amebis

Innovative Stability Testing Solutions for the Life Sciences

Flexible Compact Wireless Technology

APPLICATIONS

- Stress Testing
- Forced Degradation
- Recrystallisation kinetic studies
- Controlled Stability Testing (small scale) for any condition; 5^0-60^0C / 0%RH-95%RH
- Monitoring & Mapping of rooms or cabinets
- Recording of environmental conditions within all existing incubators & cabinets
- Preparations of Water Sorption Isotherms
- Pre-formulation and formulation development stability studies
- Exploratory & early development stability studies
- Polymorph Studies

In the context of ICH Q10, a product - can truly achieve a state of continual improvement by quality access to significant real time data as facilitated by Amebis technology. In addition, the concepts of process analytical technologies (PAT) and Quality by Design (QbD), currently applied to pharmaceutical manufacturing, could also be extended to include stability testing utilising Amebis technology.

BENEFITS

- No environmental chambers or desiccators required for small scale stability testing
- Accurate data of environmental test conditions due to small size of test chamber
- Continuous data collection throughout the study for each test
- Data on environmental conditions can be collected right up to time of analysis
- Real-time data
- Any conditions between 5^0C-60^0C / 0%RH-95%RH can be created and monitored
- Easy to perform humidity profiling of a product under development
- Improved sample integrity and less risk of cross contamination
- Improved traceability – easy to review actual storage conditions for a sample
- Ideal for use with potent or toxic materials
- System can be used for Water Sorption Isotherms
- Intrinsic monitoring and mapping function can be used in the following applications:
  - monitoring of existing incubators and environmental cabinets
  - logistic conditions (storage, transport etc)

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FEATURES

- Ease of set-up due to user friendly and portable design
- Minimal space requirements due to compact design
- Wireless technology used for data transmission
- 21 CFR Part 11 compliant software
- Software includes many features for alarming and presentation of data
- Latest in technology design including Rotronic Hygromer humidity sensor with Airchip 3000
- Sensor can be easily calibrated and adjusted

ABOUT

The Amebis Stability Testing & Monitoring System is a flexible and compliant means of performing small scale stability testing. The system can be set up in minutes with a full range of environmental conditions available. The humidity capsule which generates the required humidity and the test material are placed in separate compartments within the test chamber and the chamber is then sealed with a chamber cap.

The humidity capsule controls the humidity within the test chamber and the sensor on the inside of the sensor cap measures the temperature and humidity within the chamber. The logger cap connects to the sensor cap and captures the temperature and humidity readings before transmitting the data wirelessly to the Amebis Control Software. For monitoring and mapping purposes replace the test chamber with a stand.

Test chamber containing humidity capsule and test material and sealed with a sensor cap.

Logger cap connected to sensor cap for stability testing and monitoring applications.

Computer with connected basestation and initiated test in Amebis Temperature Control Cabinet.

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