GxP-Services for warehouse, logistics & transport

Testo Industrial Services – Mehr assurance, better service.

www.testotis.com
Pharmaceuticals are produced according to very high quality requirements which are firmly anchored in the international GMP regulations. The Good Storage Practice (GSP) and Good Distribution Practice (GDP) are the consistent continuation of the GMP-regulations. To ensure a maximum product safety throughout the entire storing- and transport process, transport and storing are placed on the same level of importance. Safety and GxP compliance is of highest priority for you and for Testo Industrial Services alike. With expertise, metrology and documentation, we support you with quality ensuring measures in the field of storage and transport. Special service packages, customized to your needs enable a pragmatic realization of the requirements you are asked to meet.

Minimizing risks, maximizing efficiency

The storing- and transport process is influenced by risks of varying level during the individual processing steps, which require adequate controlling. With qualification- and validation activities, critical influencing factors can be minimized and the compliance of GxP-requirements documented. By means of a well-structured risk management, the quality assurance measures are directed, placing the focus on the critical aspects of the storing- transport process and thereby the quality assurance efforts are optimized.
We have

Safety on stock!

GxP-services for cooling- and warehouse

Steady and constant temperature- and climate conditions are the most important requirements for the quality of your products during the storage- and logistics process. Especially for instable and compulsory refrigerated products, high requirements apply which are controlled according Good Storage Practice (GSP) regarding warehousing and monitoring. Temperature- and humidity distribution measurements are core elements of the qualification of warehouse areas.

The performance limits are determined with the support of additional stress tests. Thereby, the stability and the robustness of the warehouse towards external influences are of particular relevance. Simultaneously, critical areas are discovered during the qualification, which can be monitored constantly and controlled in the routine monitoring afterwards.

You determine the performance scope

From individual temperature distribution measurements and metrological tests up to project coordination and conception of qualification- and validation projects – you will receive appropriate and cost efficient services.
Our performances at a glance

Warehouse qualification

✓ Qualification of cooling- and storage areas:
  • Frozen-, cooled- and room temperature
  • Incubator, temperature chambers and cold storage cells
  • Warehouse, high-bay warehouse, block storage and similar ways

✓ Metrological test & documentation:
  • Climate mapping and temperature distribution studies
  • Winter- and summer mappings
  • Challenge-tests and stress tests for assessment of stress limits (e.g. doorways)

✓ Implementation of risk analysis and conception of risk management according ICH Q 9

✓ Evaluation of routine monitoring positions and “critical points”

✓ On-site calibration of measurement devices and monitoring systems

✓ Validation of the monitoring systems (CSV)

✓ Conception and implementation of standard-qualification (“Type qualification”)

Transport qualification / validation (passive temperature control)

✓ Qualification of passive tempering packaging systems

✓ Metrological test & documentation:
  • Temperature distribution studies for packaging systems
  • Determination of route profiles
  • Implementation of winter- and summer mappings
  • Test and determination of stress limits
  • Determination of appropriate packaging systems

✓ Implementation of risk analysis and conception of the risk management according ICH Q 9

✓ GDP-training and sensitization of your personnel for the transport of pharmaceuticals
Transport qualification
(Active temperature control and air conditioning)

✓ Qualification of active air conditioned transport systems:
  • Vehicles, container and trailers for the street transport
  • Integral containers or porthole-Containers for the airway
    and sea route
  • Unicameral- and multicameral system

✓ Metrological test & documentation:
  • Climate mapping and temperature distribution studies
  • Winter- and summer mappings
  • Challenge-tests and stress tests for assessment of
    stress limits
  • Inclusion of tests and route profiles

✓ Implementation of risk analysis and conception of risk
  management for the transport system

✓ Evaluation of route monitoring positions and
  “critical points”

✓ On-site calibration of measurement devices and
  monitoring systems at the location of your choice

✓ Conception and implementation of standard-qualification
  ("Type of construction qualification")

✓ GDP-training and sensitization of your personal for the
  transport of pharmaceuticals

Transport validation

✓ Risk management and risk observation according
  ICH Q 9 under inclusion of streets, roads, temperature
  profiles, transport duration as well as on the product base

✓ Conception and planning of transport validation e.g.
  from base camp to final depot.

✓ Implementation and metrological support of the different
  validation runs.
  • Testing of different products and loading conditions
  • Review of load limits in challenge tests and stress tests
    e.g. via several climate zones, maximal and minimal
    loading, door opening test, black-out test and the like
  • Testing of different routes, rotes and time profiles

✓ Creation of validation documentation according to their
  requirements- from validation master plan up to a final
  report.
In order to avoid negative effects for products during the transport of pharmaceuticals, validated transport processes are indispensable. Before the actual transport validation, in which case an entire transport route is validated from the base camp to the final depot, it is first of all necessary to qualify active cooling transport systems like refrigerated trucks. During the passive refrigeration, the transport duration and the environmental influences are particularly important factors which require evaluation before the usage in routine operations. These have to be evaluated along with any other disturbance variables. Therefore, qualification and validation always happen in accordance with certain principles, which are written down in the form of plans and test protocols.

Safely to its destination!

GxP-services for logistics & transport

With us

Your desired service is not included here?

Do not hesitate to contact us, so that we can determine and offer a suitable service based on your demands.

✉ gmp@testotis.de
Your advantages & benefits

Single-Sourcing & customized services

✓ You receive customized services based on rationalized conditions, so that you will receive what you actually need.

✓ On demand, we will deliver you our full-service-support from planning of the project, conception of the risk management up to the implementation and documentation of qualification and validation.

✓ You have the advantage of single-sourcing thanks to our versatile performance spectrum.

Fulfillment of all measuring tasks

✓ With an unique measuring equipment park, including more than 2,000 measuring equipment’s, we can realize any measuring task from fridge, container, transport up to storage areas.

✓ For major projects with approaching deadlines, a parallel realization of multiple qualifications and validation projects is possible.

✓ The combination of GxP-Expertise and metrological know-how guarantees an optimal realization of your project and an appropriate support.

Flexible use of resources

✓ With over 90 specialists in the technical field service, we deliver the required manpower and expertise especially during peak periods.

✓ Through our national and decentralized service network we are always close to you.

✓ Thanks to this manpower we can react optimally to your inquiries or projects and lead them to success.