





PASSION FOR EXCELLENCE

For more than three decades our strong customer focused approach and the continuous quest for world class quality has enabled us to attain and sustain leadership in all our major business lines. We strive to enhance the quality of life by offering comprehensive sterilization and pure water / steam solutions for the Life Science, Healthcare and Food industry.

Machinfabrik is committed to lead from the front. We understand the challenges you are facing: growing concern about risk management, healthcare liability, shrinking budget, stringent documentation requirements and the need to have standardized policies and procedures. To achieve this we put our leadership, products, services and knowledge ready to work for you.

Machinfabrik's business philosophy is based on a coordinated technology to offer complete solutions at different levels: project design, equipment selection, machine design and manufacture, technical assistance and after sales services. The basis for coordinated technology is finding the needs of the customer and analyzing requirements thus creating a background of idea which eventually shapes into a prototype for thorough trials and leading to the final product.

We have one single goal: to build the best machines. Some might find this conceited, but it is rooted in well established values & confirmed by thousands of successful references. One of these is the courage to promise, no matter how small or great.

INDUSTRY VERTICALS

LIFE SCIENCE

Today, Machinfabrik is a leading solution provider to the Lifescience Industry for a wide range of sterilization / disinfection / cleaning technologies, systems for generation of WFI and Pure Steam.

This technology is backed up by decades of expertise and knowledge shared with process engineers, microbiologist, quality control and validation personnel and end users.



HEALTHCARE

Hospital infection control is a priority agenda for every Administrator today. Machinfabrik has the complete range of products and services for Hospital infection control.

- Cleaning and Disinfection Accessories- Spray Gun Rinsers, Washing Stations, Ultrasonic Cleaners, Washer Disinfectors, Drying cabinets and OT Scrub Stations.
- Packing Accessories – Control and Packing Tables, Heat Sealing Machines, Instrument Inspection Lights and Packaging Materials.
- Sterilization Systems – Steam Sterilizers, ETO sterilizers, Plasma Sterilizers, Flash Sterilizers and Table Top Sterilizers.
- Storage and Transportation Accessories - Work Tables, Linen Fold Tables, Storage Cabinets, Baskets, Storage Racks, Pass Boxes, Table Trolleys, Distribution trolleys, Basket Trolleys and Instrument trays.



FOOD & BEVERAGE

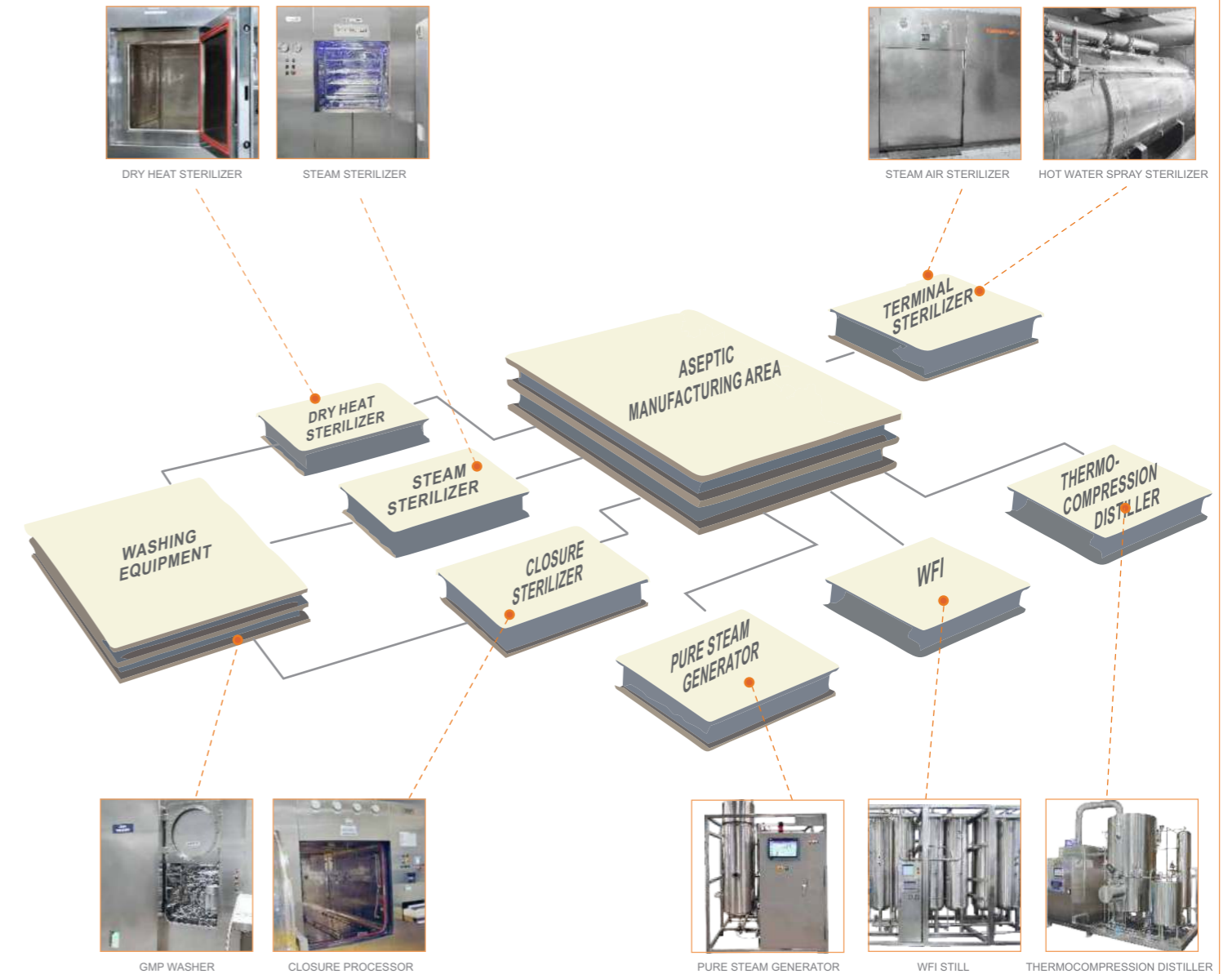
The constant diversification and increasing range of food and beverage products call for a high degree of flexibility and innovation.

Machinfabrik's range of "AQUACLAVE" Retorts are designed for sterilization, pasteurization and heat treatment of packaged food products (Ready to eat meals, meat, poultry, fish, fruits, vegetables) and dairy products (flavoured milk, fresh cream, fresh milk) in a variety of containers – laminated pouches, PP bags, plastic / glass bottles.

The "AURACLAVE" is a custom built system for spices, herbs, nutraceuticals dehydrated vegetables, seeds, etc. The system uses specially treated low moisture steam and an effective moisture trapping device for ensuring dry and free flowing product after treatment to provide you the highest degree of microbial reduction.

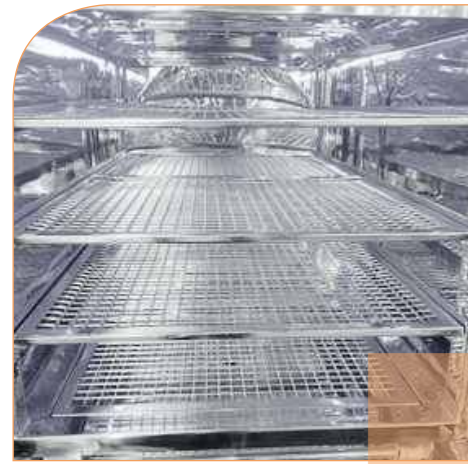


COMPLETE STERILE PROCESSING SYSTEMS



Machinfabrik's Life Sciences division provides solutions which help prevent contamination at virtually every critical point in your manufacturing process. Our systems are specially designed to answer the contamination challenges associated with regulated pharmaceutical environments, including research laboratories, aseptic processing and bulk biopharmaceutical manufacturing.

Our expert resources offer integrated solutions to help you achieve faster process validation, more efficient operations, and greater cost control. We also provide onsite training and technical support to keep your employees updated with regulatory compliance issues, product safety and new technologies and protocols. Our support is available when and where you need it through our widespread service network and broad distribution channels.



STEAM STERILIZER

EN285 compliant with unparalleled features.



RELIABLE, ACCURATE & EASY TO MAINTAIN

The production programs in the pharmaceutical industry are aimed at maximum safety, top quality and high economy. This applies in particular to the sterilization process.

Steam Sterilizers continue to be one of the most ancient but widely used sterilization techniques in the Life Science and Healthcare Industry. The process systems now have to meet the most exacting demands for Temperature and Pressure / Vacuum control and process documentation.

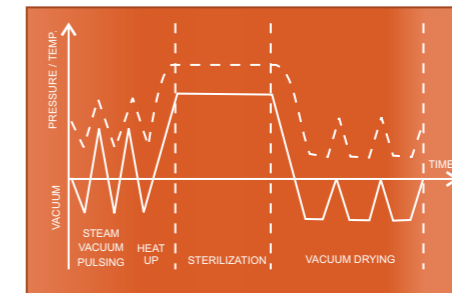
A sterilization system represents a large capital investment. Therefore, Machinfabrik takes measures to ensure that our Sterilizer provides true value with regards to design, performance and life cycle economy. Every sterilizer is produced to your specifications and needs. Flexible options allow selection of the right equipment for specific sterilization load and packaging.

APPLICATIONS

- Solid materials.
- Porous materials like garments, fabrics, etc.
- Closures, vessels, machine and change parts.
- Empty glassware, utensils, instruments.
- Solutions in glass ampoules, vials & bottles.
- Filters and respective accessories.

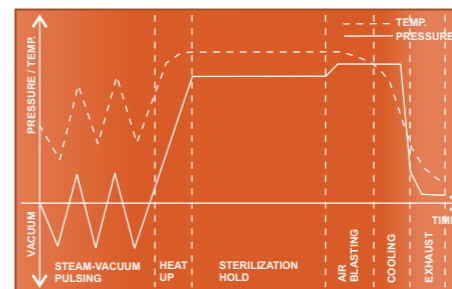
PRE VACUUM STERILIZATION

- Uses mechanical air removal with the help of vacuum pulses.
- Excellent temperature uniformity and good steam penetration because of the absence of air pockets.
- Excellent vacuum drying of the load.



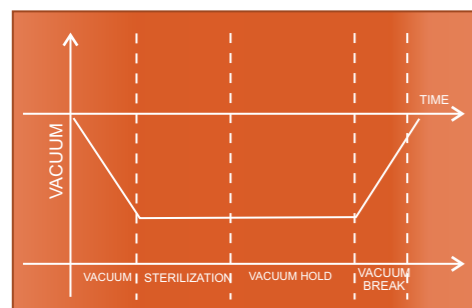
RAPID COOLING STERILIZATION

- Terminal Sterilization of ampules and glass bottles to achieve faster cooling.
- Automatic regulation of counter pressure using compressed air for superior closure integrity.
- Fast cooling by water spray.



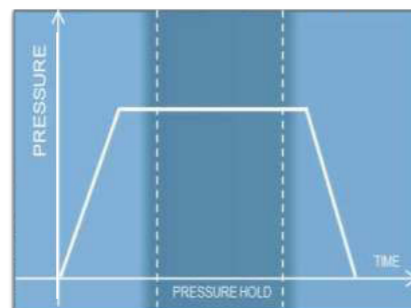
VACUUM LEAK TEST

- Checks the integrity of the sterilization system under vacuum.
- Our systems have a leakage rate less than 1.3mbar/min.



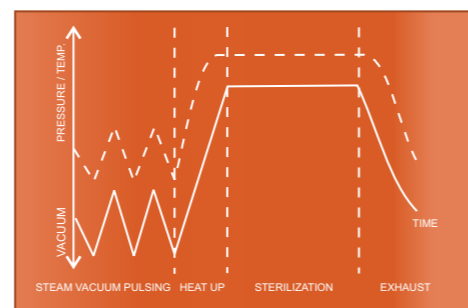
PRESSURE LEAK TEST

- Checks integrity of the chamber under operating pressure condition.
- Automatic program checks the system leakage against a pre-defined leak rate of 1.3 m bar/min.



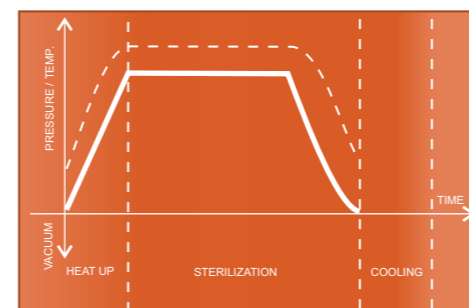
BOWIE DICK TEST

- Test program to validate the efficacy of the system to remove air and ensure penetration of the steam.
- Carried out with standard test packs at fixed intervals to challenge the system efficiency.



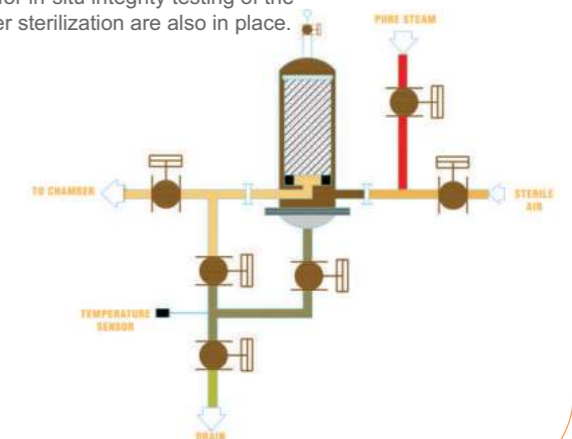
GRAVITY STERILIZATION

- This technique uses the method of gravity air removal to ensure uniform steam distribution and penetration.
- Special venting system ensures maximum air removal.



SIP FOR AIR FILTER

- A validated program with batch record for sterilization and subsequent drying of the air / vent filter.
- Fittings for in-situ integrity testing of the filter after sterilization are also in place.





HOT WATER SPRAY STERILIZER

Fast heat transfer, excellent temperature
uniformity & precise counter pressure



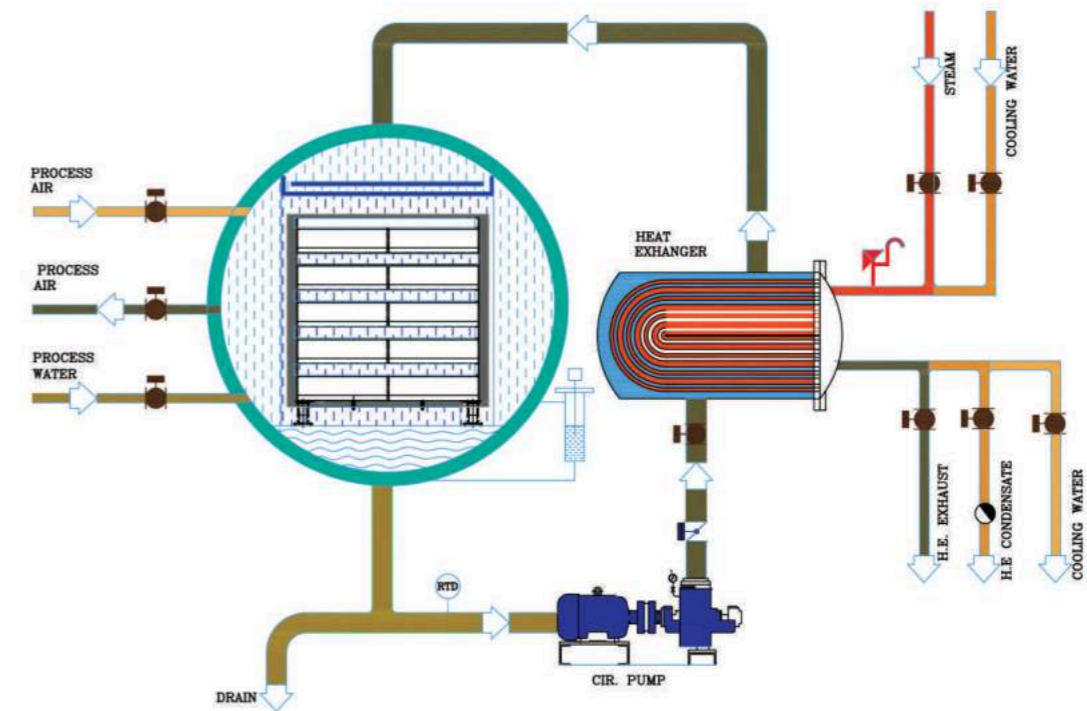
THE SUPERLATIVE TERMINAL STERILIZER SYSTEM

The principle that terminal sterilization provides a higher degree of sterility assurance than aseptic processing is well understood and leads regulatory agencies around the world to require that if the product can be terminally sterilized, it must be. The technology of hot water sterilization with counter pressure has been developed specifically for the terminal treatment of solutions in sealed containers.

The working principle is based on automatic counter pressure by injecting of compressed air into the chamber during the entire cycle, to minimize the differential pressure across the containers generated by exposure to heat. The water shower

over the product ensures that a uniform temperature distribution is maintained throughout the chamber during the sterilization phase.

The high-volume water circulation rate and the two-stage water distribution system ensure accurate and homogenous temperature distribution in the product to be sterilized. Since the water comes into physical contact with the container, the heat transfer is more efficient and the process efficiency is not affected by air pockets. The pressure in the chamber is continuously adapted to the internal pressure of the containers and the entire process can be controlled easily and accurately.



APPLICATIONS

- BFS bottles
- Bags
- Glass bottles
- Vials
- Ampoules

SUPERIOR CLOSED LOOP SYSTEM

Sterilization process uses a closed loop system for the process water, that is sterilized during the process and hence presents no hazard to the product. This ensures compliance towards regulations for cooling for sealed containers during sterilization.

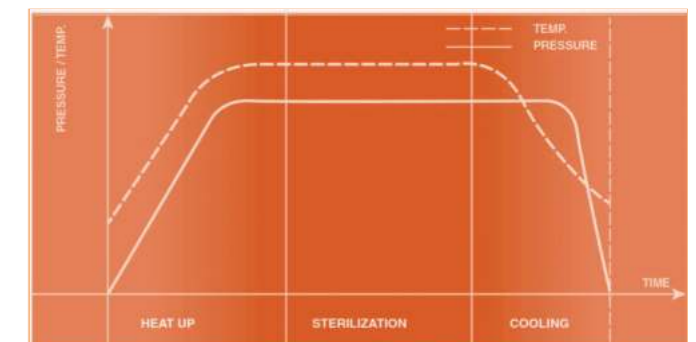
EXCELLENT HEAT TRANSFER

The homogenous water shower over the product ensures a uniform temperature distribution is maintained throughout the chamber during the sterilization phase.

Moreover, since the water comes into physical contact with the container the heat transfer is more efficient and the process efficiency is not affected by air pockets, a problem common with steam.

PRESSURE COMPENSATION SYSTEM

Steam Sterilizers have a serious drawback when sterilizing flexible containers, constant temperature pressure relationship in these systems result is the flexible containers collapsing or bursting during the process. In our sterilizers the temperature and pressure can be independently controlled depending on container material, size and the liquid being sterilized.





STEAM AIR STERILIZER

The most versatile sterilization system for all your needs.

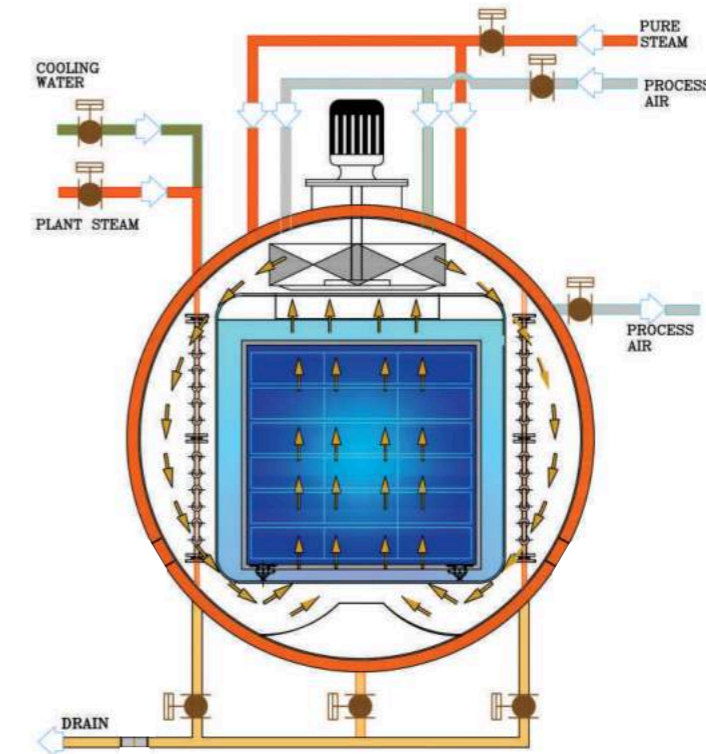
Steam -Air Terminal Sterilizers are designed primarily for sterilizing products with flexible and delicate packaging that requires counter pressure throughout the sterilization phase. Another significant advantage is that the product is dry and ready for further handling immediately after the unloading.

Sterilizers a separate medium is used for heating (steam) and pressurizing (air) and thus the relation can be varied. Due to this we can achieve a chamber pressure which is higher or lower than the corresponding steam pressure for a given temperature. Hence this system helps to overcome the drawbacks associated with conventional Steam Sterilization systems.

In a Steam Sterilizer, the temperature and pressure relationship is always pre-defined. In Steam- Air



DYNAMIC FLOW FOR EXCELLENT TEMPERATURE UNIFORMITY



APPLICATIONS

- LVP in glass or plastic containers
- Ointment Tubes
- Preilled syringes
- Ampoules, Vials and Glass bottles
- Blister packed products
- Blood bags

HEATING / COOLING EXCHANGERS

Heating and cooling heat exchangers consists of finned tubes fitted in the annular space between the inner and the outer chamber. This system besides ensuring a homogenous air and steam mix also helps to heat the cold air during the heating and drying phases and cool the air during the cooling phase.

CIRCULATION TURBINE

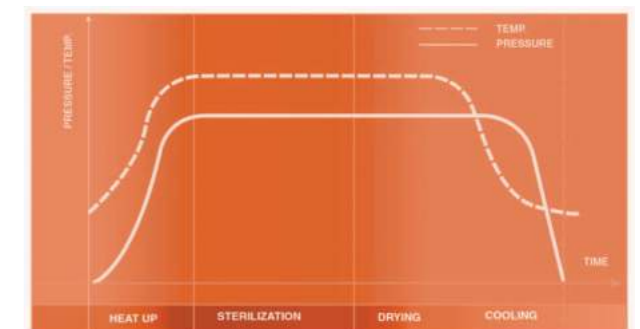
The circulation turbine is provided for mixing the air/steam mixture and imparting a velocity to the heating/cooling medium. This comprises of stainless steel centrifugal blower driven by an electric motor through a leak proof mechanical seal. The mechanical seal is provided with a seal cooling arrangement to withstand the high temperature operation.

EFFECTIVE & UNIFORM HEATING

The circulation turbine besides helping to mix the air and steam also imparts a velocity to the heating and cooling medium. This higher velocity not only ensures more effective heat transfer but also better penetration of heat thereby guaranteeing superior temperature uniformity for higher sterility assurance.

PRODUCT DRYING

The combined advantage of the heating/cooling exchangers and compressed air allows the user to program post sterilization drying and cooling phase. This phase ensures minimal fogging of plastic packaging material (eg. PVC Bags) and ensures that the product will be dry when unloaded.





CLOSURE PROCESSOR

Dual operation with aggressive but gentle cleaning.



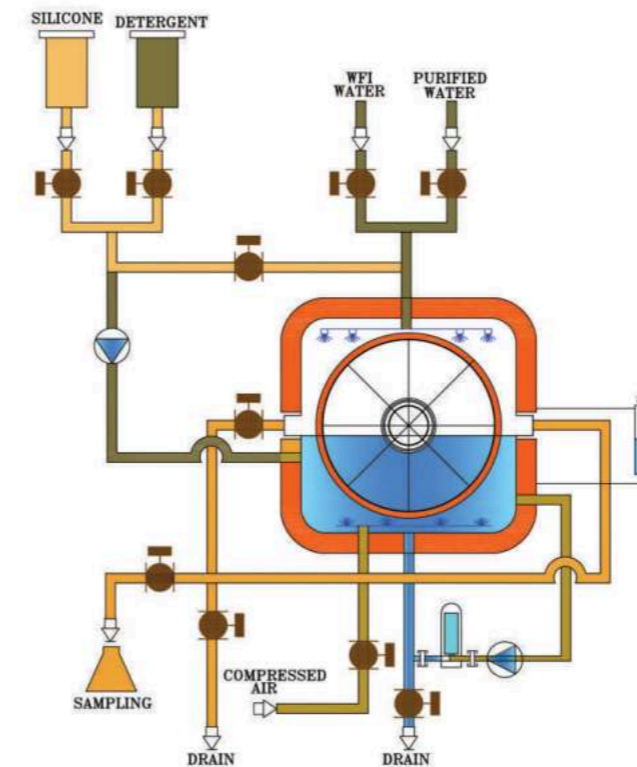
EFFECTIVE FOR ALL ELASTOMERIC CLOSURES

Processing of elastomeric closures is of high concern since they play a significant role in the quality and life of the final product.

The need for correct processing technology is even more important considering the complexities in the compounding of elastomers used for the closures

and the non-compliance to GMP by the manufacturers of these closures.

MachinFabrik Closure Processing System is designed for the complete treatment of sealing devices for pharmaceutical products, rubber stoppers, metal rings and similar products.



WASHING

- Washing with detergent
- Rinsing with Purified Water
- Final rinsing with WFI



SILICONIZATION

- Siliconization with silicon emulsion



STERILIZATION & DRYING

- Steam Sterilization
- Vacuum drying

TRIPLE PUNCH CLEANING SYSTEM

- A fluidization system with sterile air for mild turbulence of the closures.
- An overflow system for removing the floating scum and dirt from the closures.
- Finally, a recirculation system with filtration for eliminating the dirt released during the process.

DUAL OPERATION SYSTEM

The Closure Processor is designed for a unique dual operation and works as a Steam Sterilizer to save investment and space.

DRIVE SYSTEM

- Friction drives to prevent direct metal to metal contact for superior processing.
- Specially developed gears to ensure no particle generation during the process.
- A customized non-lubricated mechanical seal for pressure and vacuum tight operation of the driving system.

ONLINE PROCESS VALIDATION

- Sampling ports for online monitoring of the cleaning efficiency.
- Temperature and pressure ports for monitoring and validating the sterilization process.

ROTATING CARRIAGE

- Ensures smooth and easy loading and unloading.
- The design guarantees effective cleaning and sterilization of elastomeric closures.
- Maximum perforation and adequate unfilled volume guarantees superior cleaning action.

AUTOMATIC UNLOADING SYSTEM

- Stoppers are unloaded in the clean room under a fixed laminar flow unit without operator intervention in pre-sterilized containers or bags.
- The Unloading System is docked to the rotating carriage and the rotating carriage is rotated in the reverse direction for unloading the closures.





CONSTRUCTIONAL FEATURES

Innovative design and construction features to safeguard your business.

All Sterilizers look alike from the outside- a grey stainless steel box. The difference is what is inside the box.

Machinfabrik's Sterilization Systems are designed and constructed for sanitary pharmaceutical applications which require strict compliance with cGMP. Production systems are ISO: 9001 certified and all appropriate regulations for safety, pressure vessels and the environment are rigorously followed.

With a constant quest for new technology, design plays a dominant role. Our engineers are constantly exploring new solutions, able to anticipate technological development, to offer the best results. Careful attention is given to the selection of mechanical components and instrumentation to guarantee the highest level of performance. Every step of the production process follows rigorous manufacturing routines leaving nothing to chance.



1 PRESSURE VESSELS

The pressure vessel is a key component of the Sterilizer and is provided with comprehensive documentation which includes Weld Qualification, Radiography Testing, Surface Finish Profile, Material testing and Hydro-testing.

The inner walls have a surface finish better than 0.8µm. All rounded and sloped surfaces are designed for complete drainage. All nozzles and connections are fabricated from seamless, tubes for best hygiene and pressure security.

The chamber is equipped with a Jacket for providing strength to the chamber and for temperature regulation inside the chamber for heating, drying and final cooling by recirculating water.

2 DOORS

In the entire machine, the costliest (depending on the size of the autoclave) and most important single piece of hardware is the fast-opening door. They can be of Automatic Sliding type or of the hinged type with single or double door configuration. The tightness of the Pressure Vessel is ensured by the gasket which is seated in a groove fabricated into the chamber frame and is pressed by compressed air or steam against the door. For opening of the door the gasket is retracted by vacuum.

3 METALLURGY & FABRICATION

The fabrication of the pressure vessel is the most important activity in the manufacture of sterilizer. We have a team and well equipped facility for in house fabrication of pressure parts and this ensures we have complete control over the quality. All material used is properly identified and tested. All welders are qualified and welding documented. Proper in-process inspections and tests guarantee the required result of the fabrication process.

4 SPECIALIZED PIPING

In construction of a Sterilizer the piping defines the various processes the system can run and hence the product/loads which can be processed. Sterilizer piping is fabricated from sanitary laser welded pipelines with a surface finish better than 0.8µ. All pipe fittings elbows, tees, reducers etc. are also manufactured from prime stainless steel procured directly from steel mills. All process piping is welded using automatic orbital techniques and can be electro-polished on request.

5 VALVES & COMPONENTS

The accuracy of the sterilization process depends on the quality and reliability of critical components like valves, steam traps, safety valves, vacuum pumps, circulating pumps etc. All parts are procured from qualified and internationally recognized suppliers and accompanied by test / calibration reports.

6 VACUUM SYSTEM

The sterilization systems are provided with water ring or oil sealed vacuum systems as the application requires. The water ring systems can be optionally provided with a water saver arrangement which besides reducing water consumption also ensures consistent vacuum performance.



7 MEASUREMENT SENSORS

In any sterilization process key parameters – temperature, pressure, time etc. need to be accurately monitored, indicated and controlled. Special care is taken in selecting each sensing element. Our process and quality engineers are focused on ensuring that each sensor is properly tested, calibrated and installed.

8 IN BUILT CLEAN STEAM GENERATOR

Small or medium Sterilization Systems can be provided with an integrated Clean Steam Generator which is electrically operated or heated by boiler steam. This offers a compact and cost effective solution.

9 AIR DETECTOR

The air detector is an automatic device that operates during each cycle of operation to provide additional assurance that excess air (and/or non-condensable gases) does not remain at the end of the air removal stage to adversely affect the sterilization process. The chamber drain is fitted with an Air detector Device to generate an alarm in a situation of ineffective air removal from the chamber. The design complies with all requirements of EN285.



DRY HEAT STERILIZER

Robust construction and reproducible performance for your stringent processing

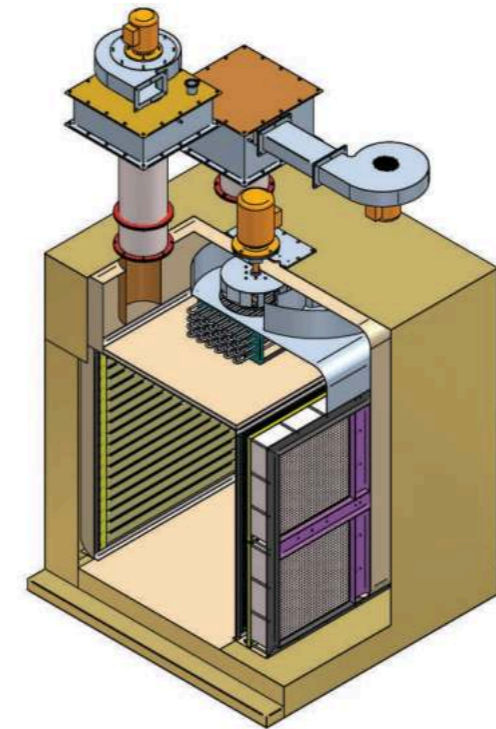
Sterilization by Dry Heat has become increasingly popular worldwide due to two reasons: first the need to sterilize small objects, particularly ampoules, syringes and secondly for de-pyrogenation of manufacturing apparatus which is not possible in a Steam Sterilizer.

Another advantage of this method of sterilization is that objects which can be damaged by water or steam e.g.; powder or ointments can be sterilized provided the heat penetrates to all parts of the substance.

The distinctive feature of these sterilizers lies in particle contamination class. We ensure a particle contamination level in the chamber that does not exceed the values prescribed by Class 100; not even during transient phase, such as heating and cooling during which the filters can release considerable amounts of particles, due to temperature-related deformations. Special air flow technique guarantees over-pressure in the chamber throughout the cycle thereby assuring sterile integrity of the load.



THE DEPYROGENATION SPECIALIST



OPERATING PRINCIPLE

These sterilization systems guarantee sterilization with 12 log reduction and depyrogenation with 3 log reduction. The cycle comprises of the following stages:-

- The exhaust phase has been designed for moisture removal from the washed load.
- The heat-up phase increases the temperature of the load from ambient temperature to sterilization temperature.
- The sterilization phase [maximum temperature 275° C] consists of a stabilization period, sterilization hold time and a safety hold period.
- Cooling phase cools the product from sterilization temperature using rapid air.
- Unloading phase continues to maintain over-pressure in the chamber as a containment barrier.

APPLICATIONS

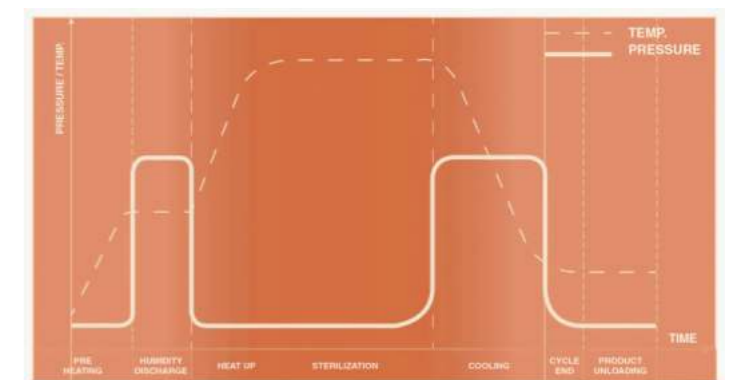
- Empty Glasswares like ampoules, vials, bottles etc.
- Containers and Metallic Components
- Thermostable basic pharmaceutical products and chemical compounds.
- Non-aqueous liquid material like oils, glycerin, etc.
- Material Sensitive to humidity

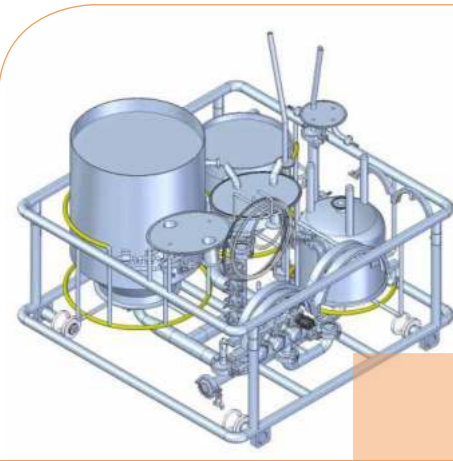
CONSTRUCTIONAL FEATURES

- cGMP compliant easy to clean SS 316L interior with smooth surface and rounded corners.
- Special gasket system to avoid any air release or cross contamination between the chamber and the external environment.
- Semi- automatic hinged doors or automatic sliding doors.
- Expansion compensation structure which prevents thermal vibration.
- Incoloy sheathed heating elements for reduced particle generation and longer life.
- Fresh air controlled cooling cycle.
- Monitoring ports for testing fresh air, exhaust, recirculating HEPA filters and validation ports for temperature mapping.
- Automatic self- regulating pressure balancing.
- Exhaust flap with pneumatic actuation and specially designed silicone ring seal for zero leakage.

AIR CIRCULATION SYSTEM

- The efficiency of the Dry Heat Process depends on the velocity and circulation pattern of air within the sterilization zone.
- Improved impeller drive system with high temperature resistance and designed for low vibration and sound.
- Dynamically balanced, high flow and high static centrifugal blowers.
- High temperature HEPA filters (0.3µm, 99.97%) for Class-100 environment during operation.
- Positive pressure throughout the process for high sterile integrity.





GMP WASHER

Effective & flexible cleaning with comprehensive validation support



UNIQUE MULTIPURPOSE ARCHITECTURE

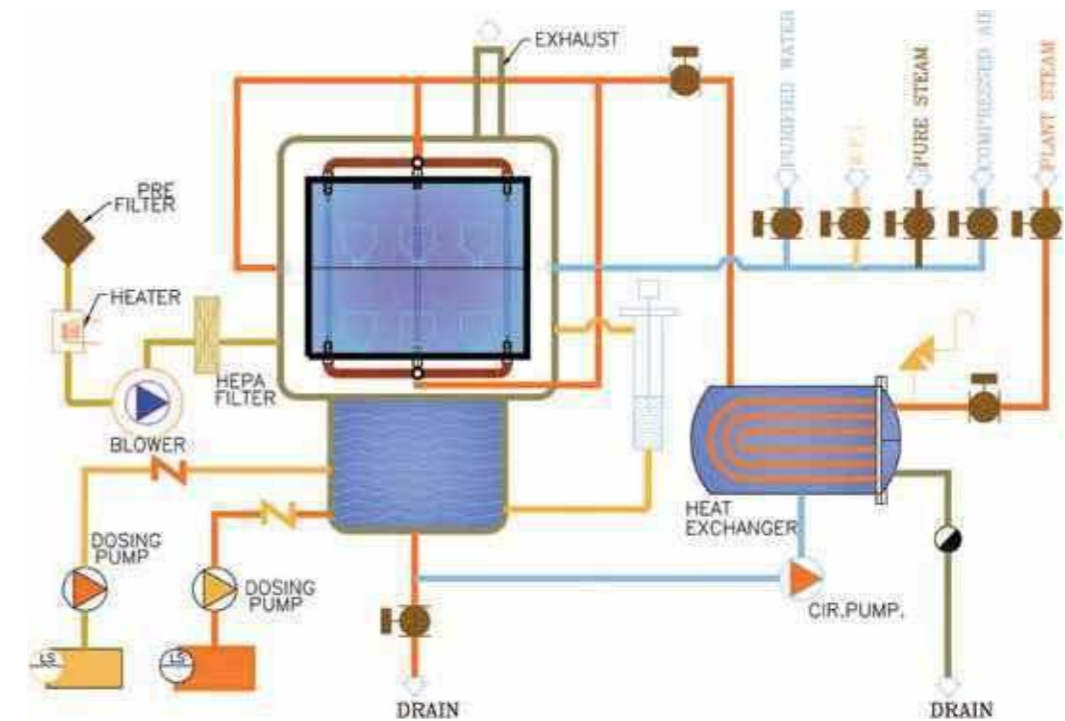
All areas of production in any pharmaceutical company increasingly demand qualification and documentation of the cleaning carried out.

Years of experience with international customers has made MACHINFABRIK a reliable partner for validated cleaning. Our washers have been designed to meet and exceed the growing cGMP requirements of the Biopharmaceutical industry. Working in cooperation with users, our equipment has been developed to satisfy the unique demands and stringent regulations

of the industry. We can provide a complete solution supported by need analysis and system design to suit your requirements.

Our systems are based on compatible modular units that can quickly be integrated and installed to form complete customized solution to satisfy your needs.

All machines are based on high-performance cleaning modules with a rinsing system and an integrated air drying system.



APPLICATIONS

PHARMACEUTICAL PRODUCTION

- Glass bottles
- Containers
- Filling Machine Parts
- Fermentors
- Pump Parts
- Filter Housings
- Carboys

LABORATORY

- Glasswares
- Pipettes
- Test Tubes
- Petri dishes
- Sterility Manifolds

CLEANING SYSTEM

- High volume of the cleaning fluid at accurate pressure to ensure a gentle but effective washing action.
- External cleaning via rotary spray arms at the top and bottom of the cleaning chamber.
- Internal cleaning via nozzles on Loading Carts.
- Automatic detergent/ chemical dosing system.

INTELLIGENT DESIGN

- The cleaning chamber has round corners and sloping bottom.
- All surfaces are polished and have smooth weld seams to avoid contamination.
- All piping, valves and fittings have special sanitary design to ensure minimum dead legs.

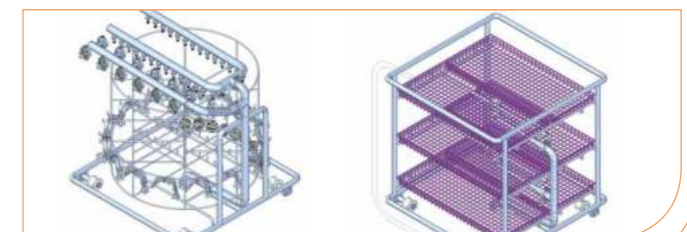
WASH PROGRAM

- Flexible user friendly wash program to meet your specific needs.
- Cold PW / DI water flush for preliminary cleaning.
- PW/ DI water recycled rinse with detergent for aggressive cleaning.
- PW/ DI water recycled rinse with or without acid/ alkali treatment.
- Final rinse using WFI with conductivity control. This procedure can be repeated automatically or extended until the measured value falls below the predefined limit.



GMP DRYING

- The system comprises of a fan, Pre-filter, H13 HEPA filter and heating system with this filter as the last element in the air-flow.
- Independent air flow paths for internal and external drying of all components.





WFI STILL

Minimal steam & cooling water consumption ensuring low operating cost.

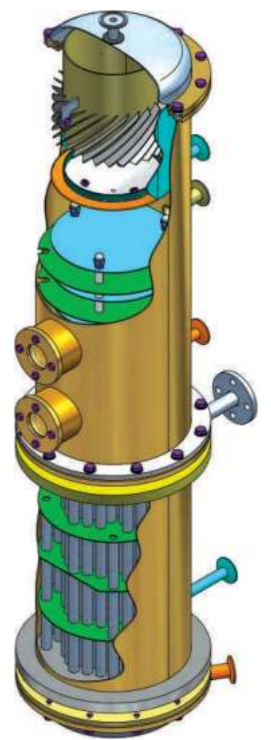
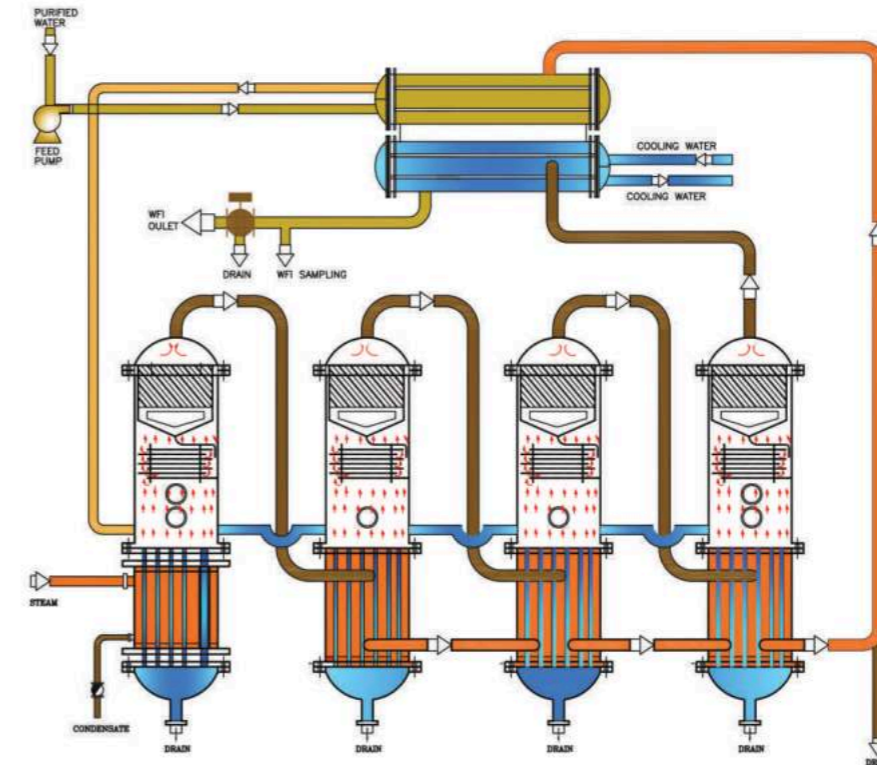


SANITARY BY DESIGN, ASEPATIC BY CHOICE

All Pharmaceutical production processes require a stable & consistent supply of quality controlled water for applications ranging from non - critical processes to product formulation. The most important equipment in any Pharmaceutical Plant manufacturing injectable solutions is the WFI Plant. Our WFI Still produces distillate that meets the current U.S. and European Pharmacopeia for Water for injection guidelines equipped with a range of features to ensure that your installation

and qualification is quick & trouble - free and that your WFI production remains efficient and reliable throughout your unit's life.

Our WFI Still is designed with efficiency in mind as the system recovers the latent heat of vaporization occurring within its own process to heat feed water and uses the feed water as the primary source of cooling, resulting in cost and energy optimization.



UNIQUE TRIPLE PUNCH PYROGEN ENTRAINMENT SYSTEM

At the feed water evaporation surface the velocity of the generated vapor is kept very low. This ensures that heavier water droplets are not carried along with the vapor and the water droplets separate out from the rising vapor. Unevaporated feed water and large droplets are separated and fall to the bottom of the column. This effluent (approx. 5-10%) is continuously discharged to drain as blowdown.

The vapor then enters a series of multi-direction baffles where the path of low of vapor is rapidly altered. The water droplets cannot change path and strike the baffle plates and drain to the bottom of the column.

Finally the clean steam enters the cyclone chamber and accelerates at high velocity within the chamber. This centrifugal action further removes water droplets and impurities, which get drained to the base of the cyclone chamber and from there to the base of the column via a discharge port.

HEAT EXCHANGER

The unique feature of our WFI Still is the heat exchanger design. The entire heat exchanger is submersed below the feed water and the heating steam at constant temperature in the entire column allows free and uniform expansion of the heat exchanger tubes and jacket. This guarantees minimal stress within the heat exchanger material and the welding. Furthermore since the heat exchanger is completely immersed and the feed water tubes are always wet, scaling is kept to a minimum.

The heat exchanger used in the first column is a "Double Tube Sheet Design" as per USP requirement. All other columns have shell & tube heat exchangers. The heat exchanger has a special "Down Pipe" to ensure that no water stagnates in the column during operation.

SUPERIOR PERFORMANCE FEATURES

- Low vapour velocity ensures less carryover of impurities.
- Triple punch pyrogen entrainment system ensures highest purity.
- Unique heat exchanger design ensures minimal stress and hence longer life.
- Automatic feed water control to prevent column flooding.
- Conductivity monitoring and control for feed water and WFI.
- Online temperature monitoring for WFI.
- Utility monitoring for easy diagnostics.
- Interface circuits for integration to the storage system.
- Auto-purging to ensure minimal contamination built up.
- Self-sterilization or sanitization program.
- Sampling valves for comprehensive quality analysis.
- All elastomers in contact with feedwater and product are provided with USP Class VI certification.
- No moving parts, thus minimum maintenance.

DUAL OPERATION

All Machinfabrik WFI Stills can be configured to produce Pure Steam from the first column. This offers a unique solution delivering optimum capital investment and space saving design. The Pure Steam Generation option is provided with all standard features - automatic pure steam pressure regulation, pure steam sampling, pure steam conductivity monitoring and many more.





PURE STEAM GENERATOR

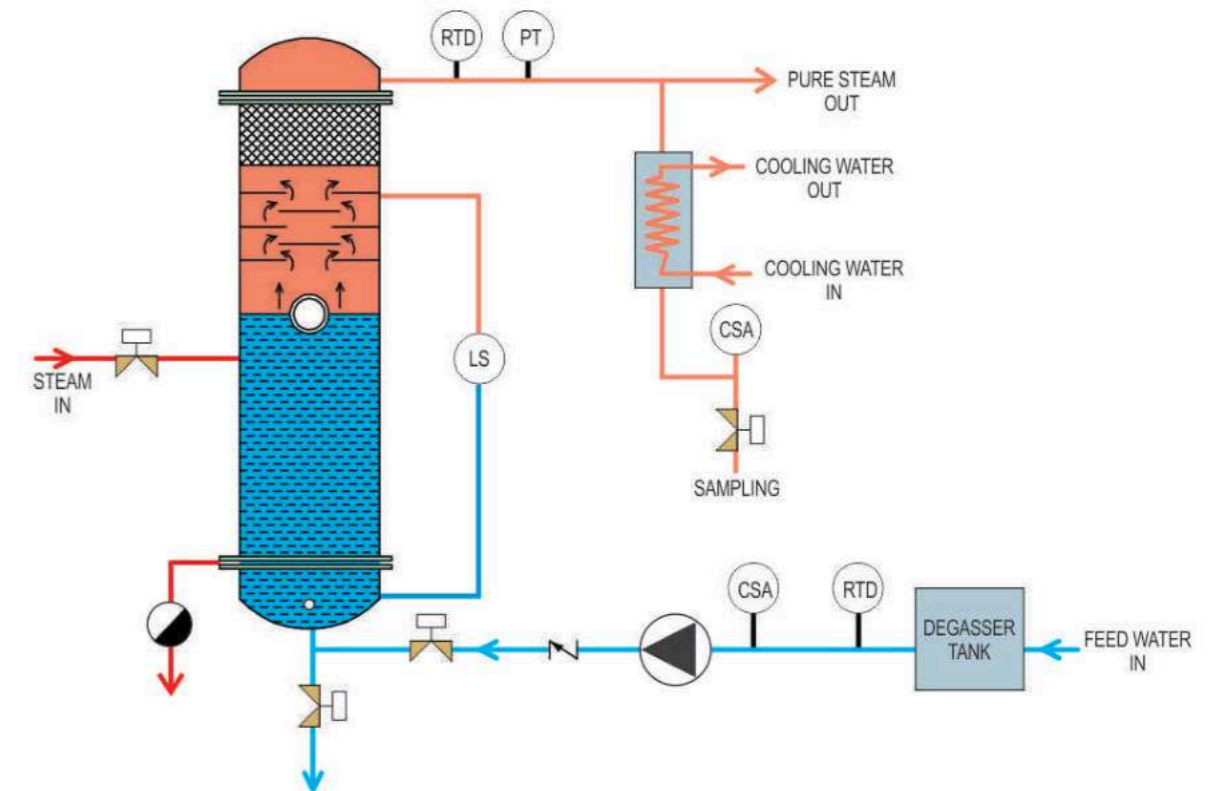
Sterile Pyrogen steam.
When clean steam is not enough



EN285 COMPLIANCE GUARANTEED

As the pharmaceutical industry continues to grow and evolve, Machinfabrik strives to deliver superior quality products that are manufactured in accordance with cGMP. By choosing Machinfabrik Pure Steam Generator you are taking a proactive step in eliminating instances of contamination thus safe guarding your company and the end user from products that could be potentially harmful.

Sterilization process in Pharmaceutical industry requires high quality pure steam with accurate pressure control and fast response times. Machinfabrik Pure Steam Generators are capable of producing pyrogen-free, sterile Pure Steam that, when condensed meets all USP requirements for use in steam sterilizers, critical area humidification and routine SIP.



ENTRAINMENT SYSTEM

In the separator majority of water is separated from steam by gravity. Steam then flows through the multidirectional baffles to the second stage – the cyclone separator. In cyclone separator the high centrifugal forces act on the entrained vapour. Finally, after passing through the mist eliminator pads the Pure Steam is discharged through a nozzle in the dome. The steam chest in the separator ensures better control over the pressure of the generated system.

SAMPLING DEVICE

A Sampling Device is provided at the Pure Steam outlet. This comprises of a heat exchanger with sanitary diaphragm valves. A conductivity sensor with analyser is provided for online conductivity monitoring of the Pure Steam condensate.

NON CONDENSABLE GAS REMOVAL

Removal of non-condensable gases is an important challenge for Pure Steam Generators because gas in the feed water causes high conductivity. Dissolved gas in incoming feed water is removed by the Degasser ensuring the highest quality pure steam and fulfilling EN285 standards during all process conditions.

PURE STEAM CONDENSING UNITS

All our Pure Steam Generators can be supplied with a Condensing Unit on the discharge line to cool the Pure Steam to produce WFI. This offers the customer a unique opportunity to minimize capital investment and save space.

AUTOCLAVE INTEGRATION

Machinfabrik Pure Steam Generator can be seamlessly integrated with all our range of Steam Sterilizers and meets all regulatory requirements of dryness fraction, non condensable gases and degree of superheat. Steam Test Ports as per EN285 for online quality check are provided.



SIMPLE & RELIABLE OPERATION

- An external evaporator provides improved access for inspection and preventive maintenance of critical O-rings and gaskets.
- The separation column contains no internal components that require inspection or periodic maintenance.
- All maintenance including replacement of critical components can be performed with limited maintenance space on all sides (including the top) of the equipment.
- All elastomers in contact with feed water and product are provided with USP Class VI certifications.
- Optionally ASME-BPE certified fittings can be provided.

THERMOCOMPRESSION DISTILLER

The most economical method to produce highest quality WFI



FLEXIBLE, ACCURATE AND DEPENDABLE

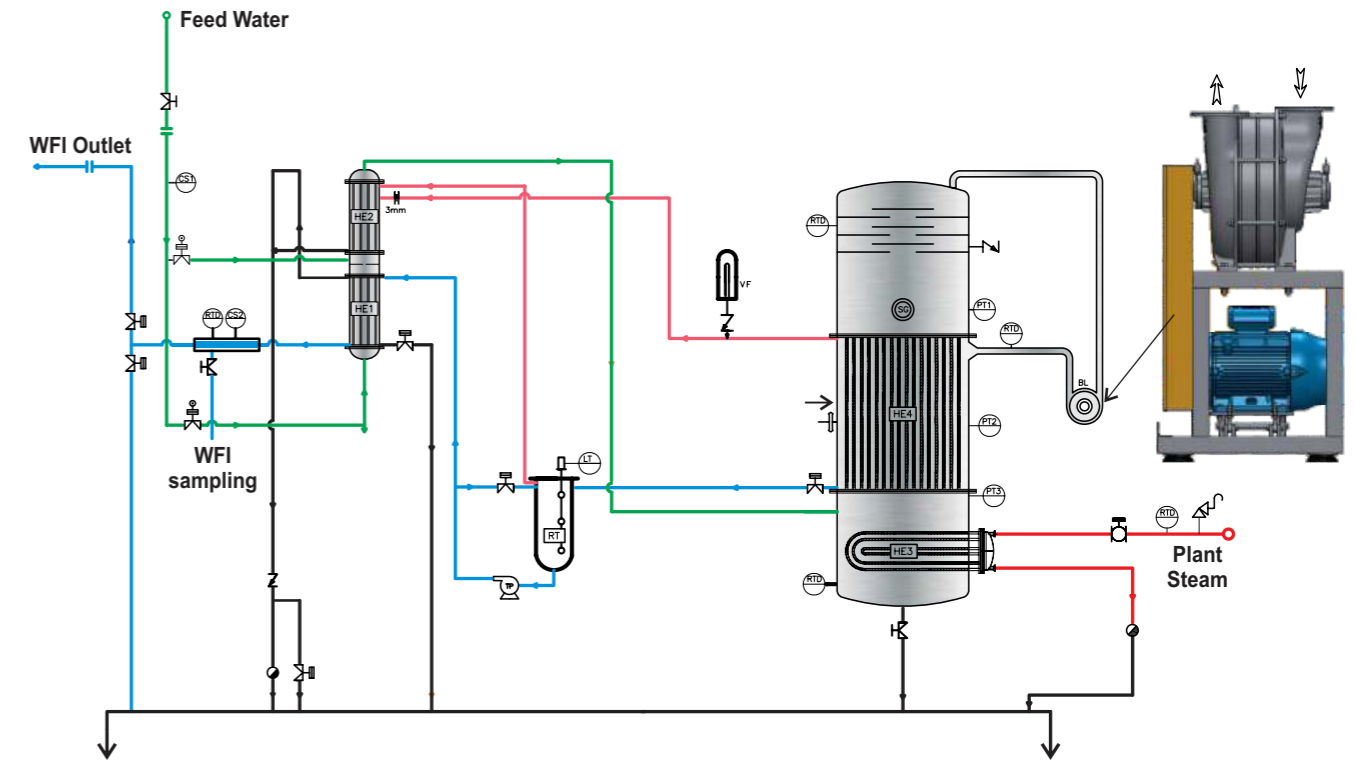
All Pharmaceutical production processes require a stable & consistent supply of quality controlled water for applications ranging from non - critical processes to product formulation.

Machinfabrik's Thermocompression Distiller are designed and constructed to produce sterile and pyrogen-free water (WFI) with critical emphasis on quality and cost.

The Thermocompression Distiller was developed before a Multi Column Distiller and is undoubtedly the safest and most efficient method of producing WFI.

The low operating pressures guarantee minimal stress build up on the metallurgy and hence guarantee long shelf life.

This technology, over the last few years, has achieved prominence and is now preferred by Pharmaceutical companies focused on zero water discharge for environmental protection.



BENEFITS

- Highest quality WFI due to strong degassing process.
- Low energy consumption.
- No need of cooling water
- No need of high quality feed water [Soft water can also suffice]
- Wide range of WFI outlet temperatures.
- Pressurised WFI available at the outlet.
- Safe process with no possibility of cross-contamination due to heating plant steam or feed water.
- The WFI is always at a positive pressure as compared to the feed water throughout the process. This means that in the event of a leakage the feed water can never contaminate the WFI.
- The Thermo-Compression Distiller offers highest flexibility to suit your varied production needs:-
Temperature of generated WFI can be varied from 35°C to 90°C. Possibility to regulate output of the plant from zero to the rated capacity of the plant.
- One of the most economical methods of producing WFI – no need of high quality feed water, reduced steam consumption and zero cooling water consumption.

FEATURES

- The most economical method of producing highest quality WFI.
- Wide range of production capacities, 100 LPH to 5000 LPH.
- Designed to comply with the latest regulatory requirements of USP, EU GMP, PICS, etc.
- Fully automatic operation in compliance with GAMP5 standards.
- 21 CFR Part 11 compliant systems available.
ASME BPE compliant systems available.





VHP PASS BOX

Safe material transfer for your aseptic processing.



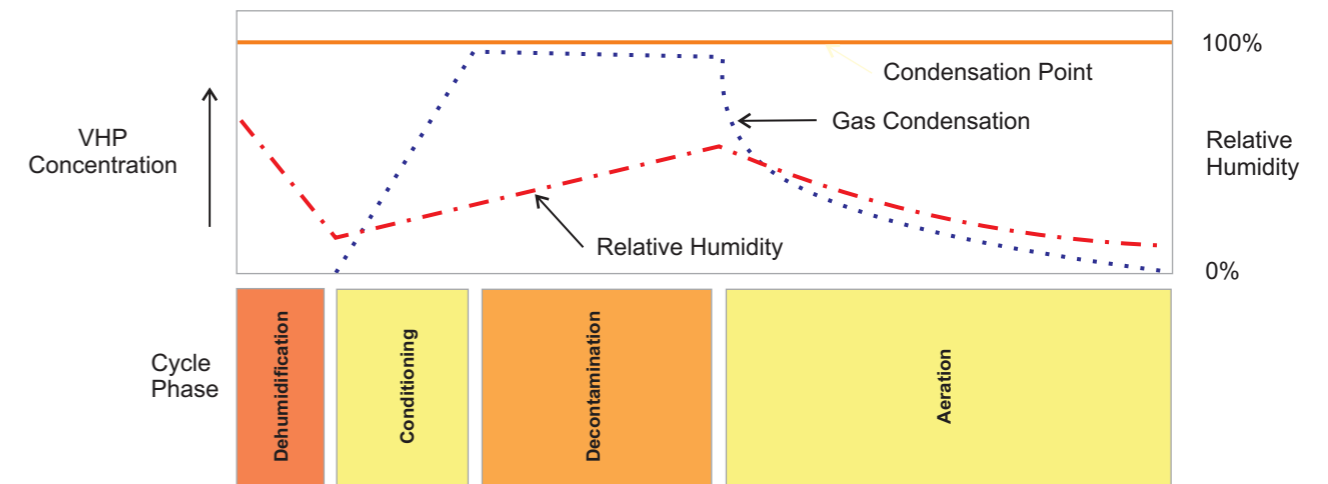
EXPERIENCE. PRECISION. EXCELLENCE.

Vaporized Hydrogen Peroxide (VHP) decontamination systems are becoming increasingly critical as regulators shift their attention away from the prevalent Steam and Dry Heat Sterilization processes to control risk of cross-contamination and bio-burden.

VHP Passbox is used to introduce into the sterile area all those materials that cannot be sterilized in an Autoclave. This is made possible by the wide

range microbiocidal properties of VHP and the fact that it is compatible with most materials used in sterile processing. Lastly and most importantly, at the end of the process the VHP breaks into water and oxygen that can be safely disposed.

Machinfabrik's VHP Pass Box is the result of years of dedicated research and experimentation that now leads into a product designed for your flexible needs.



PRE-CONDITIONING

During the pre-conditioning phase the air is recirculated via a dehumidifier and HEPA filter unit. This ensures not only controlled chamber humidity but also the required particle reduction.

VHP DECONTAMINATION

The liquid hydrogen peroxide is vaporised in a flash vaporizer for dispersal in the chamber. Internal air circulation fans result in a uniform distribution.

POST CONDITIONING

The load is aerated by circulating the VHP through a catalyzer for breaking the VHP into water & oxygen.

APPLICATIONS

Heat sensitive products like:

- Sterile petri-dishes.
- Sterile material for validation.
- Disinfectants.
- Electronic particle meters.
- Rubber stopper bags.
- API Aluminum containers.

SALIENT FEATURES

- Stainless Steel S.S. 316 L chamber with rounded corners.
- Toughened glass door with inflatable seal.
- HEPA filter for particulate reduction.
- Built in air dehumidifier for reduction of humidity for effective decontamination.
- Specially designed vaporizer to control the H₂O₂ concentration.
- In built gas concentration probes to ensure effective sterilization.
- Internal air circulation fans for achieving uniform gas distribution across the load.
- Built in dampers for achieving uniform air and gas flows.

ADVANTAGES

- Customized catalyzer for breaking H₂O₂ into water and oxygen for safe disposal.
- Variety of loading carts, trolleys and racks to handle your product.
- 21 CFR Part II compliant control system.
- Comprehensive reports for easy validation & detailed batch documentation.
- DQ / IQ / OQ protocols for structured and easy qualification.
- Effective 6-log reduction of bio-burden.
- Short cycle times.
- Completely independent of your building HVAC system.
- No separate gas generator required.
- Controlled life cycle cost for best economies.
- Reduces particulate on transferred material.
- Requires only 3Ø supply and instrument air.
- Low hydrogen peroxide consumption.



VERTICAL AUTOCLAVE

Lets Think Big !!



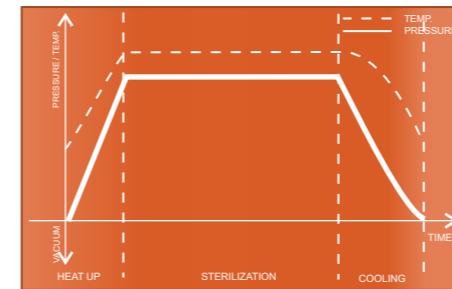
COMPACT AND RELIABLE

The vertical autoclave designed by Machinfabrik is specially developed for laboratory sterilization application with special focus on safety, reliability, accuracy and validation compliance. This machine can not only be used for all laboratory application but also for demanding sterilization processes.

The design of the vertical autoclave ensures high chamber volume with minimum foot print.

With a critical emphasis on operation and process safety all function are fully automatic and all models are provided with a versatile batch recorder.

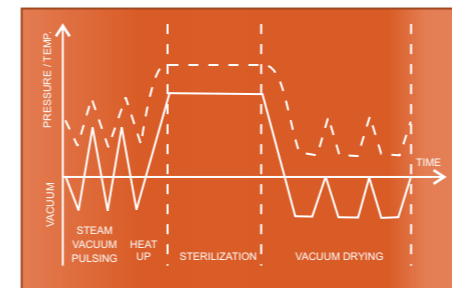
Machinfabrik's vertical are state of the art both in their electrical and mechanical components to enable you to meet requirements of today and tomorrow.



FLEXIBLE OPTIONS

Gravity Displacement Program

This program is designed for sterilization of liquids in container where slow cooling is required to prevent sudden drop in pressure.



Pre-vacuum with Active Drying

Optionally, a vacuum pump can be provided which ensures mechanical air removal so essential for effective sterilization of porous and tightly packed loads. Furthermore the low pressure in the chamber, post sterilization, caused by vacuum helps to reduce boiling temperature forcing moisture to evaporate rapidly. The vapor is then removed from the chamber by vacuum resulting in a dry load.

APPLICATIONS

- Sterilization of liquids.
 - Nutrients
 - Culture media
- Solids like instruments and glassware.
- Destructive sterilization of liquid waste in bottles.
- Destructive sterilization of solid waste in bags.
- Biological hazard in safety laboratories.

SALIENT FEATURES

PRESSURE VESSEL

The chamber is manufactured from stainless steel for best corrosion resistance. All welding is inert argon gas with x-ray inspection. Chambers have a maximum operating temperature of 134°C and protected by over pressure safety device.

AUTOMATIC DOORS

All Vertical Autoclaves are provided with swing type doors sealed automatically by a dynamic door seal. Door safety features guarantee maximum operator safety.

STEAM GENERATOR

Machinfabrik's Vertical Autoclave are provided with an independent Steam generator. This design ensures dry and saturated steam for best sterilization results. Also the readily available steam guarantees shorter heating times.

DUAL SENSORS

For effective sterilization and accurate process control the Vertical Autoclave is equipped with a temperature sensor in the drain and a pressure transmitter in the chamber

USER FRIENDLY CONTROL

The system is controlled via a PLC which is pre-programmed for performing the required sterilization programs. A color, touch screen operator panel allow users to set parameters, run programs & visualize the operation.

BATCH RECORDER

All machines are provided with an on-board printer for detailed batch record. An F_0 calculator also automatically computes & prints the lethality value for every cycle.

SAFETY FEATURES

- Over pressure & temperature safety.
- Door lock to prevent opening of the door during process.
- Process lock to prevent cycle start unless the door is closed.
- Phase time outs
- Low water protection.

Chamber Size	Volume (l)	External	Electrical Load
400 x 600	75	1010 (W) x 1166 (H) x 882 (D) mm	6 KW
500 x 600	125	1110 (W) x 1166 (H) x 985 (D) mm	12 KW
600 x 700	200	1200 (W) x 1265 (H) x 1085 (D) mm	12 KW



EO GAS STERILIZER

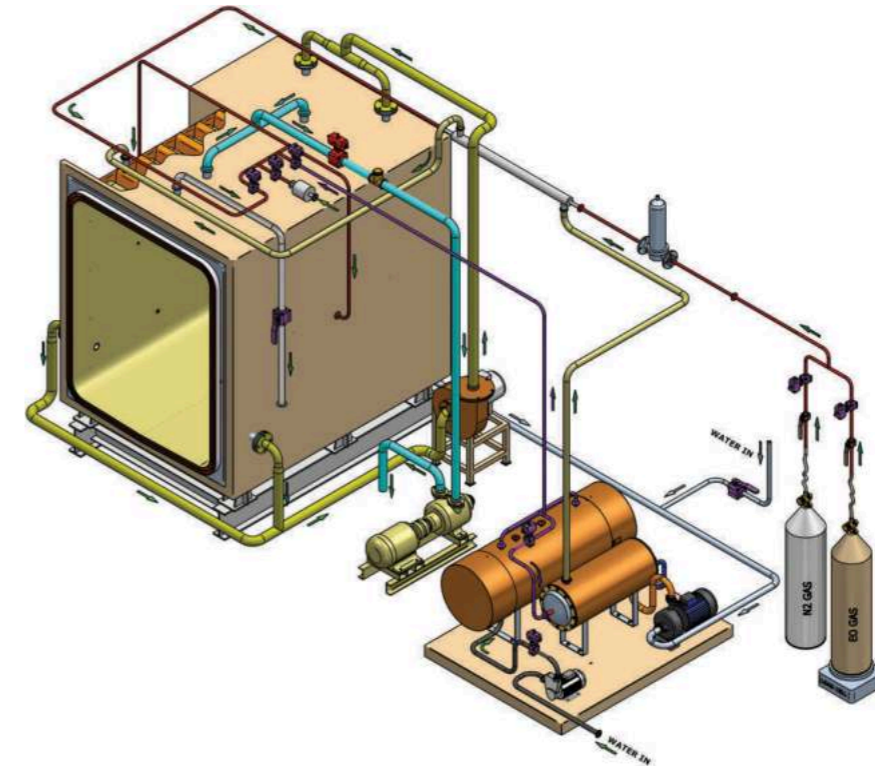
Safe, reliable and precise processing for the most delicate devices

Ethylene Oxide Sterilizers are designed to perform low temperature, chemical sterilization treatment of medical and pharmaceutical products sensitive to temperature/humidity.

Machinfabrik EO Gas Sterilizers kill the toughest of microbes but are gentle enough to protect the integrity of the product and packaging. A wide range of program options, installation arrangements and loading options increases the versatility. Whether you use external preconditioning and aeration or our unique Combined

Process Systems, Machinfabrik can offer customized solutions for your most exacting needs.

EO Gas Sterilizers operate with a sterilant which is potentially explosive, hence these Sterilizers incorporate design features, devices and additional means of protection in order to operate in potentially explosive atmosphere in conformity with the established parameters ensuring a very high level of protection against explosions.



WHEN PRODUCT & OPERATOR SAFETY IS PARAMOUNT

- APPLICATIONS**
- Syringes
 - Catheters
 - Cartridges for Dialysis
 - Plastic articles
 - Sutures
 - Heat sensitive rubber products
 - IV Sets
 - Surgical Gloves

CHAMBERS & DOORS

- Fabricated from high quality stainless steel to ensure long life.
- Provided with an U-profile jacket welded around the chamber.
- Door is sealed using a unique double gasket system.
- Heating system to ensure that the door has the same temperature as the chamber.

JACKET HEATING SYSTEM

- Comprises of a heat exchanger & a circulating pump.
- Water is used as heating medium and steam as a source of heat.
- Accurate chamber temperature control.

VACUUM SYSTEM

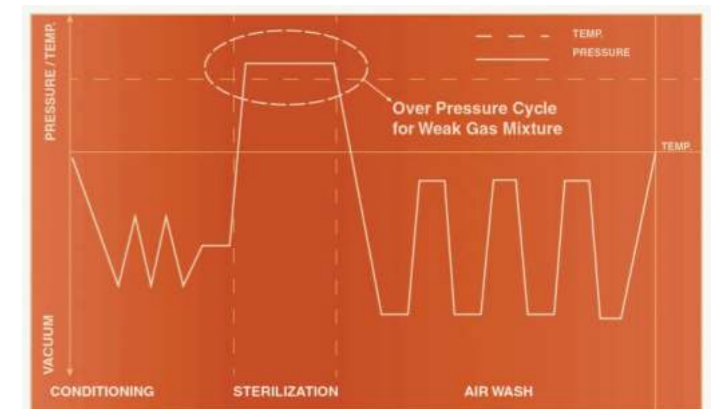
- A reliable & efficient water ring or oil sealed vacuum pump.
- For special high vacuum applications [eg. Sutures] a booster pump for generating ultra-deep vacuum is added.
- Vacuum transducers for ultra-deep vacuum measurement.

SAFETY FEATURES

- Gas detection system with audio-visual alarm.
- Flame proof construction.
- Gas scrubbing system for safely discharging EO gas.
- Evacuation hood to evacuate any residual traces of EO.
- Emergency evacuation system for rapid evacuation.

GAS CIRCULATION SYSTEM

- Special gas circulation systems to achieve uniform concentration of gas in chamber.
- Ensures even distribution of temperature and humidity, so essential for effective sterilization.





CONTROL SYSTEMS

When reproducibility and reliability of Process Control are crucial



FLEXIBLE LOADING SYSTEM

A perfect harmony of man and machine



Machinfabrik Control Systems meets the most current GAMP standards. The application software is developed and validated in house. We guarantee operating convenience, process reliability and reproducibility, safety and maximum accessibility.

VERSATILE FEATURES

- ☑ A user friendly interface
- ☑ Extensive documentation
- ☑ Automatic sensor calibration
- ☑ Comprehensive alarms/alerts
- ☑ Process and alarm logging
- ☑ Multilevel password protection
- ☑ Multilingual display

COMPLIANCE WITH FDA 21 CFR PART 11

The intelligent user management system controls access rights and password management for all users. By means of an audit trail, all user activities, including data modification, are logged. The database offers virtually unlimited storage options and process data and batch reports. Consequently, this guarantees full traceability at all times. Electronic signatures are used for batch release.



FLEXIBILITY & CONVENIENCE

All our Loading systems have been designed with two things in mind - people and movement. This makes our design a cut above the ordinary.

While moving heavy loads it is important to ensure that movement is easy and strenuous positions are avoided. It is also necessary to factor that people differ in height and strengths. This harmony of letting people handle heavy loads is the central theme of our ergonomic design.



CUSTOMIZATION & INTEGRATION

Our years of experience in the field of sterilization ensures that we can customize every Loading System for your product. This is particularly important to ensure that each product is handled carefully and placed as per the validated loading pattern. Our design team also carefully considers the interfacing of our loading system with your material handling philosophy. Last and most important is the interface of the Loading System with the machine to ensure a proper low and penetration of the sterilizing agent.



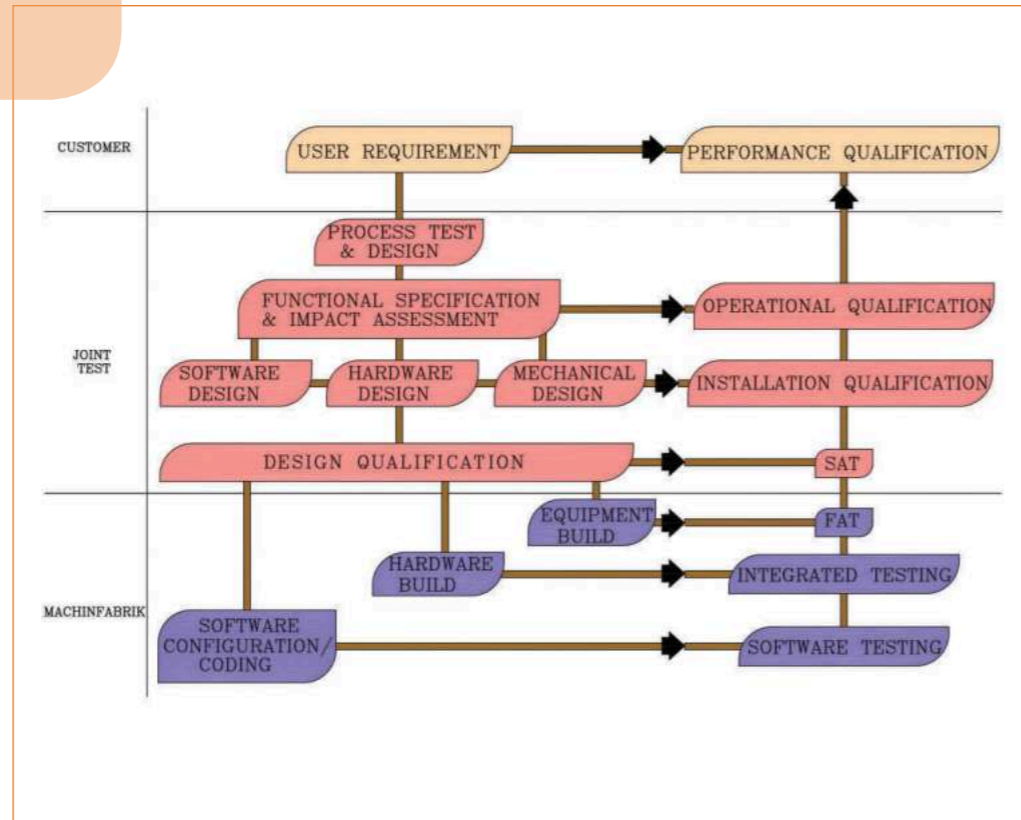


DOCUMENTATION AND QUALIFICATION

Services that adds value to your investment

Keeping in pace with rapidly evolving regulatory requirements we have in house expertise for Documentation and Validation of all our systems. Our objective is to provide a documentation package that may be used as an integral part of the clients qualification support documentation thus saving time and cost. Machinfabrik closely follows industry trends, practices, guidelines and regulatory requirements; actively participating in groups and committees working in determination of this.

The validation engineers accompany you on each step of the project as per the V-Model, starting with the URS and ending with the Performance Qualification at your facility.



WE ARE YOUR PARTNERS

Assistance in all aspects of regulatory compliance



We are one team working in partnership with you to deliver long-term value. At Machinfabrik, we have a dedicated and trained service team which provides you the quick response necessary to maintain high level of customer satisfaction. Quality is an intrinsic feature of every product, from the design specification, through component selection, fabrication, assembly and factory acceptance testing, every aspect of the manufacturing process is examined and documented to ensure and prove that the product is designed, built and tested according to the customer specification and performance requirements. We have specialized teams available to handle all these critical phases.



FACTORY ACCEPTANCE TEST

After every system has been built we have a team of engineers to thoroughly run and verify each component, sub-assembly and finally the entire system. We also assist our customers for conducting a comprehensive and well documented FAT at our manufacturing site.

The FAT is a process designed to evaluate the system after assembly and to verify that its operation complies with design specifications prior to shipment.

INSTALLATION QUALIFICATION

- Pre-qualification records.
- Documentation control.
- Compliance to technical drawings.
- Verification of components, hardware and software.
- Control of instruments and calibration records.
- Customer acceptance of qualification record.

OPERATIONAL QUALIFICATION

- Calibration and verification of all instruments.
- Evaluation of incoming media.
- Tests:-
 - ▷ Control system.
 - ▷ Interlocks.
 - ▷ Leakage test (for Sterilizers).
 - ▷ Temperature distribution in empty chambers.
 - ▷ Output and quality checks (for WFI Stills and PSG).
 - ▷ Alarms and indication check.

PERFORMANCE QUALIFICATION

- Calibration and verification of instruments.
- Performance tests –
 - ▷ Temperature distribution in loaded chamber (Sterilizers).
 - ▷ Heat penetration in loaded chambers (Sterilizers).
 - ▷ Output and quality checks (for WFI Still and PSG).
 - ▷ Reproducibility of tests.
- Customer acceptance of qualification records.

INSTALLATION, QUALIFICATION & CUSTOMER CARE

Our service starts with professional project management and culminates in superior validation methodology. We ensure the systems are installed on time and commissioned to your satisfaction.

Validation is built in our service philosophy. Our in-house team of specialists prepare the essential documents needed to support the installation, commissioning and maintenance of the equipments. The documentation provided are intended to support your subsequent qualification procedures thus saving considerable time, effort and expense on site.



RESPONSIVE AFTER SALES SERVICE

A system out of action is a big problem. Our team responds to such situations to provide prompt and effective on-site service. Our qualified service engineers are on location for understanding your needs. We offer a variety of flexible, cost effective service contracts with guaranteed short response times to minimize your down time. A wide range of spare parts are always ready for quick delivery.

Our total commitment to support means that whenever and wherever you need us, we will be there.

VALUE ADDED SERVICES

In today's highly competitive world, you need more than just service after the sale. As your supplier, we are a key source of knowledge and expertise, integrated solutions minimize unexpected downtime, delays, and expenses. Our ongoing assessments and upgrades maximize the useful life and long-term value of your capital investments.

ESTEEMED CUSTOMERS

Abbott Healthcare
Adhe-Els (Tunisia)
Alkem Laboratories
Baxter

Abacus Parenterals (Uganda)
Acme Laboratories (B'desh)
Astra Zeneca
Becton & Dickinson

Ain Medicare (Malaysia)
Aspen SVP (South Africa)
Aurobindo Pharma
Benta SAL (Lebanon)

Biocon
Cellofarm (Brazil)
Daiichi Sankyo
Glaxo Smith Kline Pharma

Cadila Pharmaceuticals
Cipla
Dr. Reddy's Laboratories
Glaxo Smith Kline (B'desh)

Cinpharm (Cameroon)
Dana Pharma (Nigeria)
Fresenius Kabi
Glenmark Pharmaceuticals

Globe Pharma (B'desh)
Incepta Pharma (B'desh)
Johnson & Johnson
Mankind Pharma

Glomed Pharma (Vietnam)
Intas Pharmaceuticals
Duo Pharma (Malaysia)
Mylan Laboratories

Hospira Healthcare
IVEE Aqua (Kenya)
Lupin Pharma
Nicholas Piramal

Novartis
Pasteur Institute of Iran (Iran)
Pharmawealth (Philippines)
Sandoz

Opsonin Pharma (B'Desh)
Pfizer
Pharmed Healthcare (Egypt)
Pasture Institute (Romania)

Panacea Biotec
Pharma Solutions (KSA)
Ranbaxy Laboratories
SM Pharma (Malaysia)

Steripharm (UAE)
Sun Pharmaceuticals
Terumo BCT (Vietnam)
Unique Pharma (Nigeria)
Wockhardt

Strides Arcolab
Tabuk Pharma (KSA)
Torrent Pharmaceuticals
USV
Zydus Hospira Oncology

Strides Arcolab (Polska)
Tenamyd Pharma (Vietnam)
Troikaa Pharmaceuticals
Venus Remedies
Zydus Cadila Healthcare



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