

SmartNotes

QA

I work in a pharmaceutical laboratory and we are held to the International Conference on Harmonisation (ICH) standard. What specific guidelines do I need to be worried about for stability testing, and what light bulbs are required to meet the standards for photostability testing?

ICH is the main organization defining the requirements used for drug developing and testing. When it comes to stability testing, ICH guideline Q1A*: Stability testing of new drug substances and products and Q1B**: Stability testing: Photostability testing of new drug substances and products are of particular concern.

Stability chambers need to provide ideal light emission to meet ICH light test requirements. It is recommended to have both standard 6500 pro industry light bulbs with high UV portion (according to DIN 3668) and also daylight bulbs that can mimic sunlight, which are included in the Thermo Scientific™ 3900 Series Environmental Chambers. The stability chamber must be able to maintain light exposure of more than 1.2 million lux hours, and emitting more than 200 watts of UV energy to the samples.



*https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Quality/Q1A_R2/Step4/Q1A_R2_Guideline.pdf, Accessed April 15, 2019

**https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Quality/Q1B/Step4/Q1B_Guideline.pdf, Accessed April 15, 2019

How can I maximize my air flow while using an environmental chamber?

Ideal air circulation with horizontal airflow systems

Advantages of a directed horizontal laminar airflow system

A horizontal laminar airflow system includes a positive pressure feed plenum on one side of the chamber and a negative pressure return plenum on the left. This helps distribute the airflow uniformly throughout the chamber, directing air across the surface of each solid shelf. Even when filled with samples or equipment, each shelf receives a consistent flow of conditioned air for optimum temperature uniformity and recovery.

Concerns when using traditional non-directed airflow systems

As opposed to our horizontal airflow system, top-to-bottom (non-directed) airflow systems use a top-mounted fan to push air down through wire shelves. Temperature uniformity and recovery can deteriorate quickly when shelves are filled because air movement is blocked. The variation in temperature, alone or when combined with frequent door openings, may compromise environmental conditions or make process validation difficult.



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