Testo Solution
Application example

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Monitoring climate in the storage of pharmaceutical goods with testo 175.

Pharmaceutical goods – whether APIs or end products – must be stored at defined and constant ambient temperatures. If limit values are violated, the consequence can be danger to human life, damage to reputation or loss of profit.

With testo 175 T1 and testo 175 H1, you can avoid these risks. Both data loggers allow GxP- and 21 CFR Part 11-compliant working, and support you with the entire process of climate monitoring: from climate mapping and the definition of critical control points to the reliable monitoring of temperature and humidity to the norm-compliant documentation of the measurement values.

Goods with a value of several million Euros are often stored in high bay warehouses like this one.

The challenge.

In many ways, pharmaceuticals are extremely sensitive to temperature, and often also to humidity. This is primarily due to proteins, which are found in many drugs. These proteins are extremely sensitive to changing environmental influences, in particular to temperature fluctuations. Even one-time freezing can have such an adverse effect on the composition of the drug containing them that its efficacy may be diminished or even lost completely. In the worst case scenario, toxic degradation products may even be formed which, unlike in food, are not easily detected outwardly, but can nevertheless cause considerably worse damage.

However, it's not only the drugs per se, or their constituents, that are at risk when stored outside the permissible temperature range. Their storage vessels or packaging are also affected: This is because sub-zero temperatures or major fluctuations in temperature can cause hairline cracks in ampoules and glass containers or dissolve glass constituents (known as leachables) out of the glass. This can lead to a loss of sterility or other damage.

Too humid storage conditions can also negatively influence the quality of medicaments, making them worthless for any further use: Damp packaging or blurred and illegible labelling occur, as well as mould on and in boxing.

In all three scenarios, those responsible face being accountable for loss of reputation, drop in turnover, and in the worst case, loss of human life.

Constant monitoring of temperature and humidity is indispensable in the storage of pharmaceutical goods.

Norm-compliant work

In order to avoid this and to ensure the safety of patients, the storage of drugs is subject to stringent national and international laws, norms and regulations. A central part in the implementation of pharmaceutical quality management is played by the GxP guidelines in particular, which are viewed by the World Health Organization WHO, as well as various national monitoring authorities such as the FDA in the United States, as a fundamental prerequisite for the production and distribution of drugs.

Parameters such as the controlled room temperature (CRT) are furthermore becoming increasingly important. This is defined in USP 1079 of the U.S. Phamacopeia as storage between 20 and 25 °C with temporary deviations between 15 and 30 °C and an MKT value of 25 °C maximum. In the past, the CRT was unfortunately hardly ever monitored. However, since less temperature-sensitive products can also not withstand excessively large deviations from ideal storage conditions, the monitoring of CRT is taking on an increasingly important role in the climate monitoring of the pharmaceutical cold chain.

The resulting requirements placed on the measuring technology implemented are highly demanding. Above all, their reliability and data security are of highest significance for secure and norm-compliant monitoring. In addition to this, limit value violations in the monitoring process as well as in the subsequent analysis and documentation of the data must be easily and clearly identifiable.

Critical temperature areas in a 2 – 8 °C warehouse for pharmaceuticals (example):

1 Near to window and skylight: 8.1 °C
2 Greatest distance to ventilation outlet: 7.5 °C
3 Close to door: temporarily up to 9.1 °C
4 Near to lamp: 6.5 °C
5 Directly at ventilation outlet: 2.4 °C

Climate mapping is the basis

Before temperature and humidity can be monitored, the measurement sites in the warehouse must first be identified, in order to obtain reliable values and to minimize the risk of incorrect storage. For this reason, a climate mapping must include the definition of specific measurement points for each warehouse, the so-called "critical control points". This step is indispensable for a reliable and precise monitoring of climate, since although the air conditioning system of a warehouse only displays a certain temperature, several different temperature zones still occur, which negatively influence the quality of the pharmaceuticals stored there. In the course of a mapping, these can be identified, verifying the critical control points. Typical examples can be:

- Storage areas in the vicinity of heat or cold sources (windows, skylights, roofs or outside walls), as the air in the warehouse is cooled or heated here
- Temperature differences in high-bay shelving between the cold air at floor level and the warm air close to the ceiling
- Doors or loading bays: Undesired temperature influences easily – and often – enter a warehouse here.
- Dead corners, as the air circulation is insufficient due to the ground plan of the warehouse, or the inadequate performance of the ventilation system.
- Heat and cold sources which are independent of the general ventilation and air conditioning system, such as fan heaters, lamps or fans, which can create collections of warm or cold air.
- Obstructed ventilation outlets which hinder air circulation.

Monitoring of a critical control point with the data logger testo 175 T1.

If you are unsure as to exactly where the critical control points in your warehouse are, it is recommended that you monitor too many rather than too few control points with the data loggers testo 175. Complementary use of a thermal imager from Testo visualizes the temperatures even better. For more information, go to www.testo.com

After identification of the critical control points, these should then be permanently monitored with a data logger in order to reduce the risk at these endangered points. By monitoring the critical points, it is possible to assume that the temperature and humidity are also within the pre-defined limit values in the other, less critical areas of the warehouse.

Caution: It is of paramount importance to note that modifications in the warehouse such as rebuilding, reorganization or changes to the air conditioning and ventilation systems, can under certain circumstances result in new critical control points, as they can lead to a completely altered temperature and humidity distribution. For this reason, a new mapping is urgently recommended after such measures.

The solution.

You can carry out a climate mapping yourself, with the data loggers testo 175 T1/H1 and lots of time for research and reading – or you can call in external assistance. The latter is to be recommended for four reasons:

1. The definition of the critical control points is considerably easier for an experienced specialist than for a staff member working in your warehouse, who may first need to familiarize himself with the topic.
2. The critical control points form the basis for the subsequent monitoring of temperature and humidity. This is in turn essential for a secure, norm-compliant storage of pharmaceutical goods.
3. The respective regulations and laws for the storage of pharmaceuticals change so quickly that without specific pre-knowledge and sufficient experience, it is difficult to stay informed of all updates in time.
4. It save you a lot of time in which you can concern yourself with your core tasks.

A specialist from Testo Industrial Services installs a data logger testo 175.

Testo Industrial Services, a subsidiary of Testo AG, is specialized in metrological services such as calibration and validation/qualification. This includes reliable and efficient climate mapping, which the company has been successfully conducting since 2000 for numerous well-known customers in the pharmaceuticals industry. For more information, go to www.testotis.com

Precision and security

Whether you have carried out the climate mapping and the definition of the critical control points yourself, or with the support of external specialists – the insights gained must subsequently be implemented in a climate monitoring system.

With the data loggers testo 175 T1 and testo 175 H1, you can check the temperature and humidity conditions in the monitoring of valuable, sensitive pharmaceuticals according to GxP and 21 CFR Part 11, thus provably ensuring product quality. Both instruments are quickly and easily installed, offer a high level of security for a comparatively low budget, and furthermore provide:

- High level of safety of the data recorded, thanks to recording in tamper-proof format and the use of a non-volatile memory. This permits the reading of recorded measurement data even when the batteries have been completely drained.
- A clear indication of limit value violations on the large, easy-to-read display.

Any limit value violations can still be identified easily in the large display of the data logger, even if it is installed at a greater height.

- Large memory for 1 million measurement values and up to 3 years' battery life, for long-term recording even at short measurement intervals
- Highly accurate measurement data and a one hundred percent reliable measurement with an accuracy of ±0.5 °C and ±2 %RH in a measuring range of -35 to +55 °C (only testo 175 T1; testo 175 H1: -20 to +55 °C
- Data transfer via USB cable or SD card
- The choice of different software versions for configuring and reading the data loggers:
  - ComSoft Basic (available as a free download)
  - ComSoft Professional (for further analysis of the measurement data)
  - ComSoft CFR (validatable software for compliance with the 21 CFR Part 11. Provides limitation of access to authorized persons, audit trails with time stamps, as well as electronic signatures).

testo 175 T1 and H1 – all the advantages at a glance:

- High data security
- Memory for 1 million readings
- Large, easy-to-read display
- 21 CFR Part 11-compliant

More information.

For more information and answers to all your questions concerning climate monitoring in the storage of pharmaceutical goods at www.testo.com

Data loggers testo 175 T1 and testo 175 H1.

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