Testo Solution
Application example

We measure it. testo

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

Pharmaceutical goods – whether APIs or end products – must be stored at defined and constant temperature and humidity values. If limit values are violated, the stability and therefore the effectivity of the medicament can be considerably affected.

With the measurement data monitoring system testo Saveris and the validatable 21 CFR Part 11 software, you can avoid these risks. It monitors temperature and humidity reliably and precisely, and thanks to automatic limit value violation alarms and redundant data archiving, additionally provides a high level of security.

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

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. Upper or lower storage conditions which are exceeded only once, often already result in a negative influence on the product quality, which in cases of serious limit value violations, can even lead to a loss of effectivity. Toxic decomposition products can furthermore be created, which particularly in the case of parenterals, can endanger the safety of the patient.

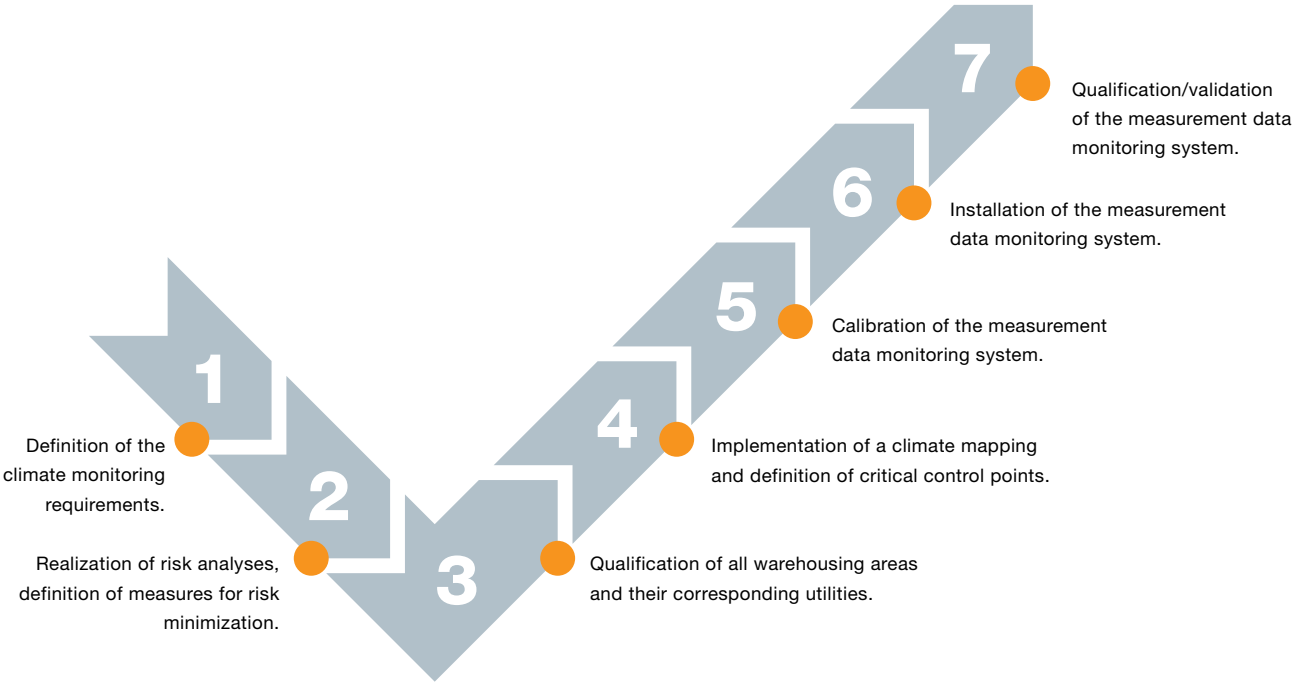
However, it's not only the drugs per se, or their constituents, that are at risk when stored outside the permissible temperature range. Their storage vessels or packaging are also affected: This is because sub-zero temperatures or major fluctuations in temperature can cause hairline cracks in ampoules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

Too humid storage conditions can also negatively influence the quality of medicaments, making them useless 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 must be prepared to answer uncomfortable questions from the monitoring authorities. There is often the danger of being sent a "warning letter". This can have far-reaching consequences. Your good reputation as a reliable partner for the pharmaceutical industry is at risk, and a fall in profit must be reckoned with.

GSP-conform storage

In order to ensure the safety of patients, the storage of pharmaceuticals is subject to strict requirements which are firmly anchored in national and international regulations, and are regarded as basic prerequisites for production and distribution. These include particularly the GSP regulations of the World Health Organisation WHO, the requirements of the AMWHV and the EU-GMP guideline, and finally the American cGMP requirements from 21 CFR Part 11.



Parameters such as the controlled room temperature (CRT), for example, are furthermore becoming increasingly important. This is defined in USP 1079 of the U.S. Pharmacopeia as storage between 20 and 25 °C with temporary deviations between 15 and 30 °C and an MKT (Mean Kinetic Temperature) value of 25 °C maximum. In the past, the CRT was unfortunately hardly ever monitored. Since it has now been recognized that temperature fluctuations can have negative effects even on less sensitive pharmaceutical products, the monitoring of the CRT is taking on an increasingly important role in pharmaceutical storage.

The resulting requirements placed on the measuring technology implemented are various. Above all, it must provide a high level of security through redundant data archiving, independence from the electrical mains and automatic alarms when limit values are violated. You should moreover have the certainty that the technology meets all the relevant regulatory requirements, provides tamper-proof data storage, and allows norm-compliant documentation.

Step by step to GxP-compliant storage

In order to be able to monitor a storage facility for pharmaceuticals safely, precisely and according to all relevant rules, norms and standards, with the corresponding measurement technology, the following steps must be followed in addition to the installation:

1. Definition of requirements:
- What is to be monitored how, and with which objective?
- Which roles, processes and responsibilities are there?
- Which documentation must exist?

2. Realization of risk analyses, definition of measures for risk minimization:
- What has to be taken into particular account in the storage of pharmaceuticals?
- Do certain warehouse areas have the potential to endanger product quality?
- Which measures are suitable for reducing these risks?

3. Qualification of all warehousing areas and their corresponding utilities:
- Does the warehouse, with all its components, fulfil the requirements of the goods to be stored there?

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

4. Implementation of a climate mapping and definition of critical control points:
- Where do routine monitoring positions have to be defined in order to obtain representative values?
- Where might there be areas with critical temperature or humidity values?

5. Calibration of the measurement data monitoring system:
- Will a first calibration of the measurement technology take place before commissioning?
- Do traceable calibration certificates exist for all measurement sites?

6. Installation of a measurement data monitoring system:
- Does the installed system and its software fulfil all relevant norms, guidelines and laws?
- To which extent does the system with its functions contribute to risk minimization?

7. Qualification/validation of the measurement data monitoring system:
- Can it be proven that the installed system fulfils the defined tasks repeatably and reproducibly?

The solution.

The correct climate monitoring of a storage facility for pharmaceutical goods is a highly complex business comprised of many different individual aspects.

One example is climate mapping, which is indispensable for a reliable and precise climate monitoring – because although the air conditioning system of a warehouse regulates its temperatures, several different climate zones occur there, which can negatively influence the quality of the stored pharmaceuticals. At the same time, these different temperature zones also represent potential critical control points which can be verified in the course of the climate mapping.

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

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: Warm or cold air can quickly enter the warehouse here.

After the identification of the critical control points, these should then be permanently monitored.

It should however be noted that modifications in the warehouse such as rebuilding, reorganization or changes to the air conditioning and ventilation systems result in new critical control points, as they can lead to an altered temperature and humidity distribution. For this reason, a new mapping is prescribed after any changes in or in the building.

During a climate mapping, specialists from Testo Industrial Services discuss the installation of suitable measurement technology at a critical control point.

Trust the experts

In order to establish a reliable, GxP-compliant qualification, validation and monitoring of your warehouse efficiently, collaboration with experts is recommended. We would like to demonstrate why this is to your advantage using the example "climate mapping": You can either do this yourself, e.g. using Testo data loggers and with a considerable expenditure of time – or you call in external assistance. The latter is to be recommended for three reasons:

1. The critical control points form the basis for the subsequent monitoring of temperature and humidity. This is in turn essential for a secure storage of pharmaceutical goods.

2. 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.

3. It saves you a lot of time in which you can concern yourself with your core tasks.

It becomes clear that there is much to be taken into consideration in this phase of climate monitoring. And that is not just the case in climate mapping, but also in the previous and subsequent processes which are connected with it – and which are crucial for overall success.

Testo Industrial Services, a subsidiary of Testo AG, is specialized in GxP- and other metrological services such as calibration, qualification and validation, and is your competent contact partner for the implementation of GSP compliance. The company can rely on their years of experience in the pharmaceutical environment. For more information, go to www.testotis.com

Temperature monitoring at a critical control point with testo Saveris.

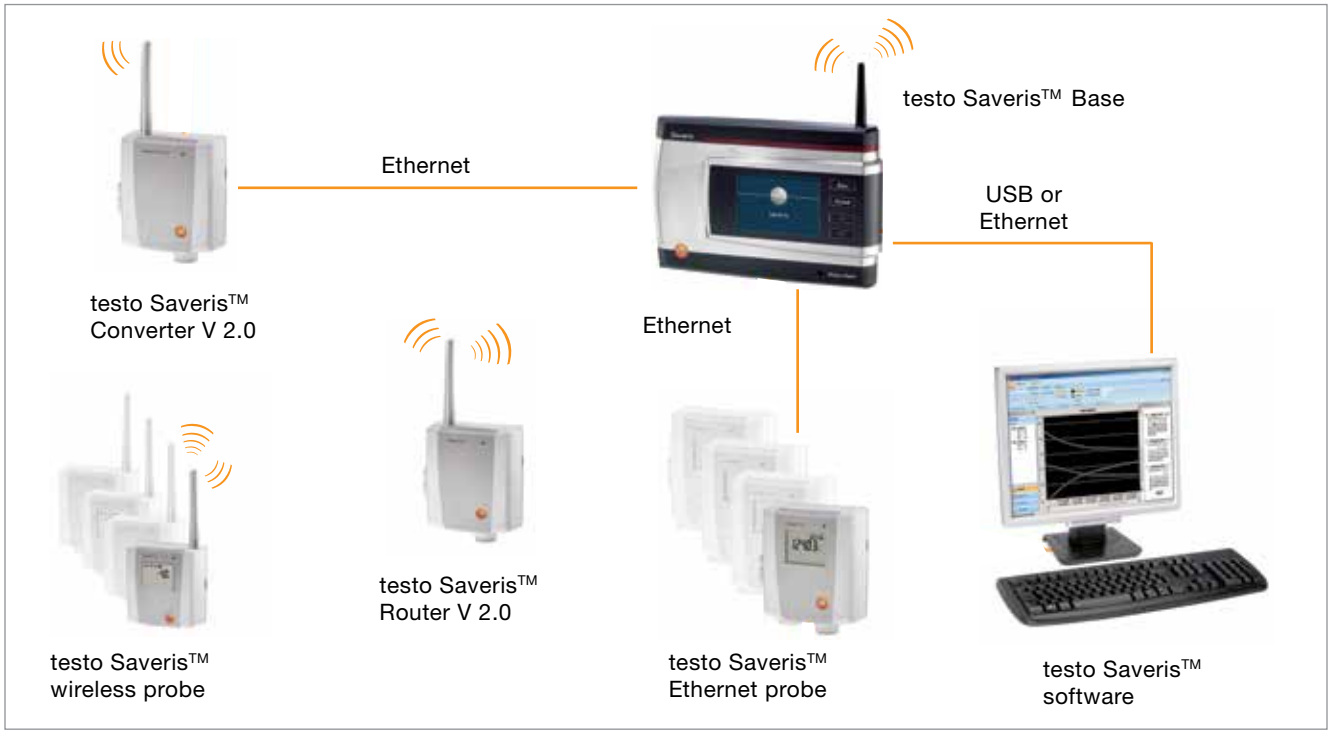
Rely on precision and security

Whether you have carried out the risk analysis and the qualification yourself, or with the support of external specialists – the insights gained must subsequently be implemented in a reliable climate monitoring system.

With the measurement data monitoring system testo Saveris, you can carry out highly accurate monitoring and uninterrupted documentation of temperature and humidity conditions in the storage of pharmaceuticals. The comprehensive alarm management as well as the automatic report creation allow adaptation to the most varied customer requirements.

Measurement data is transferred via wireless and/or Ethernet probes to a base station. It monitors and documents temperature and humidity data automatically. If limit values are exceeded, a whole range of different alarm options, such as SMS/e-mail alarm or alarm relay are available. Remote alarms can even be given when the system is not connected to a running PC. Data recording with testo Saveris continues to function without interruption, even in cases of power cuts. All recorded measurement data are furthermore centrally filed in the validatable 21 CFR Part 11 software and archived in a database. This allows you to carry out in-depth analysis and detailed evaluation of all measurement data recorded.

There are two options for calibrating the testo Saveris probes: Either in Testo Industrial Services' laboratories before commissioning, or after successful installation of the measurement technology in the course of an on-site calibration. In either case, the entire monitoring system is then validated GMP-compliantly, taking 21 CFR Part 11 requirements and the Annexe 11 of the EU GMP guideline into consideration.



The measurement data monitoring system testo Saveris with its components.

testo Saveris – all the advantages at a glance:

- Automated and uninterrupted data recording
- Comprehensive alarm management
- Validatable 21 CFR Part 11 software

More information.

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

The measurement data monitoring system testo Saveris.

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