Tech Editing Example of a Product Shelf Life Real-Time Aging Test

BEFORE EDIT:

1. Temperatures above the glass-transition temperature or maximum temperature recommended by the manufacturer of any of the materials should not be exceeded, with the exception of when the glass transition temperature is $\underline{\geq}$ 37°C

2. If any component is susceptible to moisture, humidity should be set to a level where the moisture content of the air is ≥ 95% humidity at ambient temperature. This value is 0.015 lbs water /lb dry air. Psychrometric charts can be used to determine the % Relative Humidity at the oven temperature.

3. The time in the oven is determined by the Arrhenius equation below.
   $s = (t \times q^y)$ or $t = s \div q^y$
   Where:
   t = time of accelerated exposure required (in days)
   s = number of days desired for shelf life (plus 30 days)
   q = acceleration factor (2.0 for non-aqueous solutions)
   y = (elevated storage temperature – ambient storage temperature ÷ 10

4. The ambient storage temperature for XYZ's products is 22°C.

5. For aging, 30 days will be added to the desired shelf life to simulate manufacturing time and as a safety factor.

5.1 Real-Time aging will be aged at ambient conditions for time (s).

5.1.1 After the calculated time (t), the product will be removed from the oven and returned to XYZ for testing. For real time aging, the product will be returned to XYZ after transportation testing, then aged for time (s).

5.1.2 The product will then undergo testing per the protocol, and a report will be generated documenting the findings.

5.1.3 Successful completion of real-time aging testing will allow the product to be labeled with the appropriate expiration date.

5.1.4 The start of the expiration date calculation will be the beginning of processing of assemblies by XYZ. Example: If the earliest assembly began on July 6, 2022 and the product had a 12-month shelf life, the expiration date will be June 30, 2023.

5.2 If known materials and processes are being used, the product can be labeled with a 6-month shelf life while the shelf life testing is being performed

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DURING EDIT:

1. Temperatures ~~above~~ should not exceed the glass-transition temperature or maximum temperature recommended by the manufacturer ~~of~~ for any of the materials~~, should not be exceeded, with the~~ except~~ion of~~ when the glass~~-~~transition temperature is ≥ 37°C or lower.

2. If any component is susceptible to moisture, the humidity should be ~~set to~~maintained at a level where the air's moisture content ~~of the air is ≥~~is at least 95% ~~humidity~~ at ambient temperature. This value corresponds to ~~is~~ 0.015 lb~~s~~ water ~~/~~per lb of dry air. Psychrometric charts can be used to determine the % ~~Relative~~ relative ~~Humidity~~ humidity at the oven temperature.

3. The time in the oven is determined by the Arrhenius equation below.

   $s = (t \times q^{y})$ or $t = s \div q^{y}$

   Where:
   t = time of accelerated exposure required (in days)
   s = number of days desired for shelf life (plus 30 days)
   q = acceleration factor (2.0 for non-aqueous solutions)
   y = (elevated storage temperature – ambient storage temperature ÷ 10

4. The ambient storage temperature for XYZ's products is 22°C.

5. For real-time aging, an additional 30 days will be added to the desired shelf life to simulate manufacturing time and ~~as~~ provide a safety ~~factor~~margin.

   5.1 Real-Time aging will ~~be aged~~occur at ambient conditions for a specified duration~~time (s)~~.

      5.1.1 After the calculated time (t), the product will be removed from the oven and returned to XYZ for testing. ~~For real-time aging, t~~The product will be returned to XYZ to perform real-time aging tests after transportation testing, and then aged for a specified duration~~time (s)~~.

      5.1.2 The product will then undergo validation testing per VP-38820~~the protocol~~, and a verification report will be generated documenting the findings.

      5.1.3 Successful completion of real-time aging testing will allow the product to be labeled with the appropriate expiration date.

      5.1.4 The ~~start of the~~ expiration date ~~calculation~~ will ~~be the~~ begin~~ning~~at the start of assembly processing ~~of assemblies~~ by XYZ. Example: If the earliest assembly began on July 6, 2022 and the product had a 12-month shelf life, the expiration date will be June 30, 2023.

   5.2 If known materials and processes are being used, the product can be labeled with a 6-month shelf life while the shelf life testing is being performed.

Comment [IE1]: The glass-transition temp should be lower than 37 degrees C per the validation protocol, VP-38820. The symbol provided indicates a "rise" in temp, whereas the protocol states "a lower temp". Please verify again.

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Comment [IE2]: Is there controlled charts located on the PLM for use?

Comment [IE3]: Per ISO 11607-1, the Arr equation follows the accelerated aging study, and not real-time aging. According to the standard, "accelerated aging can be used to estimate the shelf life of med dev packaging, but it must be validated by real-time aging studies. VP-38820 only validates the transportation humidity temp controls, and not the real-time aging affects. This equation is inaccurate and will need to be retested to align with the ISO standard by following its recommended Arr equation.

Comment [IE4]: Will need to be updated after real-time aging validation is completed.

Tech Editing Example of a Product Shelf Life Real-Time Aging Test

AFTER EDIT:

1. Temperatures should not exceed the glass-transition temperature or maximum temperature recommended by the manufacturer for any of the materials, except when the glass-transition temperature is ≥ 37°C or lower.
2. If any component is susceptible to moisture, the humidity should be maintained at a level where the air's moisture content is at least 95% at ambient temperature. This value corresponds to 0.015 lb water per lb of dry air. Psychrometric charts can be used to determine the % relative humidity at the oven temperature.
3. The time in the oven is determined by the Arrhenius equation below.

   $s = (t \times q^{y})$ or $t = s \div q^{y}$

   Where:
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4. The ambient storage temperature for XYZ's products is 22°C.
5. For real-time aging, an additional 30 days will be added to the desired shelf life to simulate manufacturing time and provide a safety margin.

   5.1 Real-Time aging will occur at ambient conditions for a specified duration.

   5.1.1 After the calculated time (t), the product will be removed from the oven and returned to XYZ for testing. The product will be returned to XYZ to perform real-time aging tests after transportation testing, and then aged for a specified duration.

   5.1.2 The product will then undergo validation testing per VP-38820, and a verification report will be generated documenting the findings.

   5.1.3 Successful completion of real-time aging testing will allow the product to be labeled with the appropriate expiration date.

   5.1.4 The expiration date will begin at the start of assembly processing by XYZ. Example: If the earliest assembly began on July 6, 2022 and the product had a 12-month shelf life, the expiration date will be June 30, 2023.

   5.2 If known materials and processes are being used, the product can be labeled with a 6-month shelf life while the shelf life testing is being performed.

Comment [IE5]: The glass-transition temp should be lower than 37 degrees C per the validation protocol, VP-38820. The symbol provided indicates a "rise" in temp, whereas the protocol states "a lower temp". Please verify again.

Comment [IE6]: Is there controlled charts located on the PLM for use?

Comment [IE7]: Per ISO 11607-1, the Arr equation follows the accelerated aging study, and not real-time aging. According to the standard, "accelerated aging can be used to estimate the shelf life of med dev packaging, but it must be validated by real-time aging studies. VP-38820 only validates the transportation humidity temp controls, and not the real-time aging affects. This equation is inaccurate and will need to be retested to align with the ISO standard by following its recommended Arr equation.

Comment [IE8]: Will need to be updated after real-time aging validation is completed.