填写器械型号}*** | ***{填写器械批号}*** | ***{填写器械生产日期}*** | T’1  Size: ***{填写试验样品数量}*** |
| Sample 2 | ***{填写器械名称}*** | ***{填写制造商名称}*** | ***{填写器械型号}*** | ***{填写器械批号}*** | ***{填写器械生产日期}*** | T1  Size: ***{填写试验样品数量}*** |
| ....... | ....... | ....... | ....... | ....... | ....... | ....... |

8.2.2 Test procedure

8.2.2.1 Take samples which is stored at the warehouse for three years as sample plan at ***{填写实时老化3年的时间 }***.

8.2.2.2 Maintain sample at test condition as below for ***{填写前处理的时间}*** day***【前处理的时间可以能是根据产品需要来的，也可能是测试规范，也可能是测试表标准】*** and record the storage environment.

Setting Temperature: ***（25℃）*** Setting Humidity:  ***（15%RH）***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Date | Record Time | Temperature and humidity | Date | Record Time | Temperature and humidity |
| ***{根据实际情况填写具体信息}*** | ***{根据实际情况填写具体信息}*** | ***{根据实际情况填写具体信息}*** | ***{根据实际情况填写具体信息}*** | ***{根据实际情况填写具体信息}*** | ***{根据实际情况填写具体信息}*** |
| ....... | ....... | ....... | ....... | ....... | ....... |

8.2.2.3 Conduct testing according to ***{填写器械涉及标准}*** at the ***{填写对应实时老化3年后样品测试的时间}*** and the record the testing result. The testing time is ***{填写老化前样品测试的时间}【可以是时间段】***.

The summary of the test result of sample from T’1 is as below. The details of the test result can refer to ***{实时老化3年的测试报告}【该报告中需要按照Guidance for Industry and Food and Drug Administration Staff：Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions指南中的要求进行拟制，其中检测涉及的设备，试验过程等均需要清楚明了】.***

|  |  |  |
| --- | --- | --- |
| **Model** | **Test Result** | **Conclusion** |
| ***{填写器械型号}*** | ***{填写测试结果}*** | Pass |
| ***{填写器械型号}*** | ***{填写测试结果}*** | Pass |
| ...... |  |  |

**9 Test Result**

The details of the test result at the point of T0, T1, T2, T’1 can refer to JZ/FDA-01, JZ/FDA-02, JZ/FDA-03, JZ/FDA-04.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Aging Time** | **Condition time before testing** | **Test Time** | **Test Result** | **Conclusion** |
| ***T0*** | ***Not aging*** | ***{根据实际情况填写}*** | ***{根据实际情况填写}*** | ***{根据实际情况填写}*** | Pass |
| ***T1*** | ***{根据实际情况填写}*** | ***{根据实际情况填写}*** | ***{根据实际情况填写}*** | ***{根据实际情况填写}*** | Pass |
| ***T2*** | ***{根据实际情况填写}*** | ***{根据实际情况填写}*** | ***{根据实际情况填写}*** | ***{根据实际情况填写}*** | Pass |
| ***T3*** | ***{根据实际情况填写}*** | ***{根据实际情况填写}*** | ***{根据实际情况填写}*** | ***{根据实际情况填写}*** | Pass |
| ***T’1*** | ***{根据实际情况填写}*** | ***{根据实际情况填写}*** | ***{根据实际情况填写}*** | ***{根据实际情况填写}*** | Pass |

**10 Conclusion**

The testing result of accelerated aging testing and real time aging testing prove that the ***{填写器械名称 }*** can keep the performance in the shelf life of 3 years. We can declare it has a shelf life of 3 years.

**11 Annex**

Annex 11.1. Test Report of not aging at T0

Annex 11.2. Test Report of accelerated aging at T1

Annex 11.3. Test Report of accelerated aging at T2

Annex 11.4. Test Report of accelerated aging at T3

Annex 11.5. Test Report of accelerated aging at T’1