A Comprehensive Review on Photostability Chamber of Pharmaceutical Products

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ABSTRACT

Stability studies ensuring the maintenance of product quality, safety and efficacy throughout the shelf life is considered a pre-requisite for the acceptance and approval of any pharmaceutical product. These studies are required to be conducted in a planned way following the guidelines issued by ICH, WHO and or other agencies. Importance of various methods followed for stability testing of pharmaceutical products, guidelines issued for stability testing and other aspects related to the stability of pharmaceutical products have been presented in a concise manner in the present review. The capacity of a pharmaceutical substance to remain stable within its physical confines is referred to as its stability. Physical, Chemical, microbiological, toxicological, protective, and informational needs of a certain formulation in a specific container-closure system.

keywords: Stability, Types of Stability Studies, Stability Guidelines, Stability Testing.

INTRODUCTION

Stability of pharmaceutical product is defined as "the capacity of a drug substance or drug product to remain within specifications established to ensure its identity, strength, quality, and purity throughout the retest or expiration dating period". Instability of the drug can cause an undesired change in performance that leads to product failures. Expiration period is a valuable quality attribute for all pharmaceutical dosage forms. The expiration date should be preferably accompanied by a detail of specific storage.[1]

pharmaceutical product depends on Photostability chambers are laboratory test chambers designed to simulate and evaluate the effects simulate light exposure on pharmaceutical, cosmetic, and chemical products, assessing stability, degradation, and potential toxicity. They are crucial for assessing the quality and shelf life of products exposed to light over time.[2]

Stability studies are the one of the most critical steps during the development of drug process because it assures the identity, potency, and purity of ingredients as well as formulated products.
The stability of finished pharmaceutical product depends on environmental factors such as ambient temperature, humidity, and light as well as product related factors for example chemical and physical properties of active substances and pharmaceutical excipients, the dosage form and its composition, the manufacturing process, the nature of the container closure system and properties of packing material.

Determination of shelf life of the drug product is the main objective of stability studies. The stability refers to storage time allowed before any degradation product in dosage form achieves a sufficient level to represent a risk to the patient. Based on this time, the product shelf life or expiration date is determined By photostability, we mean the capacity of a compound to keep its active ingredients unaltered when exposed to sunlight.[1]

historical background:
Photostability chambers were developed in the early 20th century to study the effects of light on chemicals and drugs. Initially conducted in natural sunlight, these studies were challenging to measure and control. In 1977, the United States Pharmacopeia outlined the need for photo stability testing to evaluate the effects of light on drug stability. the ICH published guidelines for photo stability testing, which were adopted by regulatory agencies worldwide. In the 1950s and 1960s, artificial light sources like xenon lamps, mercury vapor lamps, and metal halide lamps were developed to

simulate sunlight's effects. These chambers, equipped with advanced control systems, allowed researchers to accurately vary light intensity, wavelength, temperature, and humidity levels, creating more realistic testing conditions. Today, photostability chambers are essential tools in drug development, providing reliable data for safe, effective, and stable pharmaceutical products.[25,31,32]

key features:

1. Light Conditions Simulation*:* stability chambers are used to simulate different lighting conditions, such as natural sunlight or artificial light, to assess the impact of light exposure on products.
2. Stability Testing**:**They are used for stability testing, which helps manufacturers determine product shelf life and packaging.
3. Regulatory compliance: regulatory agencies such as ICH and WHO provide guidelines
4. Quality Control: stability testing helps identify potential quality issues early in product development.
5. Research and Development: stability chambers are also used during the R&D phase to optimize products for light exposure and enhance stability.
6. light intensity and humidity: Some chambers offer control over light intensity and humidity levels, which can impact product stability.
7. Long-term studies**:** can be conducted by exposing products to simulated light conditions for extended periods. Advanced stability chambers
8. Data logging and monitoring: capabilities, allowing for documentation of the testing process. .
9. Versatility: These chambers are versatile and can be used for various products, including drugs, cosmetics, and food additives.[11,12,13,14,15,16,17]

objectives of stability studies:

- The purpose of stability testing is to provide evidence on how the quality of drug product varies with time under the influence of a variety of environmental factors such as temperature, humidity, and light.

- To select adequate (from the viewpoint of stability) formulations and container closure Systems.

- To determine shelf-life and storage conditions

- To substantiate the claimed shelf-life.

- To verify that no changes have been introduced in the formulation or manufacturing process that can adversely affect the stability of the product.

- The main aim of accelerated stability study to predict the stability profile of a drug product that prediction of the shelf life of the product before launching into the market.[1,3,4, **,25]**

importance of stability testing:

Light radiation is all around us, it's inescapable and therefore the prolonged exposure of light on both the drug product and the immediate pack surrounding it need to be tested. If you have a drug product that contains compounds that can be altered by the excitation of light radiation, your drug product will inevitably change. This change could lead to several different outcomes from a reduction in efficacy to potentially becoming inactive or even harmful for the patient.

This is why our studies on drug products are carried out in a sequential manner starting with testing the fully exposed drug product then progressing as necessary to the product in the immediate pack and then if required in the marketing pack.

At the end of each exposure period, the samples should be examined for any changes in physical properties (e.g., appearance, clarity, or color of solution). Where solid drug substance samples are involved, sampling should ensure that a representative portion is used in individual tests. Similar sampling considerations, such as homogenization of the entire sample, apply to other materials that may not be homogeneous after exposure. The analysis of the exposed sample should be performed concomitantly with that of any protected samples used as dark controls if these are used in the test[. 4,3,5,6]

model

Photostability chamber

MK1-200 Ltr [8]

Fig.1

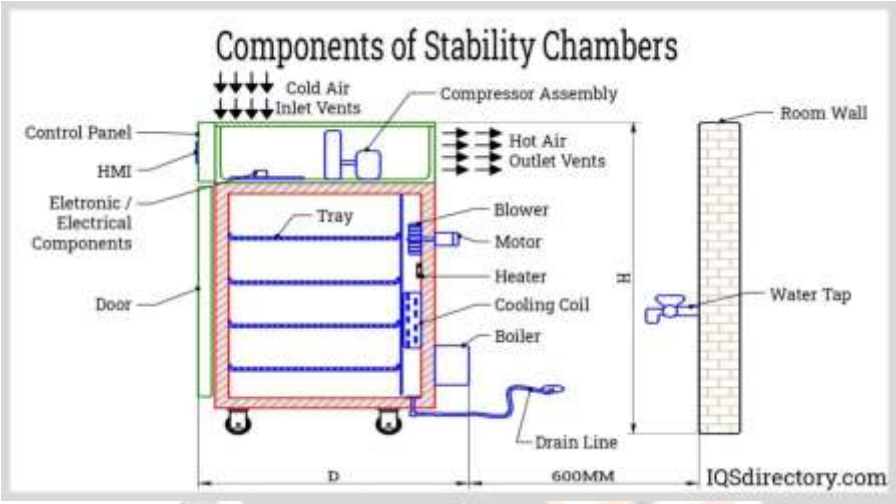
comparative study of photostability chamber:_[9,8,10]

Instrument	Capacity	Light Intensity	Temperature Rang	Suitability
MK1-200ltr	200 liters	Up to 120,000 lux	10-60°C	Photostability testing on various samples
QUV Accelerated	_	Up to 1200 J/m2/ 340nm	Up to 70°C	Testing the durability of coatings, plastics and other materials
Weathering Tester	_	_	_	Simulating outdoor weathering conditions
Atlas Weather-Ometer	_	_	Up to 80°C	Up to 80°C | Testing the weathering resistance of materials under conditions of sunlight and rain

Table No.1

CONSTRUCTION

The outside and inner bodies of the chamber are made of corrosion-resistant stainless steel, and the interior is lined with the suitable insulation. There are various shelves inside the chamber where items that can be removed simply can be kept. In the chamber, sensors are also put to measure the humidity and temperature. The humidity and temperature inside the chamber are consistently maintained because of the controlled airflow. It is advised to use horizontal laminar airflow to increase the constancy of the required conditions. With such a configuration, the shelves will continue to get a consistent flow of air even after being fully stocked with samples. The connected blowers keep the air moving properly. Data transmission and receiving are done via data loggers.[18,19]



working:

The working of stability chamber is straightforward: by keeping the temperature consistent, you keep the relative humidity stable too. A stability chamber is designed to maintain a constant temperature, which will also stabilize the relative humidity value. The amount of water that air can hold is measured by its "relative humidity". When the temperature increases outdoors, air can hold a greater amount of water causing a decrease in relative humidity. How the parameters are automatically and simultaneously updated depends on the relative humidity.

. Specialized sensors are used to monitor and control the light intensity, which ensures that the testing conditions are accurately replicated. During testing, the sample is periodically withdrawn for analysis to detect any physical and chemical changes that may have occurred due to the light exposure. The test is carried out over a specified period of time, ranging from a few days to several weeks, depending on the type of product being tested and the testing standard. [20]

storage of stability samples: [20,21,22]

STUDY	Temperature	Relative Humidity	Time period
General	25°C 2°C	60% RH + 5%	12 months
General	30°C ± 2°C	65% RH ± 5%	12 months
Refrigerator	5°C 3°C	_	12 months
Freezer	-20°C ± 3°C	_	12 months

Table No.2

types of photostability testing:

A. Forced degradation testing studies:

1. It is to evaluate the overall photosensitivity of the material for method development purposes and/or degradation pathway elucidation.

2. This testing may involve the drug substance alone and/or in simple solutions/ suspensions to validate the analytical procedures. In these studies, the samples should be in chemically inert and transparent containers. In these forced degradation studies, a variety of exposure conditions may be used, depending on the photosensitivity of the drug substan25ce involved and the intensity of the light sources used. Under forcing conditions, decomposition products may be observed that are unlikely to be formed under the conditions used for confirmatory studies[. 26]

B. Confirmatory studies:

It should then be undertaken to provide the information necessary for handling, packaging, and labeling .[26.]

ICH GUIDELINE

Testing is carried out on a single batch of material selected. Under some circumstances these studies should be repeated if certain variations and changes are made to the product (e.g., formulation, packaging). Whether studies should be repeated depends on the photostability characteristics determined at the time of initial filing and the type of variation and/or change made.

A systematic approach to testing is recommended covering, as appropriate, studies such as: **[1,3,23,24]**

- Tests on the drug substance
- Tests on the exposed drug product outside of the immediate pacand if necessary
- Tests on the drug product in the immediate pack and if necessary
- Tests on the drug product in the marketing pack

ICH Code	Guideline Title
Q1A	Stability testing of New Drug Substances and Products (Second Revision
Q1B	Stability testing: Photostability Testing of New Drug Substances and Products
Q1C	Stability testing of New Dosage Forms
Q1D	Bracketing and Matrixing Designs for stability testing of Drug Substances and Products
Q1E	Evaluation of stability data
Q1F	Stability data package for Registration Applications in Climatic Zones III and IV
Q5C	Stability testing of Biotechnological/Biological Products

Table No.3

- Q1B:

ICH Q1B, for photostability testing that provide a standardized approach to testing. Tests evaluate the photostability of new drug substances and products, excluding herbal materials.

1. ICH Q1B Option 1: This is the most commonly used photostability testing option, which involves exposing samples to UV and visible radiation at specified intensities and wavelengths for a predetermined time period.[13]

2. ICH Q1B Option 2: This option involves exposing samples to a combination of fluorescent and visible light, with extended exposure times compared to Option 1.[27,28,29,30]

Criteria	ICH Q1B	ICH Q1D
Scope	Photostability testing on drug substances and products	Evaluation of the potential for photolysis of photolabile drug substances
Test method	Exposure to UV, visible, fluorescent, and xenon arc lamps for various durations	Similar to Q1B, plus requires more testing with direct sunlight
Testing conditions	Specify general testing conditions	Stringent testing conditions, including a range of tests
Evaluation criteria	Reference material approach	Mass balance approach
Report submission	Protocol and report	Report detailing all conditions and documented evidence

Table No.4

- Light Sources: The light sources described below may be used for photostability testing. The applicant should either maintain an appropriate control temperature to minimize the effect localized temperature changes or include a dark control in the same environment [10,18,20]
- Fluorescent**:** Produce light by passing an electric current through a gas or vapor, which excites the atoms and causes them to emit ultraviolet radiation. This radiation then strikes a phosphor coating on the inside of the lamp, producing visible light. Fluorescent lamps are commonly used in stability chambers because they emit a broad spectrum of light that can simulate sunlight.
- Xenon lamps**:** are another type of light source used in photostability chambers. Xenon lamps produce a high-intensity, full-spectrum light that closely resembles natural sunlight. They are particularly useful for testing the photostability of products that are sensitive to specific wavelength ranges.
- Metal halide lamps**:** a third type of light source used in photostability chambers. These lamps produce a bright, white light that contains a significant amount of blue light. They are often used for testing products that are sensitive to blue light, such as some pharmaceuticals and plastics.[26,17,33.]

- **temperature and humidity control:**

1) Reproducibility

2) Accuracy.

3) Safety

4) Quality control

5) Equipment durability.

- **Advantages:**

1. Accurate and reliable testing: Photostability chambers provide accurate and reliable testing of the photostability of pharmaceutical products, ensuring that they maintain their quality and efficacy throughout their shelf life.

2. Controlled environment: These chambers create a controlled environment with specific conditions, such as temperature, humidity, and light, which helps in determining the photostability of the drug.

3. Compliance with regulatory requirements: Many regulatory agencies require photostability testing of pharmaceuticals, and using a photostability chamber helps ensure compliance with these requirements.

4. Cost-effective: The use of a photostability chamber is a cost-effective method of testing compared to conducting outdoor or natural sunlight exposure testing, which can be unreliable due to uncontrollable factors.

Disadvantages:

1. High initial cost: Photostability chambers can be expensive to purchase and install, which may be a barrier for small pharmaceutical companies or research labs with limited budgets.

2. Limited capacity: Most photostability chambers have limited capacity, which means that only a limited amount of samples can be tested at a time. This may lead to longer testing periods or delays in receiving results.

3. Limited range of light sources: Photostability chambers may have a limited range of light sources and may not be able to simulate all possible light conditions that a product may be exposed to during storage or use.

4. Maintenance requirements: Regular maintenance of photostability chambers is essential to ensure accurate testing and prevent breakdowns, which can lead to downtime and lost product.

5. Not suitable for all products: While photostability chambers are effective for most solid and liquid pharmaceutical products, they may not be suitable for certain types of products, such as aerosols or creams, which have different physical characteristics and require testing under different conditions.

6. Long-term stability assessments: Photostability chambers can be used for long-term stability assessments by exposing products to different light sources and intensities for extended periods, which can help predict product stability under various storage conditions.

- **Applications:**

1. Testing of drugs: Photostability testing is an essential part of drug development. It is used to determine the rate of degradation of a drug under different conditions of light exposure. The information obtained from the testing helps to establish the shelf-life of the drug.

2. Testing of packaging materials: Photostability testing is also used to determine the suitability of packaging materials for a particular drug. The testing ensures that the packaging material does not degrade the drug.
3. Testing of cosmetics: Cosmetics are also tested for photostability to ensure that their color and fragrance do not change over time due to exposure to light.
4. Testing of food: Food products are also tested for photostability to ensure that their color, texture, and nutritional value do not change over time due to exposure to light.
5. Testing of materials used in electronics: Photostability testing is also used to determine the suitability of materials used in electronics. The testing helps to ensure that the materials do not degrade over time due to exposure to light.

RECENT DEVELOPMENTS

1. LED light sources: Photostability chambers now utilize LED light sources, which provide a more consistent output compared to traditional light sources.

2. Automatic light control: Some photostability chambers now have automatic light control systems that adjust the light intensity and wavelength automatically, reducing the need for manual adjustments and improving testing accuracy.

3. Advanced controls and monitoring: Modern photostability chambers feature advanced controls and monitoring systems that allow for remote operation and real-time data analysis, making testing more efficient.

4. Increased capacity: Some manufacturers are developing larger photostability chambers with increased capacity, allowing for higher throughput and faster testing times.

5. Customized simulation: Some photostability chambers are now capable of simulating customized light conditions, such as different levels of UV-A, UV-B, and visible light, to better simulate real-world storage and usage conditions.

FUTURE PROSPECTS:

1. Integration with artificial intelligence: In the future, photostability chambers may be integrated with artificial intelligence (AI) technologies to enable automation, real-time monitoring and analysis, and highly advanced predictive modeling.

2. Microscale photostability chambers: Manufacturers may develop microscale photostability chambers that can take up less space and use fewer samples, making them more suitable for research labs and pharmaceutical companies with limited space and resources.

3. Increased accuracy through multi-spectrum simulation: Photostability chambers may be able to simulate even more extensive spectra of radiation wavelengths to improve accuracy and predictive modeling.

4. Reduced energy consumption: Further advances in energy-efficient LED-based lighting and control systems can make photostability chambers more cost-effective to operate, reducing their carbon footprint and providing even greater sustainability benefits.

5. Integration with other pharmaceutical testing technologies: Photostability chambers may be integrated with other advanced pharmaceutical testing technologies, such as stability testing and dissolution testing, to create an all-in-one testing suite.[34]

CONCLUSION

Photostability testing is crucial in drug development, ensuring stable and effective pharmaceutical products under light exposure. Photostability chambers simulate real-life exposure, providing insights into potential instability and degradation products. These tools enable drug manufacturers to create safe, effective products that can withstand light exposure.

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