

AIRGENEX[®]med

SAFE AND GENTLE DRYING OF ACTIVE PHARMACEUTICAL INGREDIENTS

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)
- The resulting **condensate might be utilized** (if it contains valuable ingredients)

MORE INNOVATION FOR YOUR PRODUCT

Pharmaceuticals are highly sensitive goods requiring very careful and, particularly, stress-free processing and production. Top quality drying spells higher quality and reliability.

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, further tempering step up to 110°C possible
- 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

PHARMACEUTICAL ACTIVE INGREDIENTS IN POWDER AND GRANULAR FORM

For these applications, drying in a chamber dryer is the best option. With temperatures in the range between 20°C and 75°C, the fabrics are gently dried to the desired degree of dryness. If higher temperatures are required, we can carry out an additional tempering step up to 110°C. Our dry air in combination with an individual air flow ensures homogeneous and exact drying results.

A special procedure is required for products containing solvents. A redundant system continuously monitors the solvent content of the air. If this rises above a defined limit value, the process air is exchanged by means of a supply and exhaust air system. As soon as the solvent content falls below the defined value, the air circuit closes again to ensure the most energy-efficient drying process possible.

MEDICINAL PLANTS

With our gentle low-temperature drying, we help you to manufacture your products. The applications in this area are very diverse and individual. So are our drying solutions.

PASTILLES AND TABLETS

Drying is also an important component in the production of pastilles and tablets. It completes the quality of your products. In addition to the advantages already mentioned, our drying has another bonus: since drying takes place in a closed circuit, process reliability is maintained. Moreover, drying in a closed system is independent of climatic conditions and other external influences.

VISCOUS SUBSTANCES / VISCOUS FLUIDS / STITCH-RESISTANT PASTES

For these applications, continuous drying on a belt (for example, after extrusion) is a good option. With our low temperatures in the normal range between 20°C and 75°C, the fabrics are thus dried **very gently** to the desired degree of dryness. Our dry air in combination with individual air guidance ensures homogeneous and exact drying results.

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

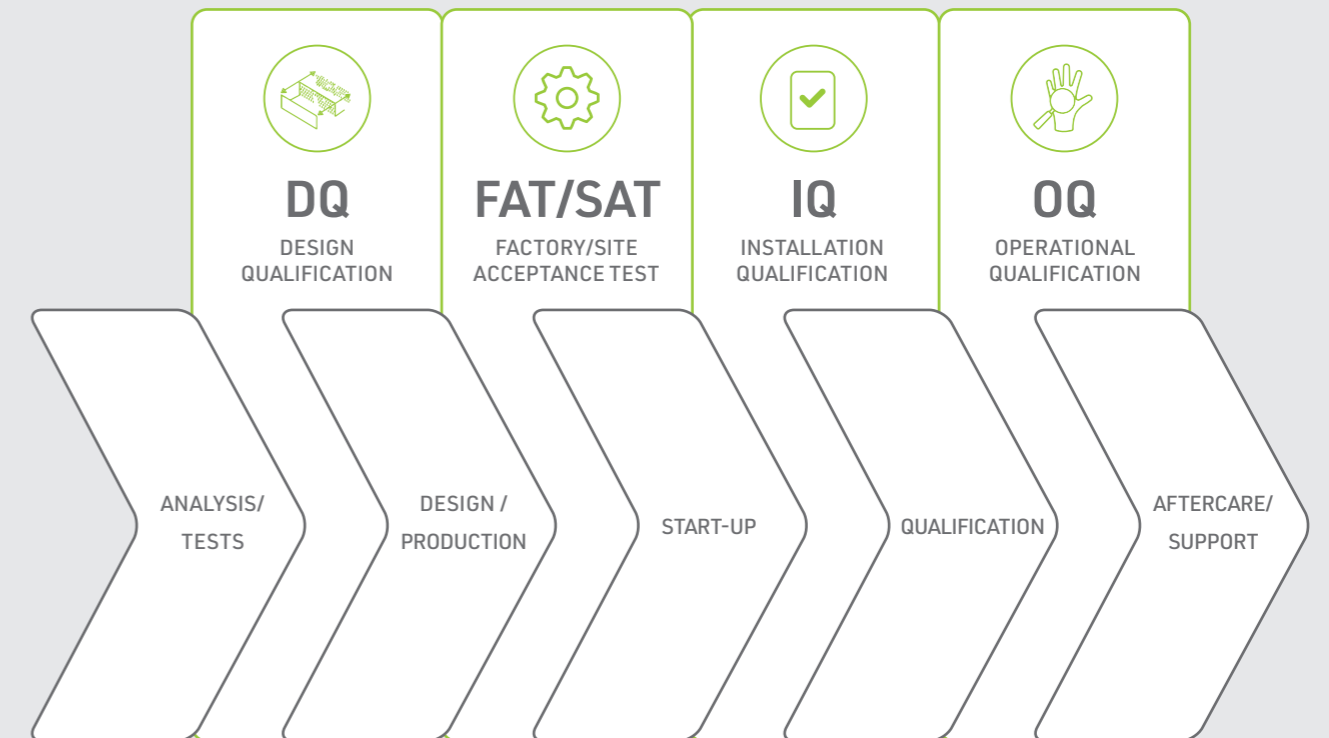
QUALIFICATION

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



For pharmaceutical active ingredients, the drying process is crucial to the quality of the end product. HARTER can meet such requirements using special, customized drying techniques and process solutions. Owing to their long-standing expertise HARTER can also offer support in developing complex drying processes and implementing these processes in the regulated industry.

Rainer Krüger, Manager of J&K Consulting, Germany

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
- Drying parameters selected to meet quality requirements and reflect product properties

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



Chamber Dryer H03-Module

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

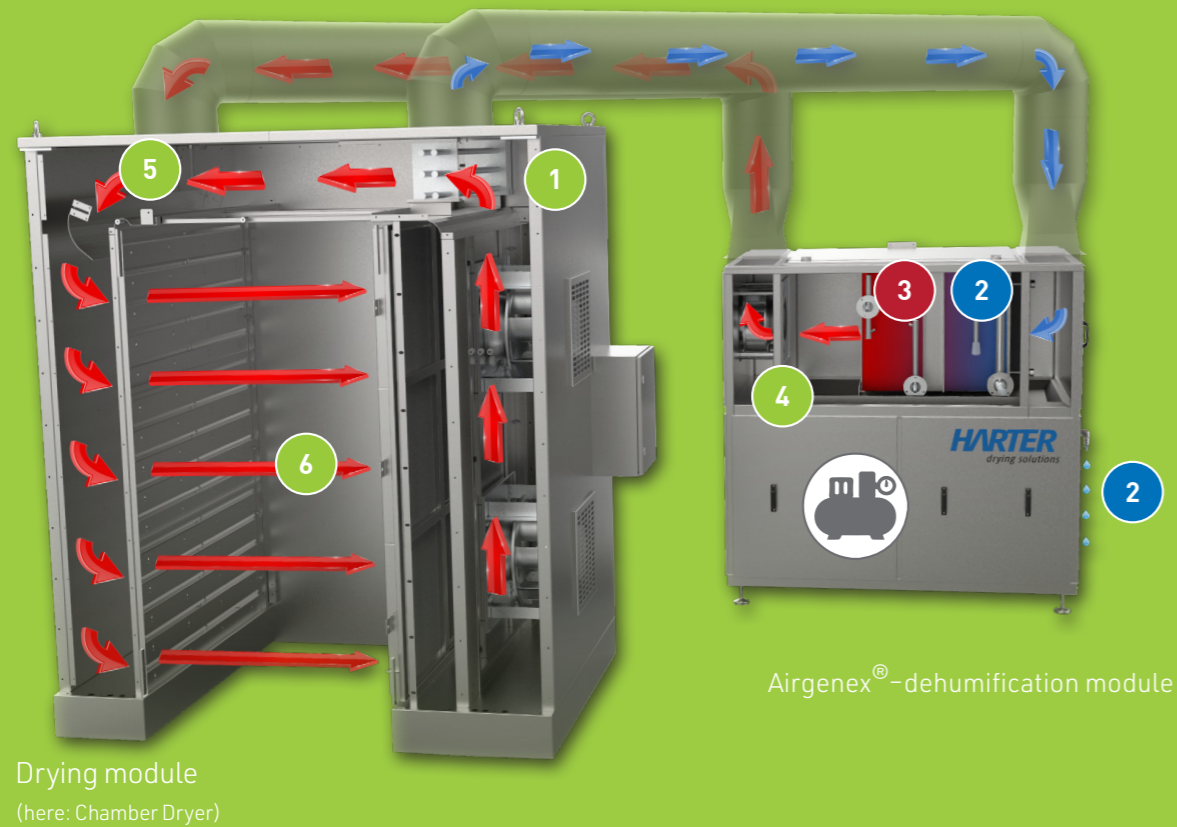
HIGH EFFICIENCY

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.

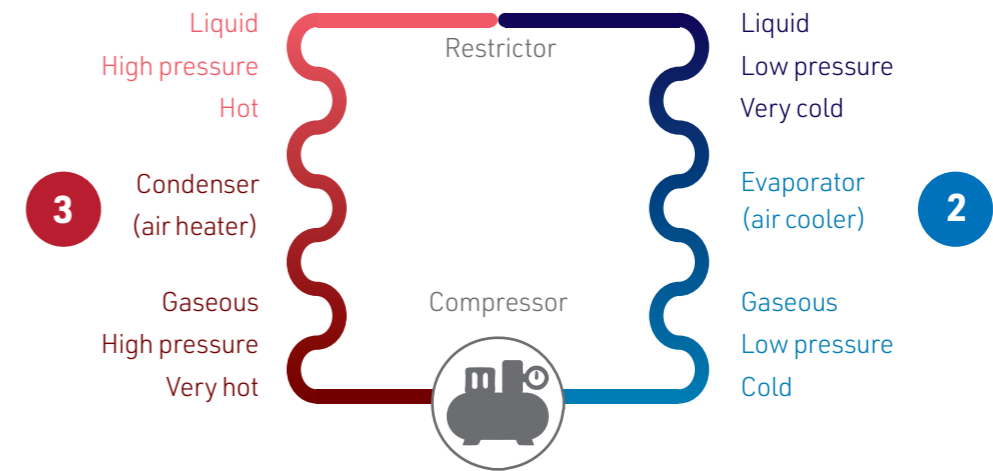
DRYING IN A CLOSED AIR CIRCUIT – WITH NO SUPPLY AND EXHAUST AIR



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.

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.

SERIES MODELS

CHAMBER DRYER H01 Series

Many Opportunities

The module of the H01 series is ideally suited for the pharmaceutical ingredients in a gentle and homogeneous manner. Depending on the required capacity, the dryer can be extended with additional modules.



BULK DRYING IN PANS OR BASKETS

Products which can be dried in bulk may be loaded 175 mm max. high. The direction of airflow is modified such that the air



entering the chamber horizontally is diverted to flow vertically through the pans to finally leave the chamber horizontally again. This is the only way to ensure uniform drying of bulk products.

SINGLE LAYER TRAY DRYING



Products are dried on trays using air routed horizontally.

H01 compact

The compact dryer for product development and laboratory use combines both the drying chamber and the Airgenex® dehumidification module in a single housing. Processors may use the H01 compact if the standard H01 module chamber dryer is deemed too big.

This compact dryer is perfectly suited for laboratory testing small quantities of items or for developing new products – the perfect solution for start-ups to assist in the initial development of their product idea.



Specifications	H01Module	H01compact
Temperature range	20 °C to 75 °C	20 °C to 75 °C
Single layer drying	Trays of various sizes and designs may be used.	
Usable surface area	48 m ² max.	12 m ² max.
Bulk material	Pans and baskets in various sizes and designs can be used. Maximum fill height is 175 mm.	
Usable volume	1.0 m ³ max.	0.2 m ³ max.
Dimensions [L x W x H]	2800 x 2300 x 3000 mm ¹⁾	1500 x 1060 x 1950 mm ²⁾
Power input max	23.4 kW ¹⁾	8.6 kW
Rated power	11.9 kW approx. ¹⁾	4.2 kW approx.
Voltage/frequency	230/400 V, 50 Hz	230/400 V, 50 Hz
Air volume	10,000 m ³ /h max.	4,500 m ³ /h max.

¹⁾ Airgenex® 6.000-dehumidification module included, further combination possibilities on page 16

²⁾ Including dehumidification technology in the lower part of the dryer

CUSTOMISED SOLUTIONS

LARGE CHAMBER-DRYERS/-TUNNEL



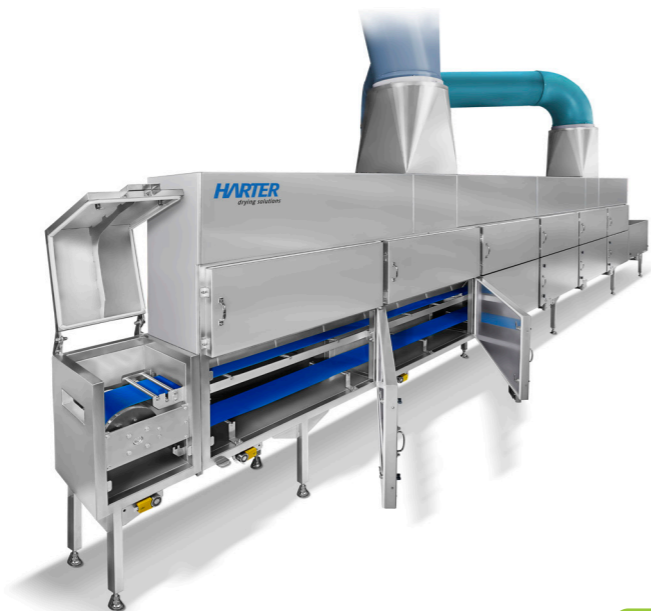
Large Chamber Dryer

The products to be dried are **in baskets or on trays** in layers in racks or tray trolleys. The racks/trolleys are automatically or manually moved into the drying tunnel, which can be equipped with a conveyor system. In this way, the racks/trolleys 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

Pharmaceutical products such as viscous substances, viscous fluids or pastes can be dried homogeneously and gently in a continuous process. Drying on the belt in automatic mode has its own demands and challenges. 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 matching to the product. The driest air is worthless if it is not directed to where it is supposed to absorb the moisture. We successfully meet this challenge.



Belt Dryer

CONTROL – SMART IN EVERY DETAIL

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

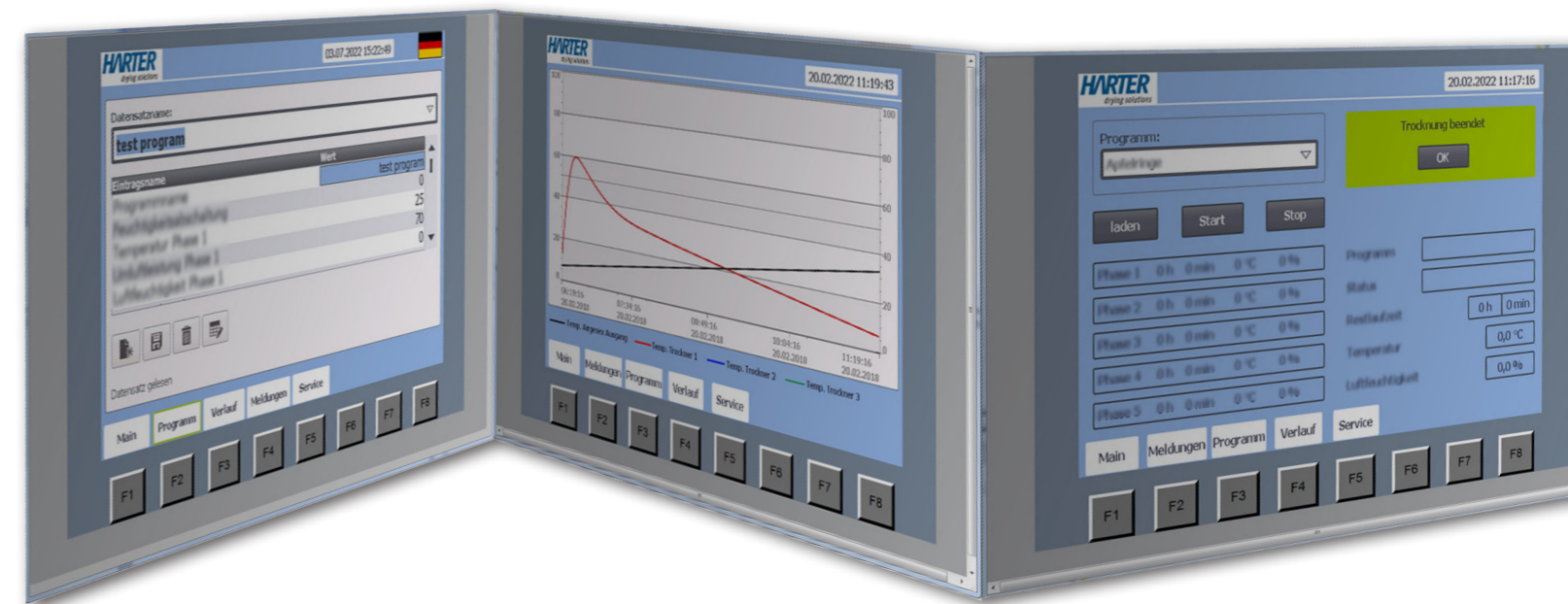
ADJUSTABLE DRYING PARAMETER COMBINATIONS

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 control unit also has an "expert" mode for product development.**

REAL-TIME DATA TRANSMISSION AND PROCESS CONTROL

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.



POSSIBLE COMBINATIONS

H01 TO H05 DRYING MODULES

Our drying systems may be extended by adding further modules to meet the requirement for more throughput. Your system may comprise up to five drying chambers combined with one or more Airgenex® modules.

With all these options, you are perfectly free to plan your future!

BASIC CONFIGURATION:

All chamber dryer modules have standard components as follows.

- 1.4301 stainless steel housing (AISI 304), double wall, sound and heat insulated (AISI 304);
- Integrated air recirculation system for forced air routing inside the drying chamber
- Airgenex®-air ducting system for constant supply, distribution and return of Airgenex® conditioned process air inside the dryer
- Two process air fan
- Drying chamber door
- Temperature sensor(s) [°C]
- Humidity sensor(s) [rF%]
- Heater battery, electrical (6 kW)



H01-L



H02-L



H03-L - H05-L

DEHUMIDIFICATION MODULES

BASIC CONFIGURATION:

Heat pump based dehumidification component to condense water from the air – for direct connection to the chamber dryer modules. The energy released in the process is returned to the system through the heat pump.

All Airgenex® modules include the following standard components:

- Framework of heat insulated sections with FDA certified powder coating, RAL 9006 colour ¹⁾
- Double walled, insulated side panels from 1.4301 (AISI 304) stainless steel
- Coolant compressor (reciprocating piston type)
- Air cooler: Heat exchanger, fin type, with 1.4301 stainless steel core tubes, aluminium fins, epoxy resin coated
- Integrated fan for air exchange between Airgenex® and dryer
- Air filter to protect heat exchangers (filter class F7)
- Condensate drain
- Switch cabinet for basic functions



Airgenex® 6.000



Airgenex® 9.500



Airgenex® 15.000

¹⁾For special applications or if required for technical reasons, we also offer the dehumidification modules as a complete stainless steel frame construction.

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 HARTER DRYING SYSTEMS

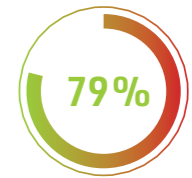
The Airgenex® condensation drying process from HARTER offers a product for this purpose in the context of active pharmaceutical ingredient drying, which offers decisive advantages not only ecologically but also economically:

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

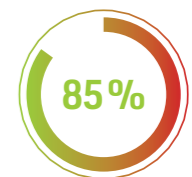
SAVINGS POTENTIAL



Energy



CO₂



DRYING SYSTEMS FOR MEDICAL PRODUCTS

After sterilising, for example, bags, bottles, vials or ampoules stacked in baskets, trays or racks, the aim is always to generate absolutely dry goods to prepare them for immediate further processing. For particularly demanding applications, 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 manufacture and therefore require stain-free, safe and complete drying.

Here, our low-temperature dryers with dry air offer the perfect alternative.



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