

Environmental monitoring and qualification of Stability Chambers and Warehouse Storage

Background

All pharmaceutical products must be placed on stability trial. Even after approval it is normal to have ongoing stability trials, which continually monitor quality throughout the lifetime of the product. Storage conditions in e.g. [stability chambers](#) and [warehouses](#), have been standardized to some degree. Normal conditions are 25°C at 60% RH and 40°C at 75% RH. However, with biotechnology and the development of more biological products, storage at -20, -40 and even -80°C is not uncommon. Some products are stored in relatively small cabinets, but bulk materials are often stored in very large rooms or warehouses. It is important that the normal storage conditions do not deviate from those of the stability trials.

Stability chamber and warehouse storage challenges

Testing products for stability performance(s) is rather time consuming, while the material costs are quite marginal, the overall costs are relatively high. Therefore, the quality of the test and data validity are of great importance. When it comes to storing the final product, be it in warehouses or freezers, can result in stocks of several million EUR being held in one place. The cost of a monitoring system with alarm conditions is insignificant compared to the cost of the product that it safeguards.

Suitable Solutions from Ellab

Ellab recommends using [TrackSense® LAB Wireless Temperature Data Loggers](#) and [TrackSense® LAB Relative Humidity and Temperature Data Loggers](#) that both are ideal for continuously monitoring and recording the temperature and humidity in stability chambers, environmental chambers and warehouses. The data loggers are equipped with a LED and have various alarm functions, making it immediately clear when a cabinet strays from its normal conditions.



Validation of stability chamber and warehouse processes

Qualification of stability chambers, rooms and warehouses do require similar standards as those applied to the qualification of autoclaves, ovens, etc. Especially for warehouses, one of the most important parameters is the calculation of MKT, Mean Kinetik Temperature, which is a part of the [ValSuite™ Software](#). Some organizations rely on initial OQ to map cabinets and then continuous monitoring afterwards. However, more companies are realizing the need to increase their process validation effort with respect to stability chambers and therefore validate on an annual basis.

Benefits of choosing Ellab data loggers for stability chambers and warehouse storage

- ✓ Minimizes loss of product cost
- ✓ Built-in alarm functions
- ✓ Real-time data with [SKY option](#)
- ✓ Stable and reliable monitoring of [stability chambers](#), rooms and [warehouse storage](#)



For more information
on [TrackSense® LAB Data Loggers](#) or
to find the right solution for your needs:

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