

Be sure. **testo**



GxP-Services for warehouse, logistics & transport

Testo Industrial Services – More service, more security.

GxP-Services for warehouse, logistics & transport

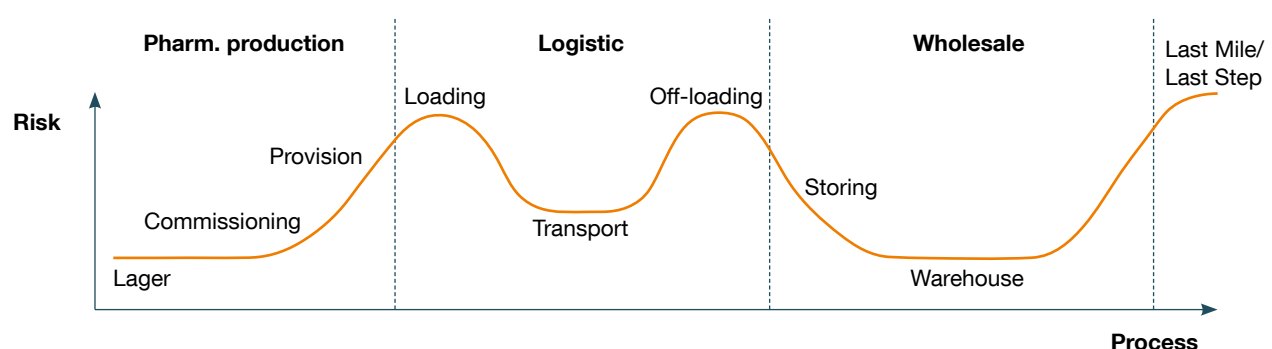
Pharmaceuticals are produced according to very high quality requirements which are firmly anchored in the international GMP regulations. The Good Storage Practice (GSP) and Good Distribution Practice (GDP) are the consistent continuation of the GMP-regulations. To ensure a maximum product safety throughout the entire storing and transport process, transport and storing are placed on the same level of importance.

Safety and GxP compliance is of the highest priority for you and for Testo Industrial Services alike. With expertise, metrology and documentation, we can support you with quality ensuring measures in the field of storage and transport. Special service packages, customised to your needs enable a pragmatic realisation of the specifications you are required to meet.



Minimising risks Maximising efficiency

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



Safety on stock!

GxP-services for cooling and warehouses

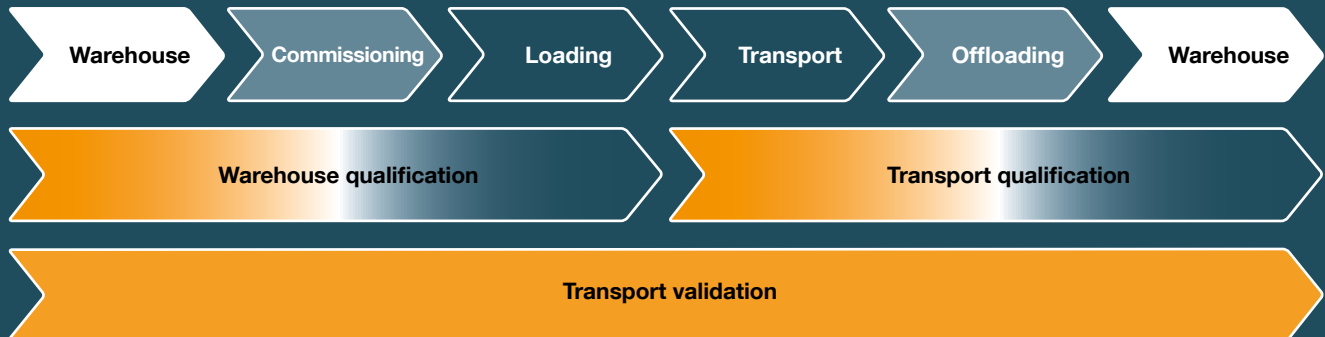
Steady and constant temperature and climate conditions are the most important requirements for the quality of your products during the storage and logistics process. Especially for unstable products and those products which need to be refrigerated, stricter rules apply which are controlled according Good Storage Practice (GSP) regarding warehousing and monitoring. Temperature and humidity distribution measurements are core elements of the qualification of warehouse areas. Safety on stock! We understand the performance criteria, these are usually 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 highlighted during the qualification process, which can be monitored constantly and controlled in the with by 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, we can provide the appropriate solution and cost efficient service.

Our performances at a glance



Warehouse qualification

- ✓ Qualification of storage areas:
 - Frozen, chilled and ambient room temperature
 - Incubator, temperature chambers and cold storage cells
 - Warehouse, high-bay warehouse
- ✓ Metrological test & documentation:
 - Climate mapping and temperature distribution studies
 - Seasonal mapping
 - 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 seasonal mapping
 - 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 raises awareness of your personnel for the process of transporting pharmaceuticals



Transport qualification (active temperature control and air conditioning)

- ✓ Qualification of active air conditioned transport systems:
 - Vehicles, containers and trailers for road transport
 - Integral containers or reefer containers for air and sea logistics
 - Single and multichambered systems
- ✓ Metrological test & documentation:
 - Climate mapping and temperature distribution studies
 - Seasonal 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 raises the awareness of your personal for the process of transporting 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 the initial collection to the final destination
- ✓ Creation of validation documentation according to their requirements from validation master plan up to a final report
- ✓ 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, minimal and maximum loading, door opening tests, black out tests and the like
 - Testing of different routes, loads and time profiles

Qualification:
www.testotis.com/transport-and-storage-qualification



Validation:
www.testotis.com/transport-validation



Safety to its destination!

GxP-services for logistics & transport

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 initial collection to the final destination, 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.



▶ Should you require an additional service not mentioned in the brochure please do not hesitate to contact us
info@testotis.com

Your advantages & benefits

Single-sourcing & customised services

- ✓ You receive customised services based on rationalised conditions, so that you will receive what you actually need
- ✓ Our Promise, we will deliver you a full service support package from initial planning of the project, conception of the risk management through to the implementation and documentation of qualification and validation requirements
- ✓ You have the advantage of single sourcing thanks to our versatile performance spectrum



Fulfillment of all measuring tasks

- ✓ With our unique measuring equipment park, including more than 4,500 measuring stations we can provide you with options for the measurement of your fridges, containers, transport and storage areas
- ✓ For major projects with approaching deadlines, a parallel program of multiple qualifications and validation projects is possible
- ✓ The combination of GxP-Expertise and metrological know how guarantees an optimal conclusion of your project and an appropriate support



Flexible use of resources

- ✓ With our technical field service teams we can deliver the required manpower and expertise especially during peak periods
- ✓ Through our service network we are always close to you
- ✓ Our country wide network of on-site service technicians ensure we that can react quickly to your inquiries or projects



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