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ACCELERATED AGING

BACKGROUND: Accelerated Aging is used to rapidly determine if there are any effects to the product or package due to the passage of time and environmental effects. The accelerated aging is based on the assumption that deterioration of the materials follows the Arrhenius reaction rate function which states that for an increase in temperature the chemical reaction rate increases. The Q_{10} in the aging equation represents the rate of reaction. A value of 2 is a common and conservative value (for every increase in temperature of 10°C, the reaction rate doubles).

PURPOSE: Packages and products are accelerated aged to determine the self life of a product or package in a shorter period of time. The standards require that accelerated aged studies be repeated on real time samples to confirm the shelf life.

TYPICAL APPLICATIONS: The material or package undergoes external stresses more severe than normal environmental stresses to determine the shelf life in a shorter period of time. The package is then tested for integrity and seal strength in order to determine the affect of aging. The product is tested for functionality, tensile strength, toxicity, and/or tests used to confirm safety. Note that the loss of sterility in a package is considered a dynamic event relation incident rather than a time related phenomenon. Damage can be caused by shipping, handling, high and low temperatures, humidity or improper manufacturing and or production processes.

SAMPLE REQUIREMENTS: The sponsor shall choose the number of samples. This may be based on the acceptable quality limit (AQL) in accordance with ISO 2859-1 or ISO 1886 or statistical process control (SPC).

METHODS: The sponsor shall choose an elevated temperature (typically between 40°C and 60°C) and humidity (low ≤ 20%, Medium 50%, High 70% or alternating between high and low). The samples may be subjected to a freezing temperature to determine if the product or package seals will separate due to cold creep (optional, but required at some point in the validation process if the package may see freezing temperatures during shipping).

The elevated temperature shall be based on the composition and properties of what is being aged. The higher the accelerated aging temperature, the shorter the aging time (time in chamber). The high temperatures may cause effects that will not be seen at room temperature. A temperature is chosen that will not degrade the product or packaging. The aging temperature should be at least 10°C below any glass transition temperature of the samples or distortion or delamination may occur. Temperatures over 60°C are not recommended.

Humidity conditions and freezing conditions do not affect the aging time, but does cause environmental stresses. These factors should be considered when setting up an aging program.

The sponsor shall choose an ambient temperature for the aging equation (ambient temperature of actual sample storage). This is typically between 20°C and 25°C. A temperature of 25°C is generally considered the conservative approach. Justification is recommended for lower temperatures (samples stored in cooler environment).

The accelerated aging temperature (AA) and the ambient temperature (RT) are placed in the following equation to determine the aging factor:

$$\text{Aging Factor} = Q_{10}\text{^}[(T_{AA}-T_{RT})/10]$$

The accelerated aging time is then determined by dividing the desired real time by the aging factor.

RESULTS: The report includes the temperature and humidity conditions as well as the number of days aged.

NAMSA CODES: C0068_000

REFERENCE:
ASTM F 1980, Standard Guide for Accelerated Aging of Sterile Medical Device Packages.
AAMI TIR 17, Compatibility of materials subject to sterilization.
ANSI/AMI/ISO 11607, Packaging for terminally sterilized medical devices-Part 1: Requirements for materials, sterile barrier systems, and packaging systems