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STABILITY TESTING ACCORDING TO ICH Q1A (R2): BASICS AND TECHNICAL SOLUTIONS

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1. Abstract

Safe and effective medications are an essential part of medical care. The shelf life of drugs plays a significant role here. To determine and verify the shelf life, manufacturers carry out extensive stability testing. The constant climate chambers used for this purpose must be absolutely precise and reliable in order to meet the strict requirements for drug stability testing. In this whitepaper, we will show which technical solutions are available to ensure smooth continuous operation and which factors need to be taken into account when choosing a constant climate chamber.

2. Official requirements

Drug manufacturers are required to state the shelf life of a drug in the approval application and to provide evidence of the stability of the active substance and the finished drug to the responsible drug authorities.

Drug authorities worldwide require stability testing according to ICH guideline Q1A (R2). Both long-term test under normal conditions and stress tests under accelerated storage conditions, for instance with elevated temperature and humidity, should be carried out. As a rule, data from three batches over at least twelve months of storage under long-term conditions must be submitted, along with data from accelerated stability tests.
Data from accelerated stability tests alone is not sufficient.

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Germany	Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)
USA	Food and Drug Administration (FDA)
Japan	Pharmaceuticals and Medical Devices Agency (PMDA)
European Union	European Medicines Agency (EMA)

Stability testing is an important step in the approval process and is decisive for whether a drug is approved or not. Both the active pharmaceutical ingredient (API) and the finished pharmaceutical product (FPP), as well as the formulation, primary and secondary packaging and all other components, such as the package insert, must be tested and pass these test. There must be documentation and verification stating that the testing was carried out in accordance with the guidelines. If the stability testing are not carried out in accordance with the guidelines, the drug will not be authorized. Likewise, no authorization is granted if it cannot be verified that the stability testing was carried out correctly. In the worst case scenario, the manufacturer has to perform the testing process again.

3. Stability testing

Stability tests are used to determine the minimum shelf life of a drug based on experiments. The expiration date is derived from the results. The manufacturer guarantees that the effect and quality of the drug are fully guaranteed until the expiration date. The storage conditions can also be defined by stability testing.

When is a drug considered stable?

A drug is considered stable if its chemical, physical and microbial properties do not change during storage and use by the patient and thus fulfill the defined specifications. For instance, the active ingredient content must not fall below a certain value. Decomposition products may also only occur in very small quantities within defined limits. The release of the medicinal substance from the dosage form must not change adversely during storage.
Stability is also one of the most important and critical quality characteristics of a drug. Stability testing provides information on whether and to what extent the quality of the products, active ingredients and additives changes over time under controlled environmental conditions (temperature, humidity and light).
Various types of instabilities may occur during the storage period, which can be of a chemical, physical or microbial nature. These instabilities are not the subject of this whitepaper.

4. How is stability testing for drugs carried out?

The prerequisite for carrying out and evaluating stability testing is the definition of qualitative and quantitative quality characteristics of a drug. The focus is on two fundamental aspects:

1. **Active ingredient content:** The active ingredient concentration must not fall below a predetermined value during the entire shelf life. This is an important parameter for chemical and most physical instabilities.

2. **Decomposition products:** Decomposition of the active ingredient produces degradation products. These products can be toxic in nature and must be identified and analyzed. The levels of the resulting degradation products must be limited with defined limit values and their safety at the specified concentration must be verified.

The drug manufacturer must prove that the analytical methods it uses are valid, meaning that they are specific and accurate.

4.1. ICH guidelines and definition of the test environment

Stability testing is done in line with the regulations of the International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). This whitepaper deals with the ICH Q1A and ICH Q1B guidelines; the other guidelines are not the subject of this whitepaper.

ICH guidelines for stability testing (ICH Q1A-Q1F)

- ICH Q1A (R2) Stability testing of new drug substances and drug products - Scientific guideline
- ICH Q1B Photostability testing of new active substances and medicinal products - Scientific guideline
- ICH Q1C Stability testing: requirements for new dosage forms - Scientific guideline
- ICH Q1D Bracketing and matrixing designs for stability testing of drug substances and drug products - Scientific guideline
- ICH Q1E Evaluation of stability data - Scientific guideline
- ICH Q1F Stability data package for registration in climatic zones III and IV - Scientific guideline
- ICH Q5C Stability testing of biotechnological/biological products - Scientific guideline

For the storage of drugs for stability testing, the storage conditions, meaning the temperature and relative humidity, are selected depending on the requirements specified by the climate zone(s).

Climate zones according to WHO guideline

Climate zone	Description	Temperature/Relative humidity (RH)
I	Moderate	21 °C / 45%
II	Subtropical and Mediterranean	25 °C / 60%
III	Hot and dry	30 °C / 35%
IVa	Hot and humid	30 °C / 60%
IVb	Hot and very humid	30 °C / 75%

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ICH guideline Q1A (R2) describes the requirements for climate zones I and II. It combines climate zones I and II into one and defines them using the worst-case condition, i.e. 25 °C/60% RH. Likewise, climate zones III, IVa and IVb can be combined into one worst-case condition with 30 °C/75% RH.

4.2. Different types of stability testing according to ICH Q1A (R2)

4.2.1. Long-term stability testing

Storage of an active substance or product at the storage conditions recommended according to ICH Q1A (R2) (25 ± 2 °C and 60 ± 5% RH or 30 ± 2 °C and 65 ± 5% RH) for the duration of the repeat testing period of the active substance or for the proposed expiration date of the product to define or confirm shelf life. The test lasts at least 12 months and up to 60 months. Packaging and formulation have to be in accordance with commercially available products.

4.2.2. Intermediate stability testing

Storage of an active substance or product under conditions that lead to a moderate increase in the rate of chemical degradation and physical changes, for instance at 30 °C/65% RH for storage conditions at 25 °C.

4.2.3. Accelerated stability testing

Storage of an active substance or product under intensified storage conditions aimed at increasing the rate of chemical degradation or physical change of an active substance or drug. In addition to the long-term stability studies, the data from these studies can be used to evaluate longer-term chemical effects under non-accelerated conditions as well as the effects of short-term deviations from the storage conditions specified on the label that may occur during transportation. The accelerated test study results are not always indicative of physical changes.

4.2.4. Stress tests (active ingredients)

Storage of an active substance under extreme conditions to test the intrinsic stability of the drug substance. Such tests are part of the development process and are usually conducted under stricter conditions than accelerated testing.

4.2.5. Stress tests (drugs)

Storage of a drug under extreme conditions in order to test the effects of these conditions on the drug. These tests include photostability tests in line with ICH Q1B and specific tests of certain products (e.g. metered dose inhalers, creams, emulsions, refrigerated aqueous liquids).

4.2.6. Photostability tests according to ICH Q1B

Confirmatory studies are done to determine the photostability properties of a product under standardized conditions. They can be used to identify the precautions necessary for manufacturing or formulation and can show whether light-resistant packaging and/or special labeling is required to reduce exposure to light. In confirmatory studies, samples should be exposed to light with a total intensity of at least 1.2 million lux hours and an integrated near-ultraviolet energy of at least 200 watt hours per square meter to make direct comparisons between drug substance and drug product possible.
A near-ultraviolet fluorescent light has a spectral distribution of 320 nm to 400 nm, with most of the energy emitted between 350 nm and 370 nm. A significant proportion of UV should fall on the two 320 to 360 nm and 360 to 400 nm bands.
Samples can be exposed to light next to each other with a validated chemical actinometric system that guarantees that the specified light exposure is achieved, or they can be exposed to light for an appropriate period of time if conditions have been monitored using calibrated radiometers/luxmeters.

In addition to the stability testing mentioned here, there are other special types of stability tests such as rocking tests or mechanical stress tests. They are not the subject of this whitepaper.

4.3. Storage condition according to ICH Q1A (R2)

Standard case for active ingredients and drugs

Testing	Storage condition	Minimum period the data relates to during transfer
Long term*	25 °C ± 2 °C/60% RH ± 5% RH or 30 °C ± 2 °C/65% RH ± 5% RH	12 months
Intermediate**	30 °C ± 2 °C/65% RH ± 5% RH	6 months
Accelerated	25 °C ± 2 °C/60% RH ± 5% RH	6 months

**It is up to the applicant to decide whether long-term stability studies are to be carried out for 25 ± 2 °C/60% RH ± 5% RH or 30 °C ± 2 °C/65% RH ± 5% RH.*
*** If 30 °C ± 2 °C/65% RH ± 5% RH is the long-term condition, there is no intermediate condition.*

Active substances and drugs intended for refrigerator storage

Testing	Storage condition	Minimum period the data relates to during transfer
Long term*	5 °C ± 3 °C	12 months
Accelerated	25 °C ± 2 °C/60% RH ± 5% RH	6 months

Active substances and drugs intended for freezer storage

Testing	Storage condition	Minimum period the data relates to during transfer
Long term*	-20 °C ± 5 °C	12 months

Drugs packaged in impermeable containers

For drugs packaged in impermeable containers that form a permanent barrier to moisture or solvents, sensitivity to moisture or the possible loss of solvents is not a problem. That is why stability studies for products stored in impermeable containers can be performed under any controlled or ambient humidity condition.

Drugs packaged in semi-permeable containers

Aqueous-based products packaged in semi-permeable containers should be tested not only for physical, chemical, biological and microbiological stability, but also for possible water loss. This assessment can be done under conditions of low relative humidity. Finally, it should be verified that aqueous-based drugs stored in semi-permeable containers can withstand an environment with low relative humidity.

Testing	Storage condition	Minimum period the data relates to during transfer
Long term*	25 °C ± 2 °C/60% RH ± 5% RH or 30 °C ± 2 °C/65% RH ± 5% RH	12 months
Intermediate**	30 °C ± 2 °C/65% RH ± 5% RH	6 months
Accelerated	40 °C ± 2 °C/no more than 25% RH	6 months

**It is up to the applicant to decide whether long-term stability studies are to be carried out for 25 ± 2 °C/60% RH ± 5% RH or 30 °C ± 2 °C/65% RH ± 5% RH.*

*** If 30 °C ± 2 °C/65% RH ± 5% RH is the long-term condition, there is no intermediate condition.*

The limit values stipulated in the ICH guidelines for deviations in temperature and humidity are upheld by the vast majority of manufacturers. Some manufacturers sell units that are significantly more accurate than required by the ICH guidelines, for instance with a temporal temperature fluctuation of just 0.1 degrees and a humidity deviation of ≤ 2 percent. This higher level of precision means a higher level of safety.

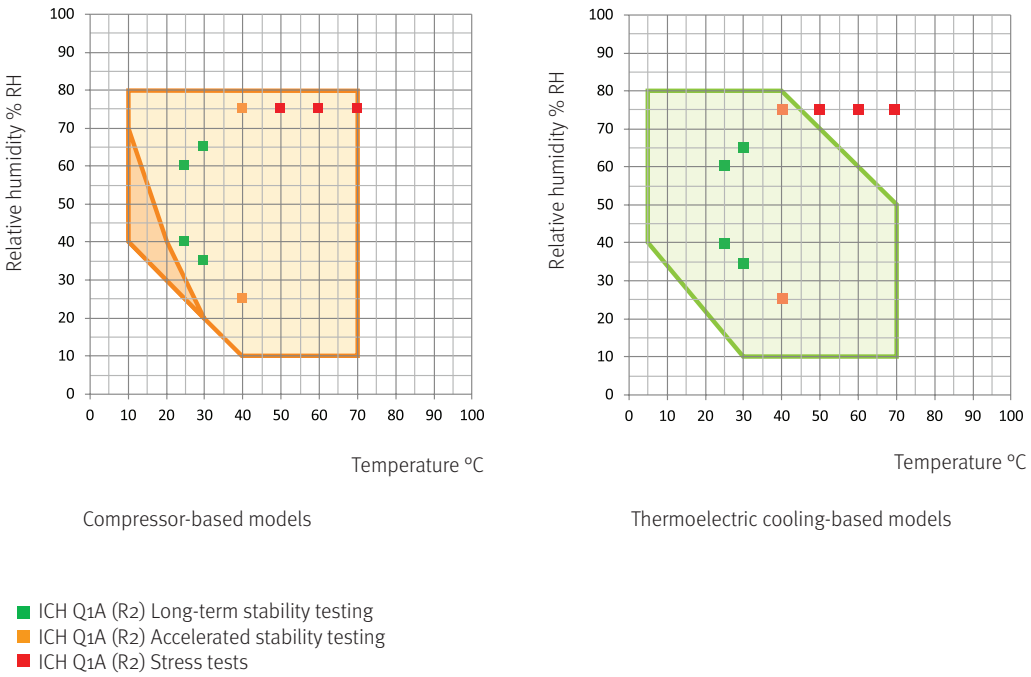
5. The technical solutions: Constant climate chambers

Safe and reliable operation is essential for any kind of stability testing. The uniformity of the temperature and humidity climate parameters is absolutely crucial. It is important to choose the right constant climate chamber here. The selected chamber can make the difference between success and failure of the stability testing. Important factors that should be observed without fail when purchasing a constant climate chamber are heating and cooling technology, air ducting, water management, light, continuous operation as well as programming, documentation and qualification. They will be explained in more detail in the following.

5.1. Heating and cooling technology

The environmental performance and performance ranges of stability test chambers are strongly influenced by the heating and cooling technologies. The temperature-humidity chart shows the differences and how each technology serves different applications and meets different requirements. While the compressor-based models easily fulfill the conditions for stress tests and all accelerated tests, the thermoelectric cooling-based models are only designed for long-term and accelerated stability tests.

Temperature-humidity chart



Thermoelectric cooling-based units operate without refrigerant. That means the global warming potential (GWP) and ozone depletion potential (ODP) are zero. Units with compressors, on the other hand, are operated with refrigerant.[1]
In addition to being environmentally friendly, the significantly lower energy consumption is another advantage of thermoelectric cooling-based technology. Thermoelectric cooling-based units are also quieter.

Which technique is most suitable always depends on the needs of the users and which stability testing is required.

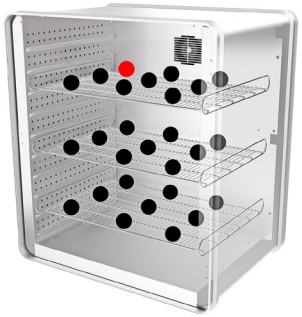
The following overview shows the main differences between thermoelectric cooling-based and compressor-based climate chambers:

The main differences between thermoelectric cooling-based and compressor-based climate chambers

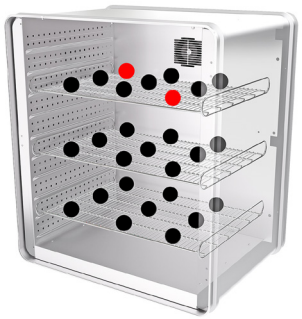
	Thermoelectric cooling-based chamber	Compressor-based chamber
Application		
• Protocol type	• Constant test conditions	• Constant test conditions
• Climate range	• 5°C to 70°C / 10% to 80% RH	• 10°C to 90°C / 10% to 98% RH
• Heat compensation	• less	• more
Environmental performance		
• Noise level	• two times as quiet	• two times as loud
• ODP / GWP	• better environmental performance	• worse environmental performance
Economic aspects		
• Energy costs	• up to 75% less	• up to 75% more
• Maintenance effort	• Certification according to Chemicals Climate Protection Ordinance (ChemKlimaschutzV), category II not required	• Certification required
	• lower	• higher
Practical aspects		
• Cooling	• Thermoelectric	• Refrigerant
• Heating	• Thermoelectric	• Electric

[1] *At the time this whitepaper was composed, the European Union had yet to make a final decision on the amendment of the F-Gas Regulation.*

The decisive factor when choosing a constant climate chamber is not only the size of the climate range, but also the specified spatial and temporal deviations. They are defined according to DIN 12 880:2007 with the 27-point measurement as follows:



The **temporal** temperature and humidity deviation is the difference between the measured values taken at a single point at different times, for instance, ±0.1 K at 40 °C and 75% RH.



The **spatial** temperature and humidity deviation is the difference between the measured values taken at two points at the same time, for instance, ±0.2 K at 40 °C and 75 % RH.

Calibration certificates from the manufacturer for temperature and humidity values document the spatial deviation. The temporal deviation is always more accurate than the spatial deviation. This should be taken into account for the comparison.

For constant climate chambers with performance data relating to room conditions (e.g. ambient temperature +10 °C bis 70 °C) or environmental conditions up to 95% relative humidity, it should be noted that the lowest temperature that can be reached depends on the room temperature of the laboratory. The actual value of the climate is highly dependent on the conditions in the installation room. That is why compressor-based models are recommended for fluctuating or higher temperatures.

It should be noted that the manufacturer's temperature and humidity specifications refer to an unloaded or empty interior. When loaded, the type of air ducting is therefore of particular importance.

5.2. Air ducting

The air movement in a constant climate chamber is crucial for high temperature and humidity accuracy above all racks when loaded. Experience has shown that constant climate chambers are often "filled to the brim", leaving hardly any space for air circulation. This leads to fluctuations and deviations in the parameters that are outside the tolerance range. This is a critical situation. Only homogeneous conditions at each rack provide representative results according to the ICH Q1A (R2) scientific guidelines.

A distinction is made between two types of air ducting:

1. Double-sided horizontal air movement

The inner side walls of chambers with horizontal air flow on both sides have hundreds of small perforations. They distribute the air flow evenly throughout the entire chamber. The air flows over each rack from both sides, creating extremely homogeneous conditions, especially under load.
That is why this type of air ducting is very well suited for fully loaded chambers. The air speed above the racks is also lower with these types of chambers. This is an advantage with lightweight active ingredients or drugs.

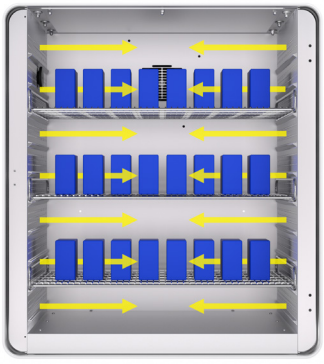
Double-sided horizontal air ducting allows for particularly homogeneous conditions. The air is returned to the rear wall via a fan for reconditioning.

2. Vertical air movement

In this case, the temperature-controlled and humidified air is directed from bottom to top through the individual racks. When loaded, the upper racks are in the lee of the lower racks. Even air movement over all racks is prevented. Restrictions in the structure of the drug are the result. Even a one-way air flow, for instance from the rear to the front, is quickly blocked on the way from and back to the fan that circulates air through the chamber. The potential advantages of horizontal air flow on both sides over each rack are not achieved.

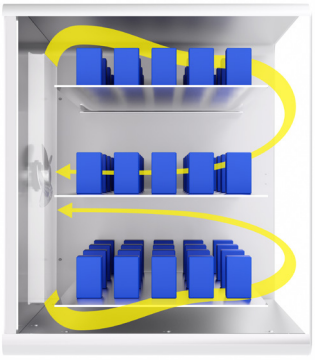
Detailed information on air ducting can be found in the operating manual of the respective unit.

Front view



Double-sided horizontal air ducting. Each rack is surrounded by an even air flow from both sides. More homogeneous loading conditions.

Side view

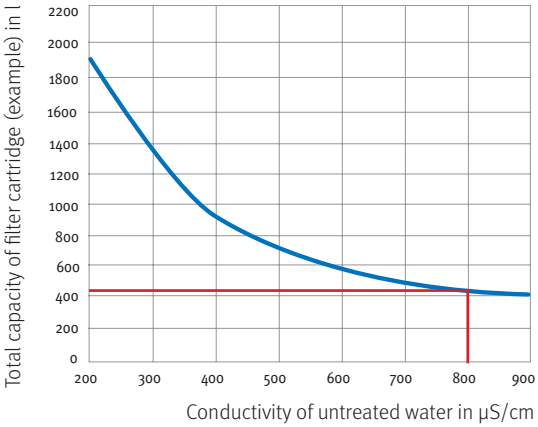


Single-sided air flow from rear to front. The samples hinder a homogeneous air flow. The air flow does not fully reach the upper and lower areas. Uniformity is questionable.

5.3. Water management

The great importance of water quality must be emphasized. With constant climate chambers, the conductivity of the water must be ensured in order to guarantee reliable operation. Fully desalinated water with a conductivity between 1 µS/cm and max. 20 µS/cm is the prerequisite for reliable continuous operation of the unit.
If the water quality is inadequate, the tap water must be treated.
Ion exchange systems with replaceable filter cartridges are suitable for this purpose.
The service life of the cartridge depends on the water quality and water consumption.
The humidification module should be serviced once a year since deposits of iron, sulfur, etc. can form in addition to limescale.

The higher the conductivity of the untreated water, the lower the capacity of the filter cartridge:



The red line shows the total capacity of the filter cartridge at an untreated water conductivity of 800 µS/cm.

The type of **water supply and disposal** and the **humidification method** are additional factors for constant climate chambers.

There are different solutions on the market:
Water supply and disposal can be provided by **connecting to the on-site water supply**. The water is then fed in automatically. This requires a supply pressure of between 1 and 10 bar and a temperature of a minimum of +5 °C and a maximum of +40 °C. Detailed data can be found in the operating manual of the respective unit.

The alternative to on-site water supply are **large-volume water canisters for fresh water supply and collecting condensed water** that are mounted directly on the climate chamber. This means the chamber can be set up independently of the stationary water supply.

If the fresh water canister is empty, a warning message must appear on the display. The canisters should then be manually filled or emptied. The water consumption greatly depends on the humidity setpoint and the number of door openings. It is not advisable to recycle the condensation water for humidification, as this can lead to a concentration of undesirable substances.

The most common types of humidification are steam and ultrasonic humidification systems.

A good steam humidifier keeps the water exactly at the boiling point so that humidification can be provided immediately if necessary. The humidifying water is constantly heated at 100 °C, reducing the risk of biological contamination to a minimum. Condensation water is drained off before reaching the test area and thus guarantees a condensate-free test area.

Ultrasonic humidifiers generate ultrafine droplets (no aerosol formation) which are directed into the test chamber and evaporate there. In order to avoid lowering the temperature in the test chamber (adiabatic cooling), it is necessary to reheat. Drip trays collect excess humidification water.

During humidification with spray nozzles, there is also a risk of deposits forming on the nozzles, which can lead to reduced unit performance.

Dehumidification is carried out by dropping below the dew point at a heat exchanger. Accurate measurement and control technology ensures stable climate parameters.

5.4. Light

For photostability tests according to ICH Q1B, the light sources and illuminance levels per time unit are precisely specified. The visible light (VIS similar to ISO 10977 (1993)) must reach an exposure period of at least 1.2 million lux hours and near ultraviolet (320 nm to 400 nm) must be at least 200 Wh/m². See point 4.2.6.
Photostability tests according to ICH Q1B. A distinction is made between systems that use an illumination cassette for UV and VIS and those that use a separate UV illumination cassette and VIS illumination cassette. The question is to what extent irradiation by two separate cassettes simulates actual daylight in which UV and VIS are not separated from each other.

Light sources above each rack illuminate the entire rack area evenly. A particularly homogeneous distribution of the irradiation is achieved with a reflector geometry.

It is important to state the distance at which the intensities specified by the manufacturer are reached, e.g. VIS 8,750 lx or UVA 1.1 W/m². The greater the distance to the light source, the lower the illumination intensity and the longer the exposure duration. Spherical sensors measure the actual amount of light, while planar sensors calculate the amount of incident light due to their plane sensor surface.

The figure shows a freely positionable spherical sensor (for VIS or UVA) that measures the actual amount of light. A planar sensor, on the other hand, calculates the amount of light incident on the sample at an angle lower than that encountered with vertical irradiation. This leads to an underestimation of the radiation energies, which results in excessive irradiation times and possibly false positive effects.

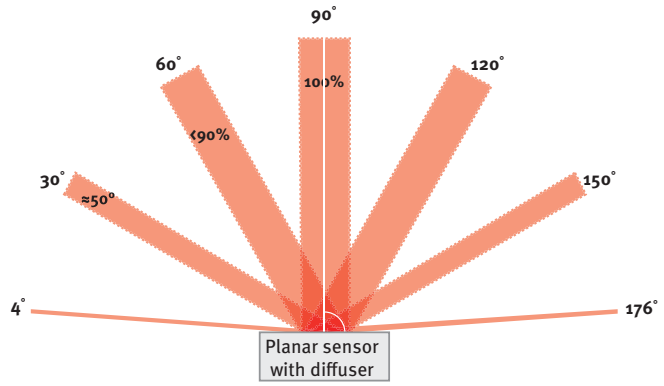


Figure 1: Lambert's cosine law states that radiation intensity decreases as angles become more oblique. As a result, the planar sensor needs cosine correction. The image shows the angle of incidence on the planar sensor surface with the percentage of incoming radiation in each case, compared to an angle of incidence of 90° (100%).

The second difference relates to the hemispheres of measurement. As Figure 1 shows, a planar sensor can only observe radiation above the sensor surface. It cannot record radiation that has an angle of incidence of either 0° or 180°. In addition, it cannot record any radiation from below.

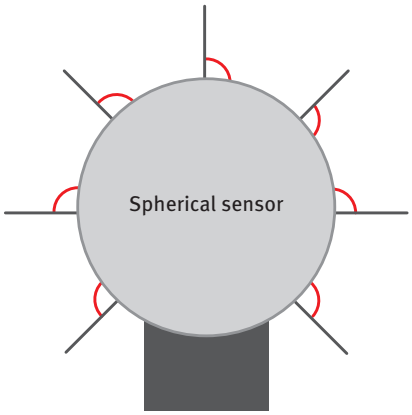


Figure 2: A spherical sensor makes it possible to measure the radiation intensity from all directions.

In complete contrast to this, the spherical sensor measures the actual radiation intensity from all directions, meaning that it even records scattered radiation (Figure 2). The radiation always hits the sensor at a 90° angle, which removes the need for cosine correction. The actual radiation intensity is measured rather than calculated.

5.5. Continuous operation

After complex and cost-intensive research and development, stability testing must be carried out to prove that the active ingredients and products fulfill the defined specifications. Often large quantities have to be tested and the schedule is tight. For such important testing, without which approval is not possible, a constant climate chamber must operate reliably over a long period of time without interruption.

The following components can increase the service life of a constant climate chamber:

1. For long-term tests, **as many components as possible should be made of corrosion-resistant stainless steel**, e.g. made of material numbers 1.4201 or 1.4501. This applies not only to the testing compartment and racks, but also to the heat exchanger. It is ideal if its connection points to the refrigeration circuit are also made of stainless steel to exclude electrochemical corrosion.

2. A **triple door gasket** guarantees maximum reliability. Unwanted influences on the test compartment climate are reduced to a minimum, ensuring successful completion of the long-term test.

3. Long-life steam humidifiers have been proven to have a very low failure rate of less than one percent in the first five years of continuous operation.

5.6. Programming and documentation

Real-time programming makes things much easier compared to manual programming. For real-time programming, simply enter the start and end date and time. On the other hand, manual programming must be carried out mathematically without reference to date and time. The number of hours the test should take must be calculated and added to the start time. This type of programming is time-consuming and involves the risk of calculation errors. Manufacturer should always offer several options for recording, controlling and monitoring the constant climate chamber.

Approval is not possible without documented proof that the stability testing has been carried out successfully. Crucial for the approval application is complete and seamless documentation of all relevant parameters for each individual operating state. That means it is essential to ensure that the climate chamber software fulfills the relevant requirements. Documentation should be in line with GLP/GMP guidelines, which meet the requirements of FDA regulation 21 CFR Part 11 for electronic records and electronic signatures. An advantage is the connection to a lab information management system (LIMS), which enables complete documentation and monitoring to be done centrally from a PC. Some manufacturers offer their software as a free trial version for 30 days.

5.7. Qualification

The consistent quality of the products we manufacture – not to mention the reproducibility of test processes – is fundamental to the laboratories and production facilities which operate subject to GMP or GLP requirements. The resulting obligation to provide supporting evidence requires a large number of unit tests to be carried out and recorded precisely. The required qualifications include the calibration certificate as well as the installation, operational and performance qualifications.

The **installation qualification (IQ)** confirms that the unit has been properly installed according to customer requirements including documentation.

The **operational qualification (OQ)** checks and confirms that the unit is operating properly in an unloaded state.

The **performance qualification (PQ)** checks and documents the unit function in the loaded state under customer-specific requirements.

When choosing a unit, take note of the services offered by the manufacturer for unit qualification and calibration.

6. Summary

Stability testing is crucial for the approval of new active substances and drugs. If standard-compliant performance cannot be proven to the regulatory authorities, approval is not possible. Stability tests worldwide must fulfill the requirements of the ICH Q1A (R2) guidelines (photostability tests ICH Q1B).

Stability testing is carried out using constant climate chambers that simulate the exact storage conditions specified in the ICH guidelines. Constant climate chambers must operate with absolute precision and reliability over the long term. Important factors when choosing a constant climate chamber are heating and cooling technology, air ducting, water management, light, continuous operation as well as programming, documentation and qualification. There are various technical solutions on that market that differ in terms of the accuracy and uniformity of the climate parameters.

Constant climate chamber from BINDER fulfill all the requirements of the ICH guidelines and provide the best, most suitable solutions for stability testing of all kinds – from long-term tests to stress tests.

https://www.binder-world.com/int-en/products/environmental-testing/constant-climate-chambers

Additional reading

- Whitepaper: Validation and qualification in a regulated environment
- Whitepaper: "Good Laboratory Practice" - What is behind all this?

Sources

International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH):
- Q1A (R2) Stability Testing of New Drug Substances and Products
- Q1B Stability Testing: Photostability Testing of New Drug Substances and Products
- ICH Q5C Stability testing of biotechnological/biological products

World Health Organization: Annex 10, Stability testing of active pharmaceutical ingredients and finished pharmaceutical products

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products: Stability: Stability Testing of New Veterinary Drug Substances (Revision)

Association of Southeast Asian Nations: ASEAN Guideline on Stability of Drug Product (R1)

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Stabilitätsprüfungen nach Vorgaben der Guidelines von ICH und WHO (https://www.sgs.com/de-de/nachrichten/2011/09/stabilitatsprufungennach-vorgaben-der-guidelines-von-ich-und-who)

DocCheck Flexicon: Stabilitätsprüfung (Pharmazie) (https://flexikon.doccheck.com/de/Stabilit%C3%A4tspr%C3%BCfung_(Pharmazie))

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Lothar Maresch is responsible for the worldwide activities of the BINDER Academy. He studied biology at Heidelberg University and has more than 30 years of experience in the fields of environmental simulation and laboratory equipment.

About BINDER GmbH:

BINDER is the world's largest specialist in simulation chambers for scientific and industrial laboratories. With its technical solutions, the company contributes significantly to improving the health and safety of people. The range of products is well-suited for routine applications, highly specialized work in research and development, production, and quality assurance. With approximately 490 employees worldwide and an export rate of 80%, BINDER 2022 sales were more than 100 million euros.

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