ahn®

Accelerated Aging of Plastic Laboratory Consumables

Summary

Plastic laboratory consumables are indispensable in scientific research and diagnostics. However, these materials are susceptible to aging, which can significantly affect their performance and reliability. This white paper explores the mechanisms of plastic degradation, the methodologies for accelerated aging testing, and the implications for laboratory practice. It also discusses the importance of microbial barrier systems and its implications on shelf life.

Introduction

Plastic laboratory consumables, such as pipette tips, microcentrifuge tubes, petri dishes and storage vessels are critical for daily operations in scientific research and diagnostics. While they offer convenience and cost-effectiveness, their polymeric nature makes them vulnerable to aging, leading to potential mechanical failure. Additionally, the need for maintaining sterility highlights the importance of effective microbial barrier systems. Understanding and addressing the accelerated aging of these consumables is essential for maintaining the integrity of experimental results, ensuring safety, and preventing microbial contamination.

Overview of Plastic Laboratory Consumables

Laboratories widely use various types of plastics, including polypropylene (PP), polyethylene (PE), polystyrene (PS), and polycarbonate (PC). These materials are selected for their chemical resistance, transparency, flexibility, and other desirable properties. Each type of plastic has unique characteristics that determine its suitability for specific applications, such as sample storage or liquid handling. The sterility of these consumables is crucial in preventing cross-contamination and maintaining the integrity of experimental work.

Mechanisms of Aging in Plastics

Plastic materials degrade over time due to several factors

- Chemical Degradation: This includes processes like hydrolysis and oxidation, which can break down polymer chains, leading to changes in the material's properties.
- Physical Degradation: Mechanical stresses, such as repeated use or exposure to solvents, can cause physical damage, such as cracking or embrittlement.
- Environmental Factors: UV radiation, temperature fluctuations, and humidity can accelerate degradation, especially in plastics not formulated for such conditions.

Accelerated Aging Testing Methods

To predict the lifespan and performance of plastic consumables, laboratories use accelerated aging tests. These tests simulate long-term aging in a shorter period by exposing samples to extreme conditions. Common methods include:

- Thermal Aging: Heating the material to high temperatures accelerates chemical reactions that lead to degradation. The Arrhenius equation is often used to model the rate of these reactions:

The accelerated aging is calculated using the Q10 factor. Q10 is the factor by which the rate increases (microbiological growth, when the temperature is raised by ten degrees.

$$Q_{10} = \left(\frac{R_2}{R_1}\right)^{\left(\frac{10}{T_2 - T_1}\right)}$$

A (Accelerated Aging Rate) = Q10 ((Te - Ta)/10)
Where... Ta = Ambient Temperature
Te = Elevated Temperature
Q10 = Reaction Rate
B (Accelerated Aging Time Duration) = Desired Real Time/A

By applying the Arrhenius equation, researchers can predict the rate of aging at different temperatures, helping to estimate the lifespan of the plastic under normal use conditions. In the case of sterile products, gamma irradiated or pre-sterilized product through any other means are used to estimate ageing.

- UV Exposure: Using UV light to simulate the effects of sunlight, which can cause photo-degradation of the plastic, leading to discoloration, brittleness, and other changes.

- Mechanical Stress Testing: Applying repetitive forces to assess material fatigue, which can reveal weaknesses in the material that might lead to failure during regular use.

Each method provides insights into different aspects of degradation, and a combination of tests often offers the most comprehensive understanding.

Impacts of Aging on Laboratory Consumables

Aging can significantly affect the functionality of plastic consumables:

Mechanical Properties: Degradation can reduce tensile strength, flexibility, and impact resistance, leading to material failure during use.

Chemical Leaching and Contamination: Degraded plastics may release additives or breakdown products, contaminating samples and affecting experimental outcomes.

Microbial Contamination: Compromised integrity in consumables can breach microbial barriers, leading to contamination and invalid results, particularly in sterile environments.

Experimental Integrity and Safety: Compromised consumables can lead to inaccurate results, compromised safety, and increased costs due to the need for repeat experiments or contamination control.

Impacts of Aging on Laboratory Consumables

Microbial barrier systems are essential in laboratory consumables to prevent contamination of sterile samples and cultures. The effectiveness of these barriers is highly dependent on the integrity and quality of the plastic material. As consumables age, the risk of microbial penetration increases due to physical degradation like cracking or porosity. Therefore, maintaining the sterility and functionality of plastic consumables is critical for preventingmicrobial contamination, and ensuring accurate experimental outcomes.

A breakdown in the microbial barrier leads to ingression of mircoorganisms into the product leading to contamination over time. Ingression studies are critical in estimating the life time of the product.

Strategies to Mitigate Aging Effects

To extend the lifespan and reliability of plastic consumables, laboratories can:

- Material Selection and Additives: Choosing high-quality, UV-resistant materials and using stabilizers can enhance durability. Incorporating antimicrobial additives can also improve the sterility of consumables.

- Proper Storage and Handling: Storing consumables away from UV light and at stable temperatures can reduce aging effects. Maintaining proper storage conditions is crucial for preserving the sterility and structural integrity of consumables.

- Guidelines for Usage and Replacement: Establishing protocols for the regular inspection and replacement of consumables helps maintain experimental quality. Using consumables within their shelf life and replacing them before visible signs of degradation appear can prevent contamination and ensure reliability.

Inference and Scope

Among the key aspects that influence the shelf life of a product is in fact its packaging. Packing protects the product from transformative radiation such as UV rays and environmental factors such as humidity or temperature. Packaging also act as part of the sterile barrier system that acts to protect against ingression of microorganisms into the product thereby protecting it from various contaminants ranging from pyrogens, nucleic acid, nucleases and more. The accelerated aging study is thereby designed to challenge the sterile barrier system and longevity of our products. Let us now explore an accelerated aging study done on petri plates.

Protocol: Accelerated Ageing for Petri Plates

- Select a temperature that represents the actual product storage and use conditions. This temperature is typically between 20–25°C.

- Considering the characterization of the materials under investigation, select a temperature for the accelerated aging testing. The higher the accelerated temperature, the greater the AAF and thus the shorter accelerated aging time. If packages containing liquid or other volatile components are tested, lower temperatures may be required for safety reasons.

- Using the Arrhenius equation with Q10 equal to 2 is a common and conservative means of calculating an aging factor.

- Calculate accelerated aging factor using the following equation:

- Accelerated Aging Time = Desired Shelf Life /AAF

For Example:

For example, where Q10 = 2; ambient temperature = 23°C; test temperature = 55°C;
AAF = 2.0^(55−23)/10;
AAF = 2.0 ^ 3.2 = 9.19;
Accelerated Aging Time (AAT) = 365 days/9.19; and
AAT = 39.7 days = 12 months (real-time equivalent).

- Once the aging time is defined, the products should be produced as per intended storage conditions, the tests to be conducted to verify the integrity and stability of the product must be defined and appropriate samples must be placed under study conditions to cover all the testing requirements.

- Accelerated aging is not a substitute for real time aging and therefore, samples must be kept parallelly to validate the claims of accelerated aging. However, accelerated aging can be used to qualify product for market release and is accepted by international regulatory bodies.

Considerations:

- Ideal ambient temperature as per ASTM F 1980 is 25 °C: Ambient temperature considered as 25 °C for this experiment.

- Aging Temperature should not exceed 60°C as per ASTM F 1980: Ageing temperature set at 55°C for this experiment.

- Recommended Arrhenius reaction rate as per ASTM F 1980 Q10 =2: Q10 =2 set for this experiment.

Aging Rate Calculation	
Ambient Storage Temperature °C	25
Q10	2
Aging Temperature °C	55
Accelerated Aging Factor (AAF)	[2.0^ (55-25)/10] =8
Target Shelf Life=> Accelerated Aging Period	3 years => 4.6 months 5 years => 7.6 months
Test Intervals	T0, T1, T2, T3, T4 &T5

Test Description & Acceptance limit:

The following tests are sufficient to measure the integrity of the sample after ageing period:

Specifics	Specifics
Observational Time Line	T0: 07-Dec-23,
	T1: 24-Jan-24,
	T2: 09-Mar-24,
	T3: 22-Apr-24,
	T4: 08-Jun-24,
	T5: 22-Jul-24
Tests	Sterility Test as per ISO 11737
	Bioburden Test as per ISO 11737
	Torque specific Leak Test
	Drop Test
	Hygiena Super Snap ATP (<10-13 mols)

Test and Date Planning:

Specifics	Specifics
Observational Time Line	T0: 27-Sep-23,
	T1: 13-Nov-23,
	T2: 28-Dec-23
	T3: 12-Feb-24,
	T4: 28-Mar-24,
	T5: 12-May-24,
Tests	Sterility Test as per ISO 11737
	Bioburden Test as per ISO 11737
	Hygiena Super Snap ATP (<10-13 mols)

Results:

(i) PET bottles

Test Method	Torque test				Leak Test after torque closure	Drop Test	Sterility test	Bioburden test	Supersnap ATP
Samples	Min Closure (fixed)	Min Opening	Min Closure (fixed)	Min Opening	No leakage	Integrity should remain	No Growth	<1 CFU	$<10^{-13}$ (ATP free)
T0-1	28.1	19.1	39.8	36.1	Pass	Pass	No Growth	Pass	0 RLU
T0-2	28.2	20.3	39.2	35.5	Pass	Pass	No Growth	Pass	0 RLU
T1-1	22.9	18.4	40.0	35.5	Pass	Pass	No Growth	Pass	0 RLU
T1-2	26.5	19.0	39.5	33.4	Pass	Pass	No Growth	Pass	0 RLU
T2-1	29	17.3	33.5	27.5	Pass	Pass	No Growth	Pass*	0 RLU
T2-2	29.5	15.5	33.3	28.2	Pass	Pass	No Growth	Pass*	0 RLU
T3-1	22.5	18.9	36.0	27.5	Pass	Pass	No Growth	Pass	0 RLU
T3-2	24.5	19.3	37.5	27.4	Pass	Pass	No Growth	Pass	0 RLU
T4-1	20.9	16.1	33.7	25.7	Pass	Pass	No Growth	Pass*	0 RLU
T4-2	21.4	15.7	34.1	25.1	Pass	Pass	No Growth	Pass*	0 RLU
T5-1	20.9	15.1	33.6	24.1	Pass	Pass	No Growth	Pass	0 RLU
T5-2	20.1	13.1	32.1	22.1	Pass	Pass	No Growth	Pass	0 RLU

Pass*- Pass as per sterility test results
RLU- Relative Light Unit, 0 RLU indicates ATP is not detected

(ii) PETG bottles

Test Method	Torque test				Leak Test after torque closure	Drop Test	Sterility test	Bioburden test	Supersnap ATP
Samples	Min Closure (fixed)	Min Opening	Min Closure (fixed)	Min Opening	No leakage	Integrity should remain	No Growth	<1 CFU	$<10^{-13}$ (ATP free)
T0-1	29.1	20.5	40.5	29	Pass	Pass	No Growth	Pass	0 RLU
T0-2	29.5	21.2	39.6	29	Pass	Pass	No Growth	Pass	0 RLU
T1-1	24.0	19.6	39.7	29.3	Pass	Pass	No Growth	Pass*	0 RLU
T1-2	27.5	15.7	43.7	36.2	Pass	Pass	No Growth	Pass*	0 RLU
T2-1	27	12	33.3	25.1	Pass	Pass	No Growth	Pass*	0 RLU
T2-2	28.2	13.1	35.4	22.8	Pass	Pass	No Growth	Pass*	0 RLU
T3-1	24.7	17.0	35.7	29.3	Pass	Pass	No Growth	Pass*	0 RLU
T3-2	26.0	16.7	35.7	28.7	Pass	Pass	No Growth	Pass*	0 RLU
T4-1	23.7	18.7	34.7	24.7	Pass	Pass	No Growth	Pass*	0 RLU
T4-2	23.1	17.9	34.5	24.1	Pass	Pass	No Growth	Pass*	0 RLU
T5-1	20.1	15.1	31.4	19.7	Pass	Pass	No Growth	Pass*	0 RLU
T5-2	21.1	15.8	32.6	19.2	Pass	Pass	No Growth	Pass*	0 RLU

Conclusion:

The results of T0 conforms to the acceptance criteria and thereby we can initiate the ageing process. As results for each T value are observed and conforms to the acceptance criteria it qualifies the product shelf life as indicated in the table below that indicates the product has qualified for a shelf life of 5 years.

Accelerated Time Frame	Equivalent Real Time Frame	Results	Conclusion
T0 (Baseline)	Not applicable	Confirms to Acceptance Criteria	We can initiate ageing study
T1 = 48 days	384 days or Approx. 1 year	Confirms to Acceptance Criteria	Product has 1 year shelf life.
T2 = 93 days	774 days or Approx. 2 years	Confirms to Acceptance Criteria	Product has 2-year shelf life.
T3 = 137 days (4.6 moths)	1095 days or 3 years	Confirms to Acceptance Criteria	Product has 3-year shelf life.
T4 = 184 days	1472 days or Approx. 4 years	Confirms to Acceptance Criteria	Product has 4-year shelf life.
T5 = 228 days (7.6 moths)	1825 days or 5 years	Confirms to Acceptance Criteria	Product has 5-year shelf life