Click to verify

Accelerated aging testing

 The Accelerated Aging test can be run to simulate a designated time period ranging from 1 month to 5 years (or longer). The time of simulated aging depends on the temperature at which the products are held. For example, at 55°C using an ambient temperature of 25°C, 6.5 weeks is equivalent to 1 year on the shelf. So at these parameters, 13.0 weeks would be equivalent to 2 years on the shelf and 32.5 weeks would be equivalent to 5 years on the shelf. After the samples have been aged, they are removed from the chamber and brought back to room temperature. Following the aging, the samples can be returned to you for further examination (such as functionality tests), or we will retain the samples to perform additional testing to confirm stability (i.e., package integrity/microbial aerosol barrier challenge, seal peel, or other physical tests). Recommended replicates: You may age as many samples as you need. The number of samples should be based on the number of time periods to be examined, and the testing to be performed after aging. Please use the Accelerated Aging Parameters form along with the Sample Submission Form when submitting samples. Testing Locations Learn more about our locations and their certifications. Contact Us If you have additional questions about Accelerated Aging testing services, or would like to consult with the experts at Nelson Labs, just send us a request or call us at +1 (801) 290-7500. Medical Device Assembly & Kitting In-House and Managed Sterilization Processing Package Testing & Validation Packaging Development & Production Point of Care Diagnostics Cleaning & Decontamination Medical Device Incubator Support Fulfillment & Distribution The accelerated aging calculator below generates a table of values for calculations based upon ASTM F1980, Accelerated Aging of Sterile Medical Device Packages. Rocky Mountain Testing Solutions has multiple environmental temperature chambers maintaining different set points that can be utilized for all of your accelerated aging needs. Our accelerated aging calculator gives our customers a hint to how their products will respond to testing conditions. We will make sure that you satisfy the internal and industry standards of your project. Accurate and reliable accelerated aging results will be provided based on your requirements along with exceptional, personal service. When testing is completed, you will receive a detailed, clear report for your product qualification and third-party validation testing. If you are ready to test now or if you need assistance in developing a test specification, call Rocky Mountain Testing Solutions. Our accelerated aging calculator allows customers to easily view different aging test scenarios involving these four variables: Test Temperature (°C) Q10 (Reaction Rate Factor) Ambient Temperature (°C) Real-Time Equivalent (Day/Week) Accelerated Aging in Detail The common and conservative means of the accelerated aging calculation is based on the Arrhenius equation. This states that a 10°C increase in temperature doubles the rate of chemical reaction. This principle is used to simulate real shelf-life aging and is conducted to validate shelf-life claims and document expiration dates. These accelerated tests help pinpoint possible seal and burst strength faults, leaks, and film delamination in the packaging of medical devices and pharmaceuticals. The tests are prominent in biomedical research, pharmaceutical packaging, and medical device packaging and are a FDA requirement. Accelerated aging uses vibration and various levels of conditions of humidity, heat, sunlight, and oxygen to accelerate products' normal aging processes. Using controlled standard test methods, such testing can help determine the long-term effects of stress within an accelerated time and at expected levels. This allows manufacturers to estimate the useful lifespan or shelf life of a product when true lifespan data is unavailable. If a product has not existed long enough for useful lifespan data to be available, such as a new polymer or unique type of car engine, accelerated aging testing is most applicable. Chemical or physical testing is conducted by subjecting products to different levels of stress for extended periods of time. Abnormally high levels of stress can accelerate the effects of natural aging while some stress levels are designed to intentionally force failures as a means of further analysis. The conditions employed are based on the kind of material being tested. For example, mechanical parts may be pushed to very high speeds, dramatically exceeding how they would normally be used. On the other hand, polymers are generally stored at elevated temperatures to accelerate chemical breakdown. The material or device being tested can also be exposed to controlled rapid changes in temperature, pressure, humidity, strain, etc. The Arrhenius Equation—The Formula for the Calculation Our accelerated aging calculator uses the Arrhenius equation to make its estimates. The Arrhenius equation measures temperature dependence of reaction rates. Based on the work of Svante Arrhenius and Jacobus Henricus van't Hoff in the late 19th century, the Arrhenius equation is indicative for both forward and reverse reactions. The Arrhenius equation is often employed to model the temperature variation of diffusion coefficients, creep rates, the population of crystal vacancies, and additional thermally-induced processes and reactions. Arrhenius' equation supports the postulate that the reaction rate of common chemical reactions at room temperature doubles for each 10° C increase in temperature. Arrhenius equation: Definition of rate constant k, the pre-exponential factor A, and activation energy. How the exponential part of the Arrhenius equation depends on activation energy and temperature. The Arrhenius equation is explained in detail courtesy of the Khan Academy. Standards for the Accelerated Aging Calculator These are primary accelerated aging standards pertaining to sterile barrier systems for medical devices: ANSI/AAMI/ISO 11607-1:2006 ASTM F1980-07 (2011) Most Common Variables For Accelerated Aging Accelerated test temperatures typically range between 50 to 60°C, the most common being 55°C. Typical ambient storage temperatures range between 22°C and 25°C. For the shortest test duration, 22°C is used. Q10 is commonly 2 for medical device testing. When you produce a product, it's essential to understand how the aging process impacts its condition or quality. This knowledge is critical across industries, from consumer goods to pharmaceuticals. The medical device industry, in particular, places a large emphasis on testing the shelf life of products. That's because as time goes on, a product's Sterile Barrier System can become altered as it faces stresses from time and the ambient environment. If a Sterile Barrier System becomes compromised, this can jeopardize the efficacy and safety of the medical device in question. Therefore, the FDA requires medical device manufacturers to determine a product's shelf life before sending the product to market in the United States. However, sometimes it may take many months or even years before you can witness the toll aging takes on a product in real-time This is where accelerated aging, also known as accelerated shelf-life testing, comes into play. Accelerated aging is a type of testing that simulates the effects that time has on a product or package by subjecting it to elevated temperatures. This testing allows medical device manufacturers to determine a newly developed product's shelf life and witness the long-term effects of aging without having to wait for years to see the real-time results. Skip to content Everything you need to know about accelerated aging Accelerated aging testing is a good predictor of real-time aging effects, but it has limitations. The Arrhenius equation models chemical reactions, but physical changes may not accelerate at the same rate. Regulatory bodies generally accept accelerated aging data for initial submissions, but manufacturers are often required to confirm with real-time aging studies running in parallel. The accuracy depends on several factors, including the Q_{10} value selected, the aging temperature, and the specific materials being tested. The Q_{10} value represents how much the reaction rate increases with a 10°C temperature increase. The most commonly used value for medical devices is 2.0, which is considered a conservative approach. However, specific materials may have different Q_{10} values: - Paper and paper-based materials: 1.8-2.0 - Most polymers (PE, PP, PET): 2.0-2.5 - Some complex biomaterials: up to 3.0 If you have multiple materials in your device or packaging, it's best to use the most conservative (lowest) Q_{10} value to ensure all components remain within specifications. ASTM F1980 recommends that accelerated aging temperatures should not exceed 60°C (140°F) for most medical device packaging. High temperatures can cause physical changes that would not occur during real-time aging. Common aging temperatures are: - 50°C - Conservative approach, lower acceleration factor but more realistic - 55°C - Balanced approach, commonly used in the industry - 60°C - Maximum recommended temperature, higher acceleration factor The temperature you select should consider the materials in your device and packaging. Some temperature-sensitive materials may require lower aging temperatures. Yes, most regulatory bodies worldwide accept accelerated aging data for initial submissions, including the FDA and European regulatory authorities. However, there are some important considerations: - Accelerated aging data is often accepted for initial market approval - Real-time aging studies should be initiated in parallel with accelerated aging - Real-time data may be required to extend the claimed shelf life beyond initial approval - The methodology and rationale for your accelerated aging protocol should be clearly documented It's always advisable to check with specific regulatory bodies for any recent changes in requirements or expectations regarding accelerated aging data. Start using our AAT calculator today to efficiently plan your accelerated aging tests Use Calculator Contact Us Discover our most recent publications Read full article The performance of electronic devices in varying environmental conditions is a critical aspect of the design and testing process, especially... Read full article Accelerated aging tests hold significant importance in understanding the durability and longevity of materials used across various sectors, particularly when... Read full article The accelerated aging of medical adhesives plays a pivotal role in ensuring the safety and effectiveness of medical devices. By... Accelerated Aging Calculator Leading provider of accelerated aging calculations for medical devices and sterile barrier systems according to ASTM F1980 standard. Get the latest updates on regulatory changes and accelerated aging techniques for medical devices. Industry insights and best practices Regulatory updates and standards changes Exclusive tips and calculator updates ISO 11607 requires sterile medical device manufacturers to demonstrate the shelf life of their packaging system. Accelerated aging is used to simulate the effects of real-time aging by subjecting samples to elevated temperatures and realistic relative humidity levels for specific periods of time, thereby generating data more quickly and allowing for shorter time to market. In parallel with accelerated aging, the manufacturer must also conduct a real-time study to validate the data generated during the accelerated aging process. Shelf-life testing is the process that demonstrates the ability of a packaging system to maintain sterile integrity and strength over a defined period of time, and is indicated by labelling the product with a use by/expiry date. Shelf life is defined as the length of time that a product may be stored without becoming: Unfit for use Unfit for consumption Unfit for sale Accelerated aging is an artificial procedure used for establishing the shelf life to estimate the useful lifespan of a product when actual lifespan data is unavailable in an expedited manner. Accelerated aging is conducted by simulated exposure of the product to elevated temperatures and realistic relative humidity levels for the equivalent period claimed for product expiration. The provisional accelerated aging expiration date will remain until real time aging results are acquired. What is real time aging? Real time aging is a stability testing process used to provide real data to determine the shelf life and the effects of aging on materials over time. The packaged product is exposed to storage conditions such as temperature and relative humidity to determine its shelf life. These studies are typically carried out at ambient temperature between 20°C to 25°C. How is accelerated aging calculated according to ASTM F1980? Accelerated aging is calculated according to ASTM F1980 using techniques defined on the basis that the chemical reactions involved in the deterioration of materials follow the Arrhenius reaction rate. This states that a 10°C temperature increase results in approximately two times an increase in the rate of the aging process. The accelerated aging process is based on the relationship of temperature and reaction rate where an increase in temperature increases the reaction rate. The level of relative humidity (RH), should be included at realistic levels. When controlling humidity during an accelerated aging study, it is suggested in the standard to use a realistic level between 45% RH and 55% RH unless there are documented reasons for using other humidity levels. If other levels are used, a rationale should be documented. It is not recommended by the standard to age packaged products at temperatures above 60°C unless knowledge of the materials shows otherwise The calculated duration is normally rounded up to the nearest whole day Ambient temperature Real Time Temperature (TRT) is typically between 20°C to 25°C The aging factor of 2.0 is the most common value but other levels between 1.8 – 2.5 may be used once sufficient knowledge of the materials are known and can be justified Product temperature storage labelling considerations: Where a product is labeled with specific storage temperature range, the upper temperature listed should be used when calculating the accelerated aging duration. This is instead of the normal ambient temperature (TRT), which is typically 20°C or 25°C. If the labelled range is 15°C to 35°C, then the 35°C should be used as the ambient temperature TRT in the calculation. Timepoints: It is recommended that minimum of two shelf-life timepoints are used. This provides a backup if post aging tests do not meet acceptance criteria for a particular timepoint. STERIS offers a range of accelerated aging chambers, which can accommodate both large pallets and single shipping units. Stability Testing What are stability studies? Stability studies are conducted to evaluate the quality of a pharmaceutical or drug product over time to evaluate the influence of various environmental factors such as temperature, humidity, and light. Typically, under accelerated conditions, this simulates the effects of long-term storage in a shorter period of time. STERIS also offers stability testing capabilities in accordance with ICH guidelines for pharmaceutical manufacturers. Conditions include: 5°C 25°C, 60% RH 30°C, 65% RH 30°C, 75% RH 40°C, 75% RH Technical Support Our technical professionals also offers guidance toward: Packaging evaluations and concept reviews Risk assessment Test planning and protocol development Evaluating prior validations and gap analysis Related content: TechTalk: Accelerated aging and real time studies TechTalk: Testing validation TechTalk webinars A potential customer calls us with a goal to have their product launched in the upcoming quarter with a shelf life target they must meet. If they are discovering sterile barrier packaging early on in product development, it is easy to plan around the packaging validation timeline. However, too many times we are brought into the picture at the end of product development. In these cases, the timeline for packaging validation is crunched. When this happens, it is our job to provide our customers with our medical device packaging validation expertise and find ways to make their timeline work, which often involves real time aging and accelerated aging testing and shelf life studies. Per ANSI/AAMI/ISO11607-1:2019 Packaging for Terminally Sterilized Medical Devices, it is a requirement that sterile packaging can maintain a sterile barrier to the point of use or expiry date. Something to keep in mind, is that per the standard, real time aging is absolutely a requirement. However, you may elect to put the product into market based on the preliminary results of accelerated aging studies, so long as the results of real time studies substantiate these shelf life claims in the future. It is always a best practice, and something we see becoming more and more on auditors' radars, is that accelerated and real time aging studies are most appropriately kicked off simultaneously. For accelerated aging, the FDA consensus standard is ASTM F1980 Accelerated Aging of Sterile Barrier Systems for Medical Devices is the most appropriate standard for medical packaging. The first part of testing (transit and materials) is wrapped up quickly while accelerated aging tests can take anywhere between 29 to 57 days to complete*. We know that time is money, and the quicker accelerated aging is complete, the faster you can go to market with your medical device. A question we get asked often is how we can speed up the accelerated aging portion of a customer's sterile barrier packaging validation. The problem with decreasing the amount of time an aging study takes to complete means increasing the temperature of the aging chamber. In doing this, we could cause defects that would never happen in the real-world setting (think a hospital storage room). In this blog, we will go over how we choose the temperature for accelerated aging studies and why increasing the temperature might not be a great option. How does the temperature you choose affect your Accelerated Aging study? A high temperature aging test can affect your study in a couple different ways. The higher the temperature, the less time it takes to complete the accelerated aging study. The standard for accelerated aging uses an equation called the 'Arrhenius Equation'. The output of this equation tells us how long the samples should be in the chamber for. If the temperature of the chamber were 55C and we were testing for 1 year in real time, the Accelerated Aging study would take 40 days. If we bump up the temperature to 60C and were testing for 1 year in real time, the accelerated aging study would be complete after 29 days. (Note: this assumes a Q10 value of 2.0 (the most conservative and default election, as outlined in F1980) and a real-world storage temperature of 23'C (again, a conservative and common selection)). Did you know we have an accelerated aging calculator on our website? Find it here! Something to keep in mind is the higher the temperature for accelerated aging, the farther you get from the ambient temperatures the sterile barrier packaging will experience during Real Time aging. The less like the real-world medical device storage temperature and overall conditions are, the more likely you are to create an unrealistic defect in your packaging. We will talk more about this later in the blog, but a solution to this is to run two aging studies at the same time at different temperatures. What's Humidity Have to Do with It? Traditionally humidity is not a factor that is given much consideration. Because some of our team of packaging engineers actively engages with members on ASTM committees, we are learning the standard will be updated in the future to accommodate this factor. Since ASTM 1980 does not call out what the humidity should be set to, it is best practice to keep the humidity low. Just like heightened temperature, high humidity can create defects that are not relative to the real-world environment the sterile barrier packaging will experience. Our goal is to target less than 20% Relative Humidity (RH) for accelerated aging studies. Aging Related Defects The defects that we look for in aging studies differ from the defects we look for in any other kind of study. During transit simulation we drop shippers and shake them around, therefore the defects we are looking for after transit simulation are event related. When the defect is caused by dynamic forces of drop & vibration is happening to the samples, we call those defects event related. In aging studies we are looking for time related defects. Some examples of this are: over time seals can soften and loosen up there might be tension in a package the material can delaminate The packaging could change in color What if I REALLY need to wrap up my aging study? What are my options? The one thing we could do is run two accelerated aging studies in parallel. This would require double the number of samples, but it could potentially speed up the accelerated aging portion of your study. We would run both studies at the same time and test the samples for the first study after 29 days. If we find there are defects associated with the temperature being too hot, we will continue with the longer study. If we tested them and there were not unrealistic defects, we could end the 40-day study and use the data from the 29-day long study! Anxious about your product timeline? Don't sweat it! PCL will help you speed your medical device to market! Learn more about our services and testing methods. Contact us Today! *29-57 days = 1 year. This increases as your RT shelf life increases. DDL conducts both accelerated aging testing and real time aging testing to help establish shelf life and expiration dates for medical devices, packaging and products. When establishing shelf life claims, it must be recognized that the data obtained from accelerated aging testing is based on conditions intended to simulate the effects of aging on and between the materials involved. The resulting 'expiration date' or shelf life from accelerated aging testing is considered a conservative estimate. Real time aging test results are used to verify accelerated aging evaluations and together are used to determine final shelf-life claims/values. Accelerated aging testing is based on a thermodynamic temperature coefficient formulated by J.H. Van't Hoff that states "for every ten degree Celsius rise in temperature the rate of chemical reaction will double." However, since this formula is based on rate kinetics of a single chemical reaction, not on packages made up of various materials, the direct extrapolation of this theory to the aging of packaging materials must be used with caution. The FDA and the package testing industry believe Van't Hoff's theory is useful in defining and justifying accelerated aging testing services. Temperature selection for an accelerated aging study should be determined by the temperature that avoids unrealistic failure conditions such as deformation due to melting. Real time aging must be performed in conjunction with any accelerated aging study to correlate the results found during accelerated aging. DDL offers Accelerated Aging testing per ASTM F1980. Our technical experts can help you determine the best types of aging variables for your testing project. Real time aging is performed in parallel with accelerated aging in order to support and verify accelerated aging conclusions. It is recognized that in some cases products are technologically obsolete before a real time aging project can be completed. The FDA provides guidance regarding medical device shelf life determination and advises manufacturers to consider several parameters including chemical and physical. The European Medical Device Directive (MDD) requires all sterile medical devices to have an expiration date. Documented shelf life evidence must exist to substantiate shelf life claims made by the manufacturer. What is Accelerated Aging? Accelerated Aging is a process of putting packaged products into a chamber, elevating the test temperature to claim a specific expiration date for a medical device product or package. ASTM-F1980 is meant for sterile medical packaging but many companies and or organizations have been using it to claim specific expiration dates for their products. When to use it? Primarily medical device manufacturers will use accelerated aging in their package validation to be in compliance with ISO 11607. How does AA work? ASTM-F1980 is the standard used for Accelerated Aging of Sterile Barrier Systems and Medical Devices. The theory itself is the Q10 theory, which stipulates that for every 10-degree increase it doubles the reaction rate of the materials. This Q10 factor came from the food industry. This is not an exact science but the FDA allows you to use this theory to get your products to market faster. But you will need to follow it up with real time aging. In doing so, you want to have conclusive evidence that you are not going to have issues with your package or product for that specific shelf life. Can you use any temperature for AA? You need to understand where the softening or melting point is before you can pick a test temperature that is going to work properly. Accelerated aging is for homogeneous materials while most medical devices are comprised of multiple materials, which can lead to trouble. What role does relative humidity play in accelerated aging? The newly revised ASTM F1980 standard (please see our blog post on the update) now addresses polymers for both the product and the packaging system. With this significant change, medical device manufacturers (MDMs) must consider whether the polymers that make up their product and/or packaging system could be affected by humidity. If any polymers that make up a product or packaging system are considered hydrolytic or corrosive, the use of controlled humidity will be required during accelerated aging (polyamides absorb moisture from the environment and may degrade, while polyolefins will not). If you have a hydrolytic polymer as part of your product or package system, the standard recommends what humidity to use in section X3.3 (45-55%RH), but ultimately it is up to each medical device manufacturer to determine if that is suitable or not. If you have identified that your polymers do not require humidity, then the use of temperature and ambient RH will be sufficient for your aging studies. Please note that you will need to have a justification in place for whether humidity is needed or not based upon your specific product and packaging system. What comes after Accelerated Aging? Accelerated aging is a conditioning step. It does not tell you if you pass or fail your package validation. What comes after accelerated aging indicates if you pass or fail. After accelerated aging comes package strength testing and integrity testing to make sure there is not a sterility breach in the package. If it is product testing, you want to go through all of the tests that you would have done at time-zero or your baseline to ensure aging has not caused adverse effects and compare those results back up. Why is Real Time Aging important? Real time aging is critical. If you have a device and that device sits on the shelf with a three-year expiration date, by the time the three years goes by, the product may be obsolete. Accelerated aging thus allows customers to bring products to market faster. Real time aging is definitive data that you are going to get with having your samples stored on a shelf for the same specific expiration date used for accelerated aging. What are some of the most common issues seen with Accelerated Aging? Planning is the number one issue with accelerated aging. If you need to run a five-year expiration date before next month, there is no physical way to do this. Even if you move the temperature to 100°C. Some may think the answer is to keep moving the temperature up to meet specific needs for the launch date. Putting the samples over 60°C however is a red flag that will come up in regulatory review. As you will run into problems with the product performance and packaging system by choosing a test temperature that is not going to mimic the real world. Contact us for more information or to talk to an engineer. The use of Van't Hoff's Theory for medical device products and packaging materials is supported by the following references:

Hemmerich, Karl J., "General Aging Theory and Simplified Protocol for Accelerated Aging of Medical Devices" Proceedings MDM-West, January, 1997 Clark, Geoffrey, "Shelf Life of Medical Devices" Guidance Document, Division of Small Manufacturers Assistance, CDRH, FDA, April 1991