Guaranteed Reliability
Equipment for Pharmaceutical Freeze Drying
For the most stringent pharmaceutical requirements

More security for your product
Sensitive pharmaceutical products often need to be freeze dried to extend shelf life. The Klee brand provides solutions for all requirements with its broad range of machines. From high-tech pilot plants up to high efficiency production plants for vials, syringes, ampoules as single units or in bulk.

Innovative forward-looking technologies
With a policy of continuous improvement in quality management, (EN ISO 9001) Optima Pharma commits to the high standards set by the pharmaceutical industry. Optimized and standardized processes ensure professional project handling. As a technology leader, Optima pharma uses the latest simulation and calculation tools to optimally design and construct the units to your specific requirements. Respective tests are carried out by our technology department. Close cooperation with leading universities and technical colleges gives us edge on training, research and development which is actively supported by Optima.

OPTIMA pharma
For over 25 years, Optima pharma has been providing one of the world’s most diverse and innovative range of machines for filling and packaging of pharmaceutical and diagnostic products. Filling of sterile and non-sterile liquids and powders, pharmaceutical freeze drying and isolator containment technologies are the core competencies.

The broad spectrum of technical design details in the equipment cater towards optimal solutions for human and veterinary medicine, clinical diagnostics, pharmaceuticals and biotech products.

Optima pharma is a constituent part of the OPTIMA packaging group GmbH, which operates worldwide and with over 1900 employees and 13 foreign subsidiaries.

25 years

MILESTONES
1993 Founding of Klee GmbH
2005 Klee GmbH becomes part of the Optima Group
2007 Construction of the new manufacturing and administration facility in Gladbach-Mornshausen
Guaranteed safety

Shelves – „The contact to the product“
- Solid construction in 316L
- Highest quality surfaces finishes
- Save and ergonomic construction
- Mesh reinforced stainless steel flexible hoses “MADE IN GERMANY”
- Highly accurate guidance and positioning system of the shelves
- Mass reduced pressure table in "frame structure" design
- Homogenous temperature distribution

Process technology for effective freeze drying
- Optimized cooling coils for compressors, liquid nitrogen (LN2) and oil
- Effective CIP cleaning in accordance with the stringent VDMA guidelines
- Modern and environmentally friendly cooling media
- Effective vacuum systems (dry and oil sealed), also for ATEX applications
- Sterilizable aeration system, including automated filter test (2 filters)
- High output CIP system with frequency controlled pump technology
- Heat exchanger in the drain system to reduce the waste water temperature and shorten the sterilization time
- Heating and cooling system for the shelves
- Individually adjusted units

- Optima proven technology for a secure product
- Guaranteed quality with comprehensive “all-in” testing prior to shipment
- Reduced energy consumption
- Reduced process time with experienced and intelligent process engineering
- Shortening of the cleaning procedure (turnaround time)

- Pre-configured for performing controlled nucleation
- Wireless temperature measurement (TEmPRIS) is possible
- ATEX / high potency drugs Mass spectrometry
- H₂O₂ sterilization
- CFD simulation (Computational Fluid Dynamics)
- Smoke studies
- Individualized tests

Integrated SCADA System
- Extendable to the complete production line
- Multiple PC stations possible
- Flexible recipe management via SIMATIC Batch for freeze dryers
- Audit Trail
- Autodidactic interface
- Easy to understand batch reports
- Comfortable review of historic trends and alarms
- High scalability
- Simple connection to on-site IT-systems
- GAMP 5
- Programming according to ANSI/ISA-88
- FDA 21 CFR Part II compliant
- Tailored to the high expectations in the pharmaceutical industry

Pharmaceutical Freeze Drying

Guaranteed safety

Pharmaceutical Freeze Drying
Modular design
High degree of flexibility with standardized modules

<table>
<thead>
<tr>
<th>Shelves</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Surface area (m²)</td>
<td>&lt; 2</td>
<td>2–10</td>
<td>10–20</td>
<td>20–30</td>
</tr>
<tr>
<td>Shelf dimensions (mm)</td>
<td>620 × 620</td>
<td>620 × 920</td>
<td>920 × 1220</td>
<td>1220 × 1520</td>
</tr>
<tr>
<td>Temperature range</td>
<td>-60°C to +80°C</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Temperature distribution</td>
<td>1°C per shelf (-40°C / +40°C)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heating rate</td>
<td>1.5°C/h (0°C / +40°C)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cooling rate</td>
<td>1.0°C/h (+20°C / -40°C)</td>
<td></td>
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<td></td>
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</tbody>
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| Chamber / Condensation Unit | | | | | |
| --- | --- | --- | --- | --- |
| Type | P | C.S | C.D.S | C.D.S | D.S |
| Codes | PED, ASME U-Stamp, CEID (China), KOSHA (Korea) |
| CIP | Robust and spray heads – ribolatin test according to VDMA guidelines |
| SIP | 1.5–2.0 bar/g (127–134°C) |
| Surface Area | < 2 m² | 2–10 m² | 10–20 m² | 20–30 m² | > 30 m² |
| Ice Capacity (kg/24h) | < 50 | 50–150 | 150–300 | 300–500 | > 500 |
| min. condenser temperature | -75°C (compressor) / -120°C (LN) |
| Cooling rate | +10°C to -40°C in c = 20 min |

Flexible Chamber Design

- Service door
- Door-in-Door
- Subdoor

1 × Service door for loading and unloading
Principle: Manual and semi-automatic
Use: Vials and frames

1 × Door-in-door for loading and unloading
Principle: Manual and semi-automatic
Use: Vials and frames

1 × Service door on the side
Principle: Fully automatic
Use: Vials

1 × Subdoor for loading and unloading
Principle: Fully automatic
Use: Vials

Chamber and condenser in a single casing or vessel
- Space saving
- Integrated intermediate valve
- Optimized for “multiples” concept
- Capable of push/pull and pass through loading
- Optimized for installation in existing facilities
- Manual or automatic loading possible

Condenser separated from chamber
- Intermediate valve as separate component
- Flexible arrangement of components
- Manual or automatic loading possible
- Customization and integration into building architecture

Intermediate valve as independent component
- 2-floor installation
- Service door on the side is possible (in case of pass through loading/unloading)
- Customization and integration into building architecture

Type C
- Compact
- Single Floor
- Double Floor
- Customizable for future technologies (Mass Spectrometer, Controlled Nucleation)
- Optional CIP / SIP

Type P
- Pilot Plant
- Manual loading
- Up to 2m² shelf space
- Customizable for integration to site architecture

Type S
- Single Floor

Type D
- Double Floor
Your needs are our focus

The design of new plants and the refurbishment or upgrading of existing plants is dependent on many factors. Process requirements, product characteristics and your spatial limitations are all being considered during design. The desired level of automation (manual, semi-automatic or fully automatic) is a key factor in the selection of the loading system. Optima pharma offers exactly the right solution for your requirements.

Manufacture, test, installation and commissioning of loading and unloading systems and freeze drying units can be performed at the facility in Mornshausen.

Loading and unloading systems to meet your unique requirements

**Row-based systems**
Loading and unloading take place row by row. The items are fed and a row of × number of items is prepared and then pushed in its entirety into the freeze drying system. During unloading, each row is individually removed and then transferred to the next machine.

**Frame-based systems**
Loading and unloading take place frame by frame. The items are arranged into vial packs and loaded into frames, which can then be loaded and unloaded in the machine. During unloading, the frames are removed, the vial packs are unloaded and the items are fed to the next machine.

**Shelf-based systems**
The items are pregrouped in a large pack with exactly the same dimensions as a mounting plate in the freeze drying system. This pack is then loaded into the machine in a single step and then unloaded again in a single step. The packs are then removed and fed to the next machine.

Sample facilities
Linear – double L-shape configuration

ADVANTAGES
- Modular construction
- Toolless format changes
- Standardized software modules
- Turnkey

Sample facilities diagram
Service

A Complete Service Program

Process reliability is also a question of service. Even the best machines and lines are subject to a certain extent of wear. With our team of experts and the worldwide available service network of the Optima Pharma, you will reduce the risk of machine downtime to a minimum. Additionally, a 24-hour hotline as well as an extensive spare parts supply within a very short time are at your disposal. Electronic spare parts catalogs, comprehensive technical documentation and operating instructions as well as the teleservice, facilitate the competent handling of trouble-shooting. Service already starts when commissioning the machine.

The Optima Pharma offers you training specifically adapted to your requirements. Incidentally, it is not always necessary to invest in new machinery. Innovative machine upgrades and individual retrofitting packages of the Optima Pharma upgrade your machines to the state-of-the-art. Ask us for a service package meeting your requirements. It will be our pleasure to assist you.

Service Contract

- Tailored service package
- Assurance and control of the service budget
- Flexible – from basic service, to modifications, online monitoring, and complete process optimization
- On-time execution of service
- Maximum output with optimized operation costs
- Expert Training
- General freeze drying process and process boundaries
- Training on automation
- Customer specific properties
- Creation of specific maintenance plans and SOPs
- Process optimization and adjustment of process parameters

Training

LEVEL 1
Basic training
- Basics of freeze drying and equipment
- Basic training of equipment operation
- Error diagnosis
- Basic service and maintenance
- Safety features

LEVEL 2
Operator training
- Learning the main functions of the freeze dryer (SCADA)
- Batch and recipe management (Batch Control Center)
- Using the HMI
- Fault analysis corrective measures
- Preventive maintenance according to the operation manual

LEVEL 3
Technician Training
- Workings of the freeze dryer in-situ
- Service and preventive maintenance
- Corrective measures

LEVEL 4
Expert Training
- Increasing uptime with specially trained machine operators
- Faster fault analysis with trained technicians
- Effective communication through knowledge base
- Reduced cost thanks to planned preventive maintenance
Preventive Maintenance of the Freeze Dryer

Keeping stable processes up to date with regular maintenance intervals

Everything in sight: Preventive maintenance checks and takes into account all components of the freeze dryer. New and future needs are taken into consideration for upgrades.

Scope of Delivery

- Equipment-specific documentation for inspection and service
- Equipment specific documentation for PC-Service
- Preventive exchange of defined wear parts
- Identification of the most critical replacement parts prior to maintenance or inspection
- Standardized scope and reproducible processing
- Re-qualification (calibration) of measurement systems
- Assessment of electrical and mechanical functions
- Identification and review of required repair and maintenance requirements
- Identification of deficiencies and risks
- Consideration of „Lessons Learned“
- Shelf temperature distribution measurements, sterility assurance distribution measurements

Professional maintenance ensures that your freeze dryer remains up to date for current and future needs. Our team of qualified and experienced service personnel can make recommendations for suggested and required modifications.

Spare Parts Service

Safety in every process step

Optima pharma commands a large spare parts stock and offers fast service. Individual concepts for stocking spare and wear parts are a further cornerstone of equipment reliability.

Scope of Services

- Information on cost and delivery of spare parts
- Personalized consultation for first set of spare parts and of wear parts
- Parts catalog on CD-ROM
- Fast service for manufactured parts
- Guaranteed quality
System Integration – Closely Coordinated

Modern building infrastructure

for the installation and operation of the units under real conditions. Single floor as well as dual floor units can be built and installed to mimic the architecture of the final site, thereby allowing simulation of potential conflicts prior to site installation. The installation / de-installation as well as the transport is fully prepared in the factory. The units are shipped in sealed trucks. This ensures optimal delivery at the installation site and speeds the installation on-site, saving valuable time to commissioning and production.
More information:
www.optima-pharma.com