HOF-PRODUCTS ...

HOF FREEZE DRYING SYSTEMS
THE SPECIALIST FOR INDIVIDUAL SOLUTIONS

TAILOR-MADE QUALITY, RELIABLE AND FUTURE-PROOF

- VIAL- AND BULK PRODUCTION SYSTEMS
- LOADING/UNLOADING SYSTEMS
- LABORATORY SYSTEMS
- FREEZE-THAW UNITS
- SERVICE

www.hof-sonderanlagen.com

HOF

KNOWLEDGE AND EXPERIENCE YOU CAN RELY ON ...

With over 25 years' experience, HOF Sonderanlagenbau GmbH is the leading specialist in the manufacture of individual freeze drying systems, loading and unloading systems, as well as freeze-thaw units for the pharmaceutical and biotechnological industry.

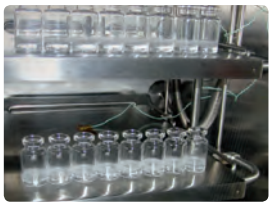
At our company site in Lohra, near Marburg, Germany, highly motivated and specially qualified employees work on the company's own production area of some 12,500 m². A flexible service team keeps close contact with our customers, both nationally and internationally, providing support for the users of HOF systems.

ENSURING FURTHER SUCCESS

In the pharmaceutical and biotechnological environment, quality and reliability are the decisive parameters in determining whether a company will be successful or not. This is guaranteed by using HOF's customized systems, but also because the company's systems technology is developed with an eye on future requirements.

INNOVATIVE CAPACITY AS BRAND ESSENCE

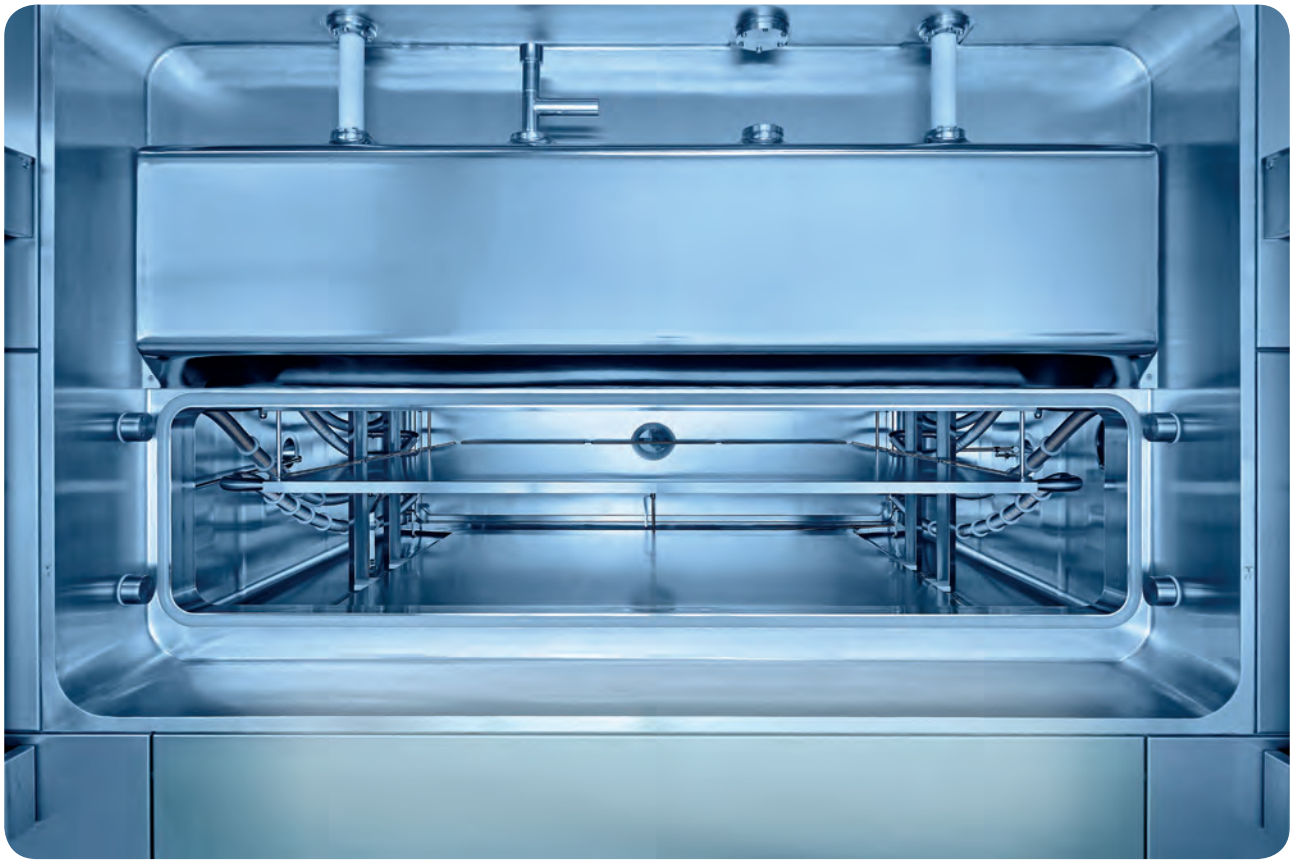
HOF's answer to steadily new customer requirements is: innovation! The company focuses on the search for new and best solutions, always considering one perspective: the customer's perspective. An innovative capacity is essential for the customer's success.



THE HIGHEST QUALITY AT EVERY STEP OF THE WAY

... distinguishes the company, a specialist in individual solutions, since its founding: from the idea to the fully developed plan, all the way to the scrupulous manufacturing of the system, which is customized and convincingly reliable. HOF systems are always a good investment for the future.

HOF - THE SPECIALIST FOR INDIVIDUAL SOLUTIONS ...



HOF-SYSTEMS - LATEST TECHNOLOGY, GAINED IN PRACTICE, FOR USE IN PRACTICE

HOF devices and systems are designed meeting individual customers' challenges and are custom-made. For this and to achieve excellent results, HOF focuses on the latest technologies in the equipment and in the plants. Innovative charging systems, flexible shelf adjustment, use of liquid nitrogen and natural refrigerants, control integration of advanced measuring systems such as NIR and mass spectrometers, HOF SynchroFreeze and vacuum insulation: these are some examples for the company's innovative potential and willingness to take on new approaches.

In many cases, HOF systems distinguish themselves by their innovative character. Many of new developments are patented. There are three words to describe HOF products: future-proof, powerful and practical. All of them are essential in the everyday life of pharmaceutical and biotechnology companies and of blood transfusion services.

INNOVATIVE POTENTIAL – LOOKING FOR THE BEST SOLUTIONS

HOF is renowned for its innovative products that are developed using the latest technologies and much know-how to meet the customer's requirements.

The company deals with the entire plant planning, from the initial design and concept studies, up to the draft of layouts and pressure vessel design, further up to production drawings of individual parts or creation of P&I diagrams. All works are being executed at HOF in-house- in due time and in excellent quality.

The best technique is important- but that is not all. Therefore, HOF provides a service based on the knowledge, the skills and the experience of our employees. For its machines and for its service, HOF is the specialist for individual solutions, its service offers are made case-by-case.

SYSTEMS FOR VIALS AND BULK PRODUCTION – DIVERSITY IN BEST QUALITY ...

FREEZE-DRYERS

HOF is the specialist for individual solutions, therefore the freeze-dryers are designed and constructed according to the exact production requirements and challenges of our customers. Thus, each machine can be installed optimally fitting the structural conditions of the building.

HOF offers a wide range of system sizes, designs and configurations. Essentially, the product range extends from small (approx. 2,5 m² shelf area) to large (75 m² shelf area) systems.

CONFIGURATION OPTIONS

The following configuration options are available:

- vertical design
- horizontal design
- modular technical units, which can be installed according to the building situation
- Door designs such as:
  > single door
  > double doors (opposite each other as pass-through unit)
  > slot door especially for automatic loading and unloading systems
  > slot door integrated in hinged-doors

- The systems can be equipped with various cleaning and sterilization mechanisms used in aseptic processing area and with systems used for decontamination of plant periphery
- Plant systems for drying of products with organic solvents
- Systems for process control and process analysis

- Refrigeration systems:
  > two-level self-contained systems with synthetic refrigerants
  > cascading self-contained systems with natural refrigerants
  > LN2 cooling via heat exchanger for shelves and ice condenser
  > LN2 cooling as direct evaporation for ice condenser

HOF offers several options of vacuum systems for different requirements:

- Oil-sealed rotary vane pumps with or without roots blower
- Glanded pumps with roots blower
- Screw compressors with or without roots blower
- Upstream and downstream exhaust filtration

As the specialist for individual solutions, HOF also offers various system designs for bulk production:

- Systems with fixed shelves for loading with trays
- Systems with hydraulic height-adjustable shelves for easier handling of trays
- Systems with tiltable shelves for cascade filling, which are shaped at the same time as product trays. Here, the product can be reloaded into the system after the CIP/SIP process without having to open the chamber door.

Different unloading systems are also available, which can be chosen according to each individual requirement. Complimentary options are available for vial and bulk production systems.

HOF ACS: AUTOMATIC LOADING AND UNLOADING SYSTEMS – SAFE AND PATENTED ...

The core property of the loading and unloading systems of HOF is the safe, optimal and integrated transport of pharmaceutical products and primary packaging. The variety of models for loading freeze driers range in size from pilot plant to production size and enable the individual customization for any layout.

A new design, adapted to customer-specific requirements, was developed. High performance in connection with reliability is a determining factor in this case.

The performance range covers manual, semi-automatic or fully automatic systems. Special packages, dual-chamber carpules or dual-chamber syringes are transported. Patents for technologies are held worldwide.

VERSATILE AND INDIVIDUAL

The loading and unloading systems are installed and tested in our own production area in combination with the freeze dryer or a specific equivalent dummy. All settings and functions can be tested extensively. This has the advantage that the installation and testing times are shorter at the customers site.

It is possible to upgrade existing freeze dryers with HOF loading and unloading systems and therefore to meet customer requirements. Depending on the requirement it is possible to couple a freeze-drying plant and loading and unloading system with isolator or RABS technology.

BULK- UND VIAL-HANDLING

BULK-HANDLING

Automatic Systems

- Roboter for filling
- Roboter for unloading by suction tube
- Vacuum units for unloading of dried products

Semi-automatic

- Flexible filling systems with dosing pumps
- Flexible filling systems without dosing pumps

Manual

- Filling tubes
- Unloading suction tubes
- Vacuum units for unloading of dried products

VIAL-HANDLING

Frames/Magazines

- Accumulation
- Manual transfer to FD
- Semi automatic loading and unloading
- Automatic loading and unloading

Frameless Row by Row

- Loading and unloading row by row
- Loading row by row
- Unloading row by row
- Unloading in multisegments
- Accumulation for cart systems

Frameless Shelf by Shelf

- Loading and unloading with transfer cart
- Loading with transfer cart
- Unloading with transfer cart

LABORATORY SYSTEMS – OPTIMAL SYSTEM ENGINEERING AND OPTIMAL CONFIGURATION ...

The qualitative high-class and customized HOF's laboratory systems are used by a number of well-known companies and scientific facilities for research purposes and for product and process development.

HIGHLY EFFICIENT PRODUCT RESULTS

HOF offers advanced systems in both compact and split designs with shelf area between 0,2 m² and approx.. 2.5 m². Control, visualization and technical operation are complementary to a production plant. This way, the transfer of the determined process parameters onto the production system is guaranteed and this is the basic requirement for a safe production.

Each laboratory system consists of one fully operative basic unit. Additionally, individual configuration options are at disposal for a customized solution and thus provide the required flexibility for each specific purpose.

TECHNICAL DATA

- Total shelf area: 0,22 m² up to 2,5 m²
- Number of shelves: 3+1 up to 7+1
- Shelf dimensions (mm): 250/300; 420/470; 600/600
- Hydraulic adjustment of the shelves
- Operating voltage: 400 V / 50 Hz
- Shelf cooling from +20° C to -50° C ≤ 40 min
- Shelf heating from -40° C to +20° C ≤ 60 min
- Temperature area from -55° C to +80° C (optional to -60° C)
- Evacuation time from 1000 mbar to 0,1 mbar ≤ 20 min
- Final vacuum: 5 µbar
- Leak rate: < 0,01 mbar*l/s
- Ice capacity: 4 kg up to 40 kg
- Minimal condenser temperature: < 70° C (optional ≤ -75° C)
- Control system: Siemens SPS S7-300
- User interface: HOF Freeze Viewer Professional

FREEZE-THAW UNITS – EXACT PROCESSES AND SPECIFIC SOFTWARE ...

Variable freezing speed and full process control are at the top of the list of specifications when it comes to the freeze-thaw units of HOF. All contents are fully and equally frozen irrespective of the bag size.

Every product bag has the same process conditions at all times and the same shape in the end. Reliable documentation of temperature and time throughout the whole procedure is a matter of course.

The freeze-thaw units of HOF show low energy consumption due to indirect cooling and don't consume any power when idle. The large doors guarantee the ability for rapid loading and unloading. The inner section of the device is made from stainless steel and is easy to clean.

DEVICES FOR BLOOD DONATION SERVICES

Blood plasma must be frozen as quickly as possible: indeed, a temperature of -30° C in the centre of the bag has to be reached within 45 minutes. HOF devices guarantee these values and can hold up to 120 ml of the usual 400 ml bags at any one time.

Blood donation services can use the HOF Freeze Viewer Professional software for documentation purposes. This software records all relevant data sets like temperature sequence, barcodes and notifications, which can then be printed in the form of a report or transmitted electronically to a superordinate data acquisition system.

DEVICES FOR THE PHARMACEUTICAL INDUSTRY IN THE AREA OF BIOTECHNOLOGY

These devices are designed for the controlled freezing and thawing of product bags with a filling volume between 4 and 12 liters. The system's control unit enables to regulate temperature profiles ranging from +40° C to -60° C (optional: with ramp function to -70° C). These devices can make use of the HOF Freeze Viewer Professional control system. This system complies with FDA requirements (21 CFR Part 11) and is equipped with recipe administration, notification system, data acquisition, trend display and report function.

TECHNICAL DATA

- Number of shelves: 5 +1
- Shelf dimensions (mm): 1092/618/17,5
  1250/700/17,5
- Shelf distance: max. 75 mm
- Parallel shelf adjustment (optional)
- Adjustable surface pressure
- Temperature homogeneity of ≤ +/-2 K
- Heating temperature: +40° C
- Min. freezing temperature: -70° C
- Power supply: 400 V / 50 Hz
  (optional for example 60 Hz)
- refrigeration system optional:

  > compressor with refrigeration R404A/R507

  > compressor system with natural refrigeration

  > ethane/propene

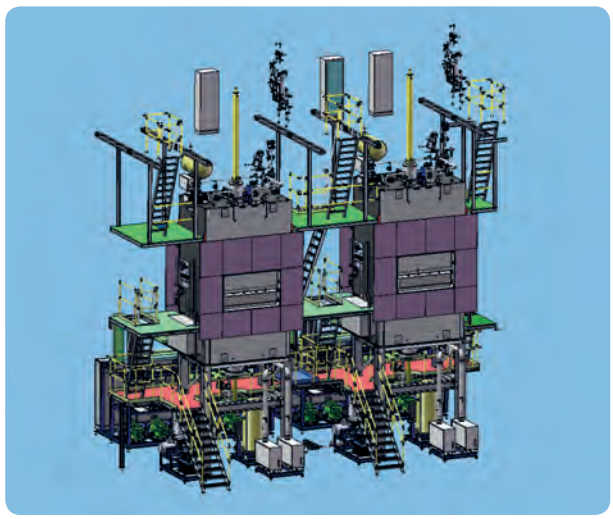
  > liquid nitrogen (LN_2)
- Visualization: HOF Freeze Viewer Professional
- external heat transfer system (optional)

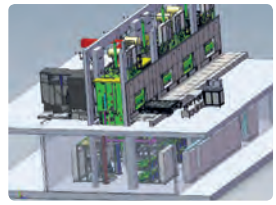
OUR SERVICE FOR YOU - AS INDIVIDUAL AS OUR SOLUTIONS ...

At HOF, only our own employees work on your system, even if the system has left our factory. HOF employees transport your system, assemble it, put it into operation and qualify it, too. This way, interfaces can be minimized and problems eliminated.

24-HOUR SERVICE

You can reach our emergency contact under the following phone number: +49 (0)6462 9169-0. This number is valid 24 hours a day, 365 days a year. Why? Because we know that our systems play an important role in the flow of production and idle times need to be kept to a minimum. Additionally, your emergency team from the Service and Production departments know all the ins and outs of your system and can provide immediate assistance.Our own warehouse with over 60,000 articles makes sure that the most essential spare parts for all systems are quickly available at all times.





QUALIFIED PROCESS DEVELOPMENT

The services provided by HOF include qualified process development and process optimization, which means that our customers can be provided with greater security in these areas. With the help of extensive equipment and an available lab freeze dryer, we are able to support our customers when it comes to answering questions on process management. It may be possible to reduce process times and optimize the quality of the dried products. Among other things, we have devices for measuring resistance and temperature, as well as a cryomicroscope, which enable a comprehensive examination of the pharmaceutical product.

INDIVIDUAL DESIGN AND CONCEPT STUDIES

A coherent concept is always the basis of any successful project. As a specialist in individual solutions, HOF provides the best integration of freeze drying facilities and systems possible, for both, research purposes and for the industry.

TAILOR-MADE AND FUNCTIONAL

These are based on customized concept studies as well as 2D and 3D designs, which, alongside functionality, take other important parameters into account:

Reliability of the system | Easy access for servicing and maintenance | Safety | Investment and availability of the systems | System capacities

OUR SERVICE FOR YOU - AS INDIVIDUAL AS OUR SOLUTIONS ...

QUALIFICATION – GOOD CONDITIONS FOR A RELIABLE PRODUCTION

The employees of HOF perform validation of the systems in a GxP-regulated environment. The company's own qualification department generates the qualification and validation requirements of our systems on a case-by-case basis. This includes:

Functional specification | Project and quality plan | System description | Risk analysis for system-dependent risk scenarios | Hardware-Design-Specification | Software-Design-Specification | Traceability Matrix | Calibration and SAT (Site Acceptance Test) | Qualification documentation for IQ and OQ

COMPREHENSIVE MEASURING EQUIPMENT IS AVAILABLE

The documents are coordinated with the customer and generated according to their specifications documents. Furthermore, the tests scheduled in the qualification documents are carried out by HOF. Comprehensive measuring equipment for calibration and qualification is available. The following parameters can be calibrated:

Temperature | Relative pressure | Absolute pressure | Vacuum Pirani and capacitive | Conductance | Flow rate | and others

During qualification, the validation systems of GE-Kaye, among others, are used when measuring the temperature distribution and sterilization validation. All measurement devices are frequently checked and revalidated to allow a fundamental and precise calibration.

TRAINING SESSIONS – SPREADING THE KNOWLEDGE

HOF's training opportunities combine intense and personal transfer of knowledge with the focus on operational practice. In order to perform a targeted communication of knowledge, HOF offers training sessions, which are individually assigned to the respective companies.

MAINTENANCE – CONTROL IS BETTER

Regular maintenance is needed to keep a system functioning properly. This is why we recommend to carry out yearly inspections as the durability of seals, etc. make this necessary. Logically, a yearly calibration of the measurement equipment and sensor technology should be performed at the same time. Once maintenance and calibration work is completed, documented test runs are carried out on the systems. If additional problems are identified during this phase, executed measures can rectify them. Important in this context: The HOF team is available to work on freeze drying systems of all manufacturers.

HOF AT A GLANCE ...

HOF PRODUCTS

- GMP freeze drying systems
- Pilot freeze drying systems
- Laboratory freeze drying systems
- Loading/unloading systems
- Freeze-thaw units
- Modification and system upgrades
- Automatic control and visualization
- Retrofitting of refrigerants
- Nitrogen refrigeration technology
- Construction of stainless steel piping/orbital welding
- Process development and optimization

Corporate video

HOF SERVICES

- Engineering
- Consulting and application support
- Complete assembly
- IQ installation qualification
- Calibration
- OQ operational qualification
- PQ assistance for process qualification
- RQ requalification measures
- Vacuum leak detection
- Repair and modification of existing systems with GMP-compliant documentation

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