ARTICLE

Implementing Successful Stability Testing Operations

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Why Stability Studies?

The primary reason for stability testing is the concern for the well-being of the patient suffering from the disease for which the products is designed.

Apart from degradation of the unstableproduct into toxic decomposition products, loss of activity may lead to failure of the therapy resulting in death.

It has become a legal requirement to provide data for stability tests for the regulatory agencies before approval of a new product.

Second important concern is to protect the reputation of the manufacturer by assuring that the product will retain fitness for use with respect to all functionally relevant attributes for as long as they are on the market.

Other benefits of stability studies at the developmental stage of the marketed products are to provide a database that may be of value in selection of adequate formulations, excipients and container closure systems for developmentof a new product.

Implementing Successful Stability Testing Operations

- Regulatory Compliance
- Ensure compliance to ICH guidelines and federal regulations
- Studies are performed under cGMP regulatory compliance
- Timely and accurate evaluation of product stability
- Validated storage conditions
- Validated computer systems and software applications
- Calibrated monitoring devices
- Perpetual inventory system.
- Protocol documentation with audit trails

An important aspect of all stability studies is the Stability Chambers themselves the Stability Chambers:

These are specialized environmental chambers that can simulate the storage condition and enable evaluation of product stability based on real-time, accelerated and long-term protocols.

These chambers are expected to be dependable and rugged because of the requirement of uninterrupted use for years.

Operations of Chamber:

- Simple operations
- Alarms for deviations
- Performance recording, observations
- Safety devices
- Stand by system
- Multiple sensors
- Economical operations

Energy Efficient Go-Green Technology:

- Save Energy with "Green Mode".
- Increased energy efficiency in test chambers.
- In view of the high share of operating energy in overall energy consumption.
- Specific solutions are required even at higher investment costs through lower energy output and reduced costs. Consequently, companies can benefit from additional advantages such as lower consumption, lower noise emissions and a lower system load.
- Optimization concentrates on companies have a high degree of technical expertise.
- The system planning is essential in order to create a total system which is optimally suitable, intelligent composition of all components. It must avoid any over-dimensioning which would result in a waste of energy.
- Innovations in the construction & design aspects of the chambers ensure dramatic reduction in power consumption.

Stability Chambers using chill water:

- Energy Efficiency on Chilled Water Systems
- Chilled water systems are often the preferred option of cooling for large walk in chambers. Water serves as secondary refrigerant and to transports heat.
- With chilled water air conditioning, the refrigeration machinery (the compressor, condenser, evaporator, etc.), doesn't directly cool the air of walk in chambers.

The Trouble with Sensors for Stability Chambers:

Stability studies are worst affected by wrong humidity readings or sensor selection. Accuracy, repeatability, response time, yearly drift are some of the most important parameters for the selection of humidity sensor of stability chamber. Check for the accuracy of sensor defined for the operational range. Response time of many RH sensors is more than 10 minutes; this results in more oscillations of humidity which may not be detected. The results of this, samples are exposed to continuous humidity variations

Selection of good RH sensor is very important for proper stability results.

Features of Stability Chamber:

Alarms for deviations

ALARM

- Alarms are generated for
  1. Temperature deviation
  2. Humidity deviation
  3. Mains failure
  4. Door opening
  5. Water supply failure
  6. Component failure
- Alarm Log
  1. alarm acknowledgement with user comments
- Alarm Transmission
  1. Locally at equipment

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2. Remote alarm at service floor or security gate
3. E-mail
4. Mobile; SMS

SAFETY

- Temperature
  1. High temperature
  2. Low temperature
- Humidity
  1. High Humidity
- Component
  1. Boiler heater, Compressor
- Human (Walk-In Chamber)
  1. Door opening and unlock from inside.
  2. Emergency Alarm Hooter
- Door Access
  1. Physical lock
  2. Password access control
- Standby System (Auto Switch Over)

Chamber Qualification:

- As with most pieces of equipment used in a GMP operation, stability chambers must go through a qualification process prior to use.
- This process traditionally includes three stages identified as the Installation Qualification (IQ), Operation Qualification (OQ) and Performance Qualification (PQ).
- At each stage a qualification protocol is written, approved and executed
- After successful execution a qualification report is written and approved. Upon approval, the next qualification stage is performed. Many components of equipment qualification are common to all pieces of equipment. A brief definition of each stage of qualification will be provided along with what might be included that is unique to stability chambers.
- In some cases an additional stage of qualification called the Design Qualification (DQ), which precedes the IQ.
- The DQ assures that the chamber is suitable for its intended purpose and that the equipment manufacturer has utilized appropriate systems for design, manufacturer and testing.
- In some cases, especially with a customized chamber, it might be appropriate to have a separate DQ.

Presentation and Recording of Stability Data:

Stability data is recorded in an organized, comprehensive and cumulative format.

The stability data table is the means for reporting the results of the stability study in concise format for ease of review and interpretation.

Conclusion:

Stability testing is now the key procedural component in the pharmaceutical development program for a new drug as well as new formulation.

Stability tests are carried out so that recommended storage conditions and shelf life can be included on the label to ensure that the medicine is safe and effective throughout its shelf life.

Over a period of time the regulatory requirements have been made increasingly stringent.

Therefore, the stability tests should be carried out following proper scientific principles and after understanding of the current regulatory requirements and as per the climatic zone.