

AIRGENEX®med

SAFE AND GENTLE DRYING OF MEDICAL DEVICES

GENTLE.PROCESS-SAFE.ENERGY-SAVING.GMP READY.



OUR WAY OF DRYING PHARMACEUTICALS IS SPECIAL:

VERY SAFE.

VERY FAST.

VERY GENTLE.

VERY EFFICIENT.

HARTER DRYING SOLUTIONS - COMPETENCE IN ALL ASPECTS OF DRYING.

- Gentle drying at temperatures between 20 °C and 75 °C
- High efficiency levels achieved by heat pump technology for dehumidification
- Carbon and energy saving drying process
- Drying system may be customized to best meet your specification requirements
- Drying in a closed system (no interchange with ambient air, thus no dependence from climate and no impact on cleanroom conditions, emission-free drying)
- Reproducible processes (qualification)
- Machine design in accordance with GMP and hygienic design requirements
- Drying may easily be combined with cooling (requiring only minor modification of machine design)
- Compressed air-free blow-off technology as a preliminary stage of drying in special cases

MORE INNOVATION FOR YOUR PRODUCT

After cleaning, washing or sterilising, for example, containers, baskets and trays, the aim is always to generate absolutely dry goods to prepare them for immediate further processing. For particularly demanding applications, as is often the case with containers, we combine our drying with an upstream compressed air-free blow-off unit. Our drying system is flexible in every respect and can be integrated into any existing or planned type of process.

Medical technology items such as implants and biomaterials, diagnostic and surgical instruments are surface-finished during production and therefore require stain-free, safe and complete drying afterwards. Here, our low-temperature dryers with dry air offer the perfect alternative.

Heat pump-based condensation drying is the solution to your drying challenge. With its physically alternative approach, it combines seemingly contradictory attributes such as gentle drying through low temperatures and short drying times.

- Gentle on products due to low temperatures in variable temperature range from 20° - 75°C
- High-quality results with short drying times
- **High efficiency through air dehumidification using heat pump technology**
- Drying in a closed system without exchange with the ambient air and therefore independent of the climate. **Emission-free drying does not affect cleanroom environments**
- Drying systems can be integrated into existing infrastructure

APPLICATIONS

BAGS AND BOTTLES FOR INFUSION AND INJECTION THERAPY

After hot water sterilisation, for example, your products are hot and wet. With our low-temperature drying, you can dry your bags or bottles, made of plastic or glass, gently and safely at the same time and, if desired, cool them immediately afterwards. Our drying or dry-cooling solutions are flexible and therefore suitable for both continuous processes and batch processes - in manual or fully automatic operation. The drying temperature is normally between 20°C and 75°C.

AMPOULES AND VIALS

Whether the products to be dried are made of glass, plastic or other materials makes no difference when using our dryers. In any case, drying takes place at low temperatures. No matter how many of your ampoules or vials are in which containers - with our solution they will be dried safely and completely.

BLISTER PACKS

In the case of medicine blisters, the aim is usually to dry up the surface water and at the same time protect the contents.

IMPLANTANTS AND BIOMATERIALS/ DIAGNOSTIC AND SURGICAL INSTRUMENTS

Implants and instruments are surface-finished during manufacture and therefore require subsequent stain-free, safe and complete drying. Our experience shows that hot air blowers are often used in this area, which do not deliver the desired results and are also energy inefficient. Here, our low-temperature dryers with dry air offer a perfect alternative.

CONTAINERS, BASKETS AND TRAYS

Whether after cleaning, washing or sterilising, the aim is always to generate absolutely dry goods to prepare them for immediate further processing. Containers, baskets and trays are cleaned or sterilised to prevent contamination. Afterwards, the containers are wet and have to be dried in order to be transferred directly back into production. Especially for containers made of plastic, the low drying temperature of the HARTER dryers is a decisive advantage.



HYGIENIC DESIGN

In conventional drying rooms not designed according to Hygienic Design, there is a risk of pathogen or germ formation. Also, problems such as mildewing may occur again and again. HARTER drying systems are designed and built in accordance with hygienic design requirements.

Ease of cleaning and conformance with hygienic standards was first reflected in the development of pharmaceutical active ingredients systems and extended to the drying of medical products. This ensures responsible drying of sensitive products.



Hygienic design precludes potential hygienic trouble spots by design. All materials and surfaces of HARTER drying systems can be easily cleaned or sterilized, if required. The use of filter systems also ensures that contamination does not settle in the first place or can be easily removed.

HARTER hygienic design ensures product reliability.

- Conformance with high hygienic standards
- Ease of cleaning operations
- Reduction of downtime

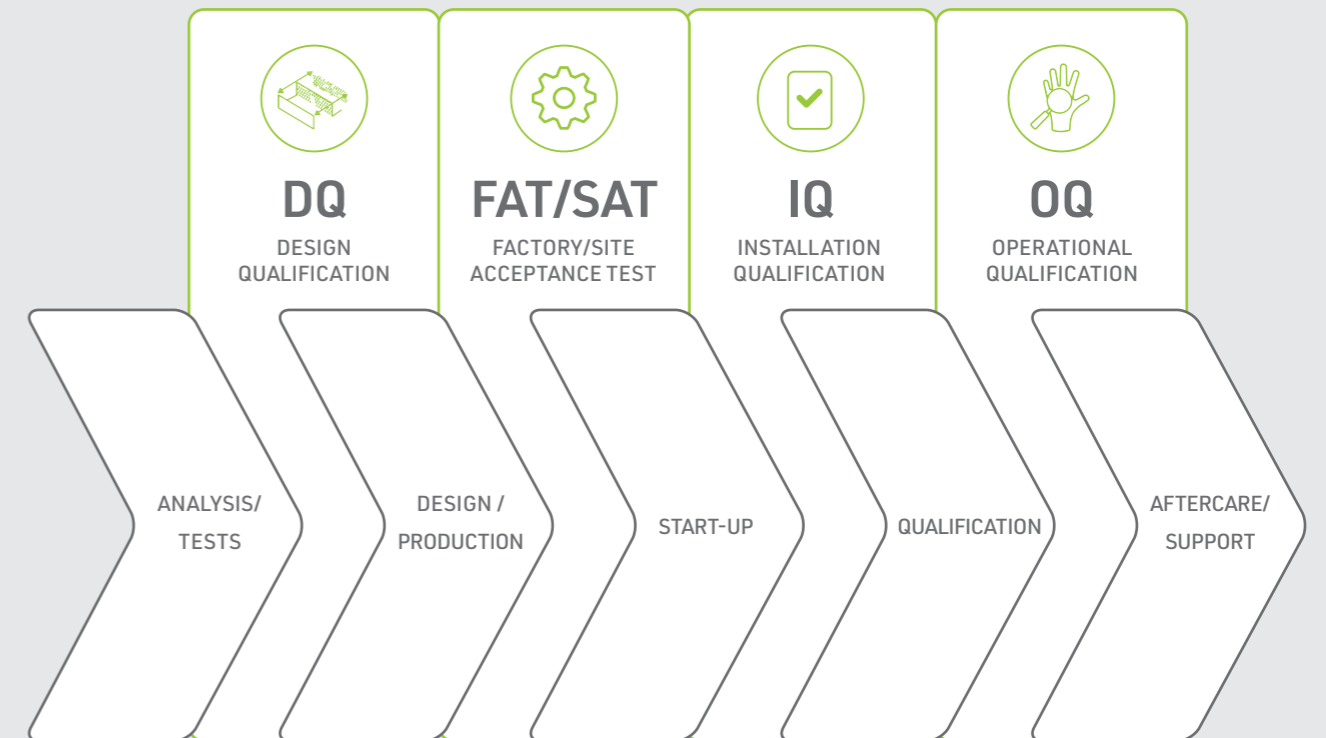
QUALIFICATION

International standards are the basis for the handover and operation of a drying system from HARTER.

It goes without saying that we comply with all qualification, GMP and GAMP requirements and provide documented proof that our systems are suitable for the intended purpose.

Our GMP service includes the preparation of specific design documents as well as the performance of qualification with

- Design Qualification (DQ)
- Installation Qualification (IQ)
- Operational Qualification (OQ)
- FAT and SAT



GENTLE AND RELIABLE DRYING

The Airgenex® drying system developed by Harter is capable of drying any kind of medicinal ingredients in a **gentle and energy efficient way, fast and reliably**. Heat pump based condensation drying resolves drying problems and optimizes production processes. Many years of experien-

ce in and know-how of many hundreds of drying applications ensure that you get the solutions exactly suiting your product and your production process. This is the only way to success for you, the customer, and us, the supplier. Top priority features for the drying process are as follows.

PRODUCT QUALITY

- Gentle product treatment by drying at low temperatures
- Even difficult geometries are dried safely by forced air guidance
- Individually adapted drying systems according to product and process

PROCESS RELIABILITY

- Control of drying parameters:
 - > Control and monitoring of parameters
 - > Various programmes may be set
 - > Data may be analysed
- Drying takes place in a system closed air-wise:
 - > No interaction with ambient air
 - > Independence from climate



Dry-cooling-chamber for racks

GENTLE DUE TO LOW TEMPERATURE

Your product is sensitive and requires very gentle processing. In terms of drying, this is achieved by **highly efficient dehumidification at low temperatures** between 20 °C und 75 °C as required for the specific application. This absolutely stress-free low temperature drying prevents undesired heating of the materials and products.

Drying with AIRGENEX®med guarantees **constant parameters** such as temperature, time, humidity, air speed and air flow rate and thus makes your process independent of climatic conditions. Drying works reliably, stabilises the production sequence and thus optimises the process. AIRGENEX®med thus becomes the answer to all quality questions in the drying process.

HIGH PROCESS RELIABILITY

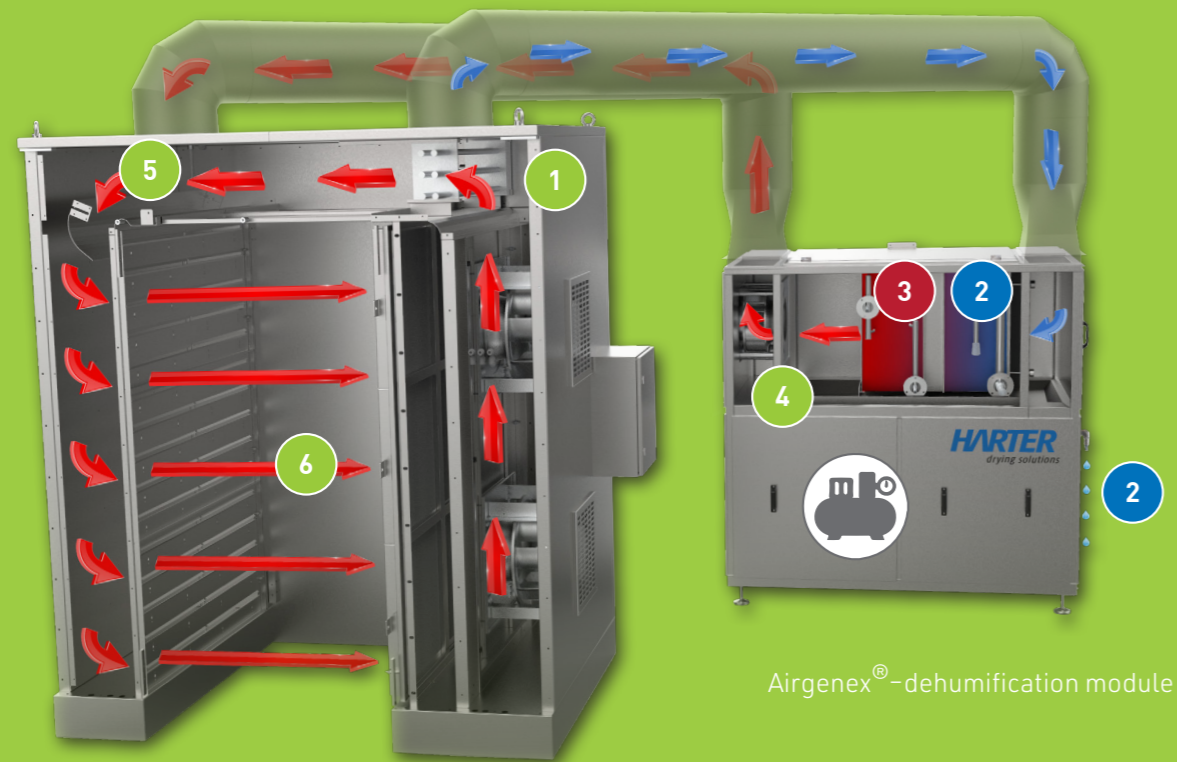
HIGH EFFICIENCY

AIRGENEX®med achieves **maximum efficiency** in the drying process through air dehumidification using heat pump technology. A combination of air treatment and air flow perfectly matched to the product ensures **high-quality drying results** with **short drying times**.

INDEPENDENT TECHNOLOGY

Drying with AIRGENEX®med takes place **without exchange with the ambient air**. It is emission-free and does not influence clean room and production conditions. Likewise, Airgenex®med drying systems are independent of operational infrastructure.

DRYING IN A CLOSED AIR CIRCUIT – WITH NO SUPPLY AND EXHAUST AIR



Drying module
(here: Chamber Dryer)

Airgenex®-dehumidification module

Harter's low energy drying systems are capable of drying your pharmaceutical ingredients in a gentle, reliable and uniform way to obtain the desired dry matter content.

The drying system consists of a drying module and one or more dehumidification modules. The purpose of the dehumidification module is to provide the necessary dry process air. The drying module is the place where items are dried.

THE AIRGENEX®-DEHUMIDIFICATION MODULE

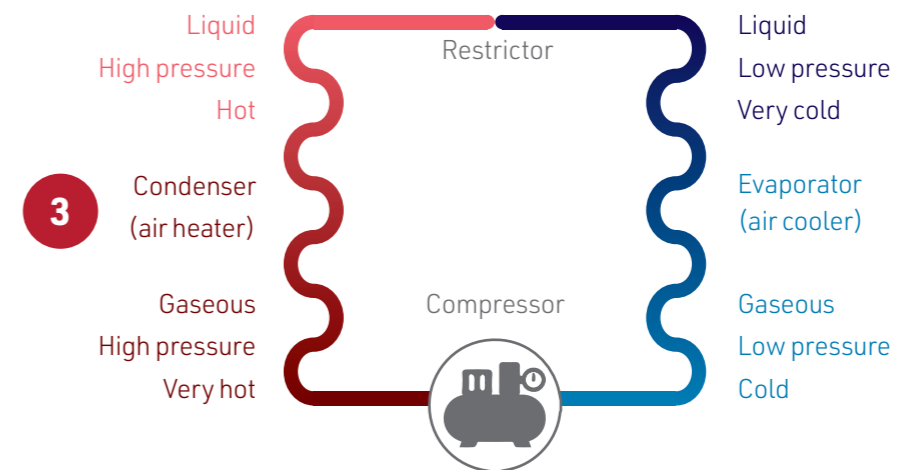


Airgenex®-dehumidification module

Airgenex® is our heat pump-based dehumidification module for condensing water from the air - for direct connection to the drying modules. The energy released during condensation is fed back into the system via a heat pump.

Depending on the application, Airgenex® dehumidification modules in different sizes or several modules are used.

OPERATING PRINCIPLE OF A HEAT PUMP



Moist air is taken from the drying module and passed to the Airgenex® dehumidification module.



The moisture condenses on the air cooler fins and runs through the collector to the condensate drain where it leaves the dehumidification module.



The air heater heats the dry air to the required process temperature.



The process air fan circulates the air between the dehumidification module and the drying chamber.



The dry unsaturated air is supplied to the drying module where it mixes with the controllable main recirculation air and passes over or through the products to be dried.



The main recirculation air circulates within the drying chamber and ensures uniform drying.

CUSTOMISED SOLUTIONS

LARGE CHAMBER-DRYERS/-TUNNEL



Large Chamber Dryer

The products to be dried are **in baskets or on trays** in layers in tray trolleys or racks. The racks/trays are automatically or manually moved into the drying tunnel, which is equipped with a conveyor system. In this way, the racks/ trays move through the tunnel continuously or in a timed manner. A purely manual process is also

possible without any problems. The conveying speed is adapted to the specific product. **Your products are gently dried at low temperatures in the desired time frame and thus stress-free.**

BELT DRYERS

Pouches and ampoules sometimes have to be dried fully automatically in continuous operation. Drying on the belt in automatic mode has its own demands and challenges, with mostly very fast throughput times. Thanks to our compressed-air-free blow-off technology, no expensive compressed air is no longer required and the products are efficiently freed from the water load. Here, too, we adapt our dehumidification technology perfectly to your product and your throughput. In order for the drying process to run reliably in the desired time and at the optimum temperature, the air flow must be perfectly matched to the product. The driest air is worth nothing if it is not guided to where it is supposed to absorb the moisture. We successfully meet this challenge.



Belt Dryer

CHAMBER DRYER H01

The module of the H01 series is suitable for medical products with simple geometries can also be dried in one or more layers. The H01 series can be extended to up to five drying modules.



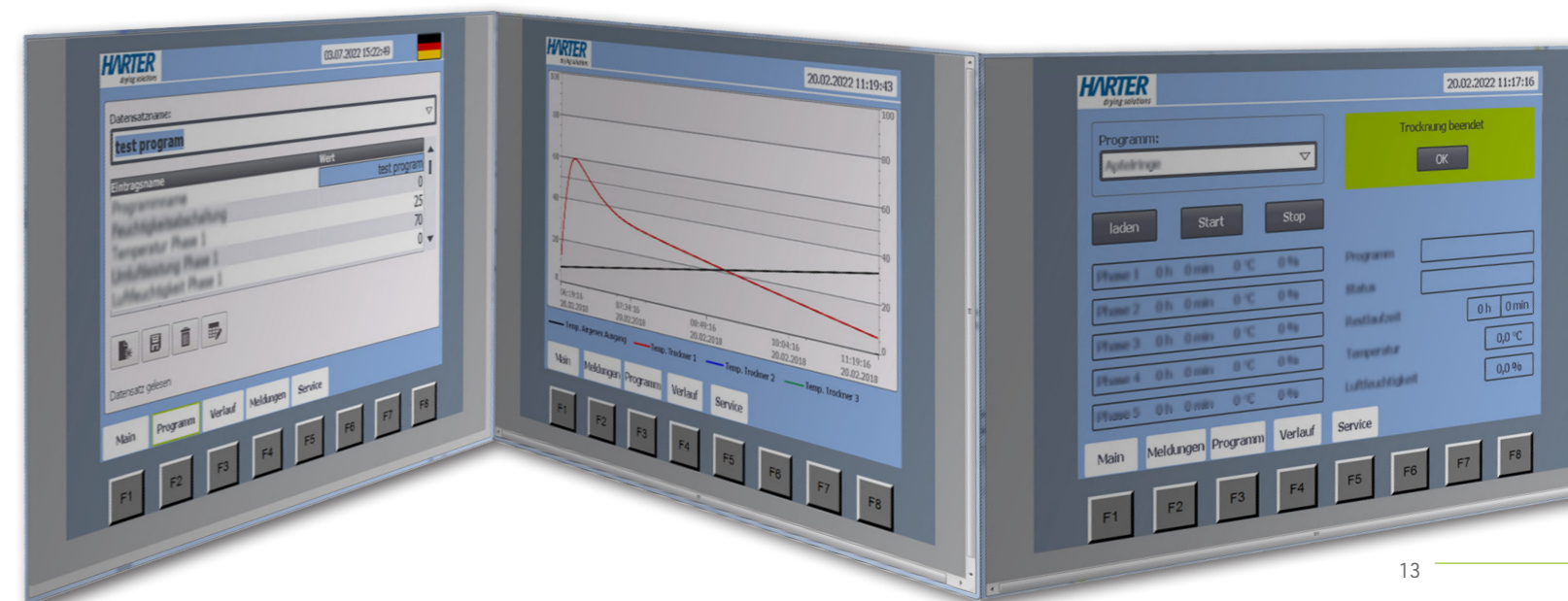
INTELLIGENT CONTROL

— SPS-Control Siemens Simatic S7-1200 | Siemens Simatic HMI Panel

With our control system, various drying parameter combinations are possible with regard to time | recirculating air humidity | temperature over time | airflow rate | belt speed

Any number of product specific recipes may be programmed and stored. Once started, the process runs in fully automatic mode until its end.

The controller may be operated and the drying process monitored in real time through the inbuilt HMI or external devices such as PC, tablet or smartphone. Drying parameter output or reading is possible at any time.



TRIAL DRYING FOR BEST RESULTS



Our services include series of tests in our pilot plant station. This appears to be the best method for determining the parameters for successful drying. We run these tests – which you are welcome to witness – to identify the best temperature, humidity, drying time, air speed and airflow.

The documented results, our long experience plus your know-how form the basis for further system design which will also draw on approaches for solutions in many and most various projects.

ADDED VALUE AND REPRODUCIBILITY

We are an independent enterprise and have a continuous and homogeneous value chain with high know-how throughout our organization. We offer a comprehensive service package including expert advice, research, development and engineering, documentation, commissioning and after-sales service. Our extensive vertical range of manufacture and qualified supplier management follow the lines of our „Made in Germany“ philosophy.

Decades of experience and our understanding of processes are the basis of our self-contained technology which continuously monitors and automatically controls temperature and other drying parameters of your processes. Product drying results are reproducible and support your zero defects production.

**„You need reproducible results.
We deliver them.“**

CUTTING DOWN CARBON EMISSION WITH HARTEK DRYING SYSTEMS

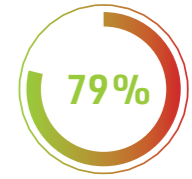
The Airgenex® condensation drying process from HARTEK offers a product for this purpose in the context of active pharmaceutical ingredient drying, which offers decisive advantages not only ecologically but also economically:

- Lower operating costs
- Less resource consumption
- Independence from fossil energy
- More stable process conditions

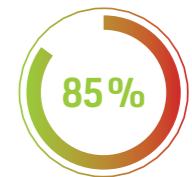
SAVINGS POTENTIAL



Energy



CO₂



DRYING SYSTEMS FOR MEDICAL PRODUCTS

Pharmaceutical active ingredients are highly sensitive products and require the best and most and, above all, stress-free handling during their production and further processing. High-quality drying means more quality and more safety.

Our drying technology is also ideally suited for the application areas of drying active pharmaceutical ingredients in powder or granule form, pastilles and tablets, medicinal plants as well as viscous substances, viscous fluids and stab-resistant pastes.



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