sterinox



EXPERTS IN
PROCESS DESIGN AND EQUIPMENT MANUFACTURING FOR WATER AND VESSELS

ABOUT
OUR COMPANY

Sterinox Systems is an innovative & quality-driven company. Since its inception, Sterinox Systems has always strived for the highest quality standards and customer satisfaction through innovation, optimization, latest infrastructure, and skilled manpower.

Our expertise is in manufacturing for **Pharmaceutical, Biotechnology, Cosmetics, Food & Beverages, Semiconductor, and Dairy industries.**

100+
PROJECTS

50+
CLIENTS
(Domestic + International)

10+
COUNTRIES



VISION

Evolve as a global manufacturer through innovation, skilled workforce, quality management and professional approach.

MISSION

Explore new opportunities and optimize design & engineering processes by standardization and strictly adhering to the quality and safety standards. Also to offer solutions to new challenges in the respective areas of application.



> The core values of our organisation are positive attitude, innovation, ethics, openness, quality management & teamwork.

INFRASTRUCTURE

Sterinox Systems office is in Mumbai. It is a design & engineering center. A team of certified engineers and draughtsmen carry out design & engineering activities with a completely professional approach.

Sterinox Systems factory is located in the Thane district (Near Mumbai). Our factory is set up with well-equipped machinery backed by a dedicated team of well-qualified engineers, draughtsmen, and skilled workers.

We have a separate team of site engineers responsible for providing support on-site.

20+ YRS
EXPERIENCE

50+
PROFESSIONALS

QUALITY

Sterinox Systems strictly adheres to cGMP guidelines and our products comply with ASME (BPE), ASME Section VIII Div 1, FDA, EP, BP, IP, and USP design standards. Our philosophy of continuous improvement and professional performance helps us in achieving new peaks in quality and safety standards. We are in process of ISO 9001:2008 certification. QAP (Quality Assurance Plan) and internal test reports are always submitted to customers prior to dispatch.



VAPOUR COMPRESSION DISTILLATION PLANT (WFI)

STERINOX Vapour compression (VC) distillers are designed for pharmaceutical & Biotech water applications.

WE BRING THE EUROPEAN WFI VAPOUR COMPRESSION (VC) TECHNOLGY TO INDIA WITH INDIAN EXPERTISE IN MANUFACTURING.

The STERINOX Vapour Compression Distillation machine produces Water for Injection (WFI) by continuously recycling latent heat of the pure steam through mechanical vapour compression.

It converts feed water into pure steam, compresses that steam to raise its temperature and pressure, and uses it as the heating source to boil more feed water. This way energy within the distillation cycle is recovered and makes the entire process of generation of WFI very efficient.

CORE WORKING PRINCIPAL

- Pre-Heating
- Evaporation
- Vapour Compression
- Condensation & Heat Recovery
- Collection & Degassing

APPLICATIONS

- LVP / SVP Manufacturing
- Vaccine Manufacturing
- Ophthalmic Application
- Nasal Application
- Insulin Manufacturing
- Propofol Manufacturing
- Any kind of Liquid Sterile & Dry Sterile products



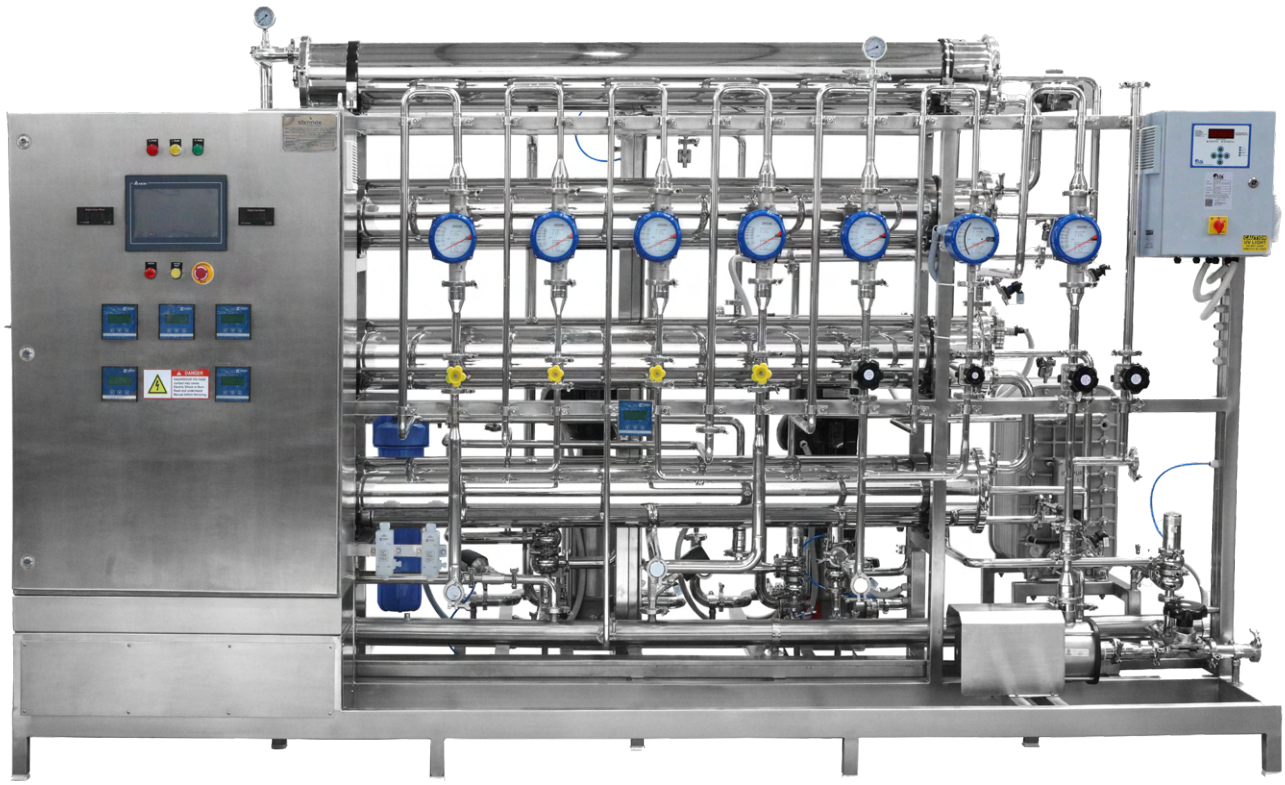
FEATURES

- Capacity varies from 500 to 5000 Litres per hour
- Can produce hot as well as cold WFI
- Low utility requirement and cooling water is not required. Low boiler steam pressure requirement
- Sanitary blower design for sturdy & reliable operation with low noise levels
- Inbuilt Non-Condensable Gas removal facility
- Depends on Raw water quality, soft water or Single pass RO water can be taken as feed water
- Low reject water means better recovery of WFI per litre of feed water
- Designed for Self Sanitization
- SCADA based operation with latest 21 CFR Part 11 and latest GAMP compliance
- Lower footprint
- Pre-Heating with boiler steam or electric heater or both is possible
- Designed and manufactured as per ASME BPE and cGMP guidelines
- The WFI generated meets USP, EP, BP and IP standards
- Specially designed and constructed to remove pyrogen / endotoxin
- All heat exchange tubes will be seamless quality
- Designed and constructed to achieve 100 % drainability
- All wetted parts are made from AISI 316L stainless steel and rest are made of AISI 304 stainless steel
- All water contact surfaces are finished to electro polished to Ra < 0.4 and are crevice free
- Our compact and optimised design required minimum human interference. This means low maintenance and low operational cost.
- Complete set of documentation and certificates to ensure compliance with regulatory authority. We provide DQ, OQ, IQ, FAT & SAT. Also assist client to develop PQ

PURIFIED WATER TREATMENT PLANT

Purified Water (PW) Treatment Plants (RO-EDI Plants) generates High Purity water for pharmaceutical, Biotech, Semiconductor and Food & Beverages Industry. Sterinox Purified Water Treatment plants are designed and optimised for hassle free, low maintenance operation.

The entire system utilizes the best instruments and equipments ensuring solid performance and reliability. Sterinox Purified Water Treatment Plants are skid based and designed to accommodate minimum footprint.



APPLICATIONS

PW Plant produces Ultra Purified Water required to produce any kind of Pharma products. Purified Water is required for

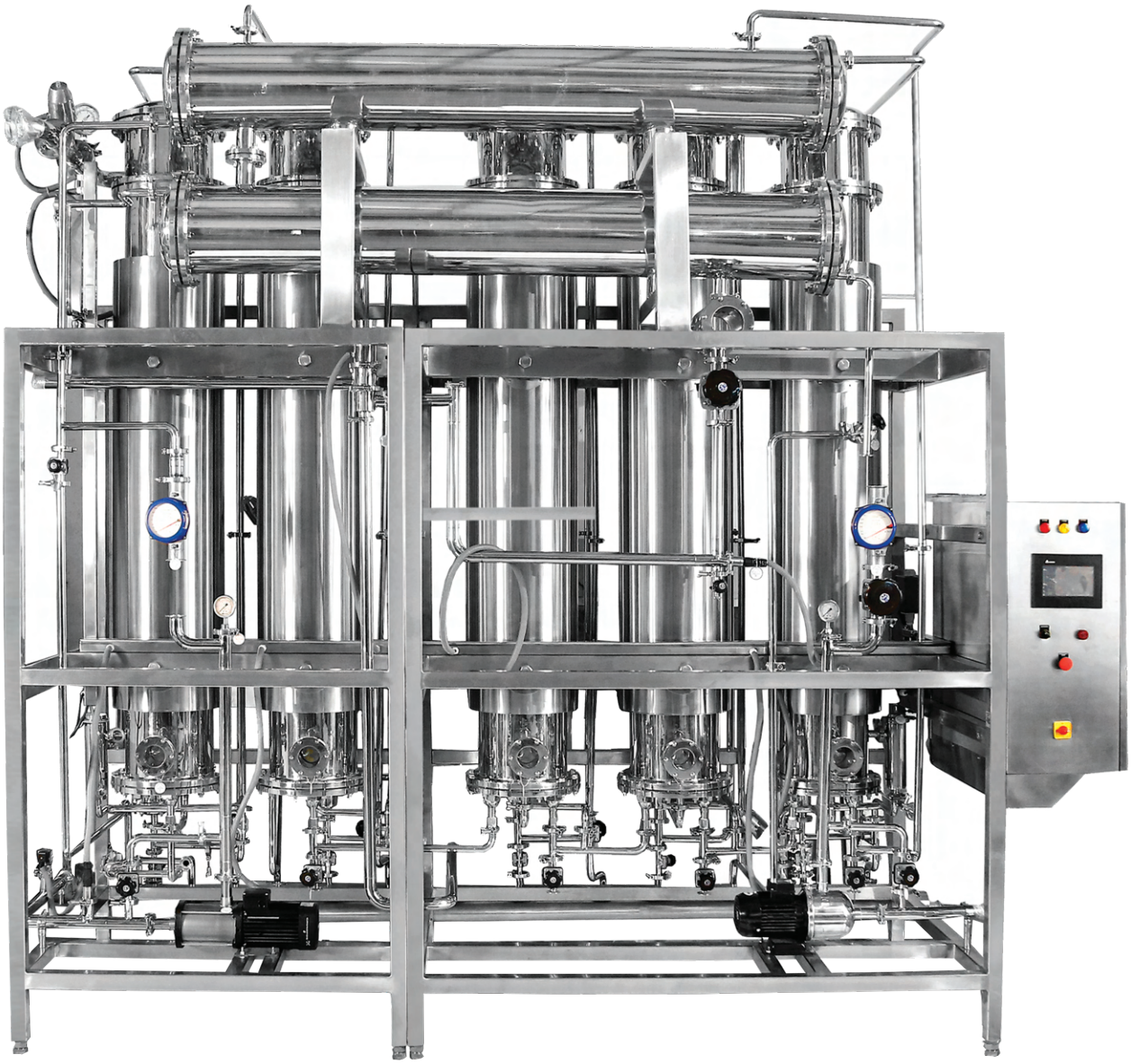
- Tablet / Capsule Manufacturing
- Liquid Orals Products
- To Produce WFI
- To Produce Pure Steam
- Cosmetic Products
- Ointment / Cream / Gel / Paste / Lotion Manufacturing

FEATURES

- The final output quality complies with USFDA, MHRA, WHO, EU & other international pharmacopeia's and standards
- Plants are manufactured as per cGMP guidelines and complies with ASME BPE Standard
- IPC & PLC based fully automated plant complies with 21 CFR Part 11 & GAMP 5. Hence low maintenance and minimum human interference required
- Designed for minimum dead leg criterion of <1.5 D. Also 100% drainability can be achieved by maintaining the minimum slope of 1:100
- Complete inter connecting piping is semi seamless tubes as per ASTM A270
- All contact parts are AISI 316L Stainless Steel and Non-Contact parts are AISI 304 Stainless Steel
- All contact parts surface is electro polished to less than 0.4 Ra finish.
- All interconnecting piping are orbital welded using High Purity (99.99%) argon gas and welding joints can be inspected by boroscopy machine
- Complete set of documentation and certificates to ensure compliance with regulatory authority. We provide DQ, OQ, IQ, FAT & SAT. Also assist client to develop PQ



MULTI COLUMN DISTILLATION PLANT (WFI PLANT)



The Multi Column Distillation plant produces low conductivity pyrogen / endotoxin free Water For Injection (WFI) by stage distillation process. As the name suggests, the unit consists of a series of pressure vessels in the form of columns / stills which are inter connected. Boiler steam is utilised only in the first column to produce pure steam and remaining columns utilize this pure steam to produce furthermore pure steam. During this heat exchange process, pure steam condenses. Additional condensers are provided on top to condense the pure steam completely to produce WFI. The plant is designed for maximum heat recovery and hence very economical in operating cost.

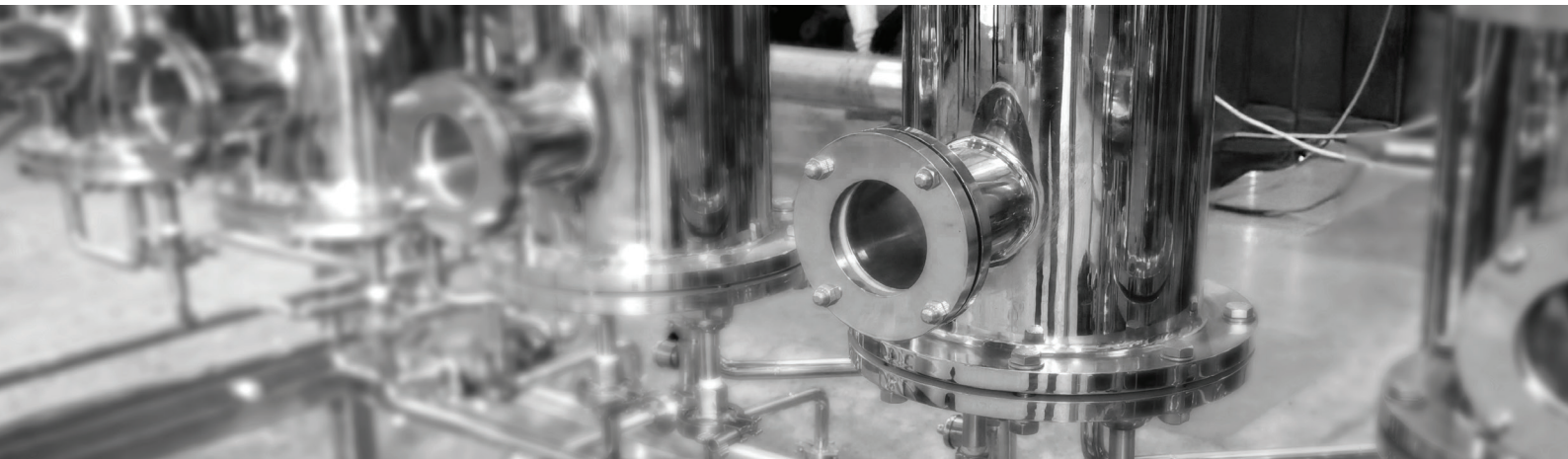
APPLICATIONS

Multi Column Distillation Plant produces WFI (Water For Injection)
WFI is required for

- LVP / SVP Manufacturing
- Vaccines Manufacturing
- Ophthalmic Products
- Nasal Products
- Insulin Manufacturing
- Any Kind of Liquid or Dry Sterile Products

FEATURES

- Capacity varies from 5 to 6,000 litres per hour
- Designed and manufactured as per ASME BPE and cGMP guidelines
- The WFI generated meets USP, EP, BP and IP standards
- Phase separation is based on falling film evaporator technology
- Specially designed and constructed to remove pyrogen / endotoxin
- All heat exchange tubes will be seamless quality
- Designed and constructed to achieve 100 % drainability
- All wetted parts are made from AISI 316L stainless steel and rest are made of AISI 304 stainless steel
- All water contact surfaces are finished to electro polished to Ra < 0.4 and are crevice free
- IPC & PLC based 21 CFR part 11 complied fully automatic control panel with online printing facility
- Double tube sheet construction for the first column, where boiler steam is present
- Our compact and optimised design required minimum human interference. This means low maintenance and low operational cost.
- Complete set of documentation and certificates to ensure compliance with regulatory authority. We provide DQ, OQ, IQ, FAT & SAT. Also assist client to develop PQ



PURE STEAM GENERATOR

The pure steam produced by PSG is used for sterilisation in storage tanks fermenters, reactors, pipelines & autoclaves.

It is also used for humidification of sterile area and can be used wherever sterilization is required.





APPLICATIONS

Pure Steam Generator (PSG) produces Pure Steam.
Pure Steam is required for

- In Situ Sterilization of any equipment
- Autoclave Sterilization

FEATURES

- Capacity varies from 5 to 3,000 Kg per hour
- Designed to produce pure steam @ 3 kg/cm^2 pressure
- Designed and manufactured as per ASME BPE and cGMP guidelines
- The Pure Steam generated meets EN 285, USP, EP, BP and IP standards
- All heat exchange tubes will be seamless quality
- Phase separation is based on falling film evaporator technology
- Specially designed and constructed to remove pyrogen / endotoxin
- Designed and constructed to achieve 100 % drainability
- The unit and all its components are mounted on AISI 304 stainless steel skid
- All wetted parts are made from AISI 316L stainless steel and rest are made of AISI 304 stainless steel
- All contact parts are finished to electro polished to Ra < 0.4 and are crevice free
- IPC & PLC based 21 CFR part 11 complied fully automatic control panel with online printing facility
- Double tube sheet construction for the first column, where boiler steam is persent
- Our compact and optimised design required minimum human interference. This means low maintenance and low operational cost
- Complete set of documentation and certificates to ensure compliance with regulatory authority. We provide DQ, OQ, IQ, FAT & SAT. Also assist client to develop PQ



STORAGE & DISTRIBUTION SYSTEM FOR PW / WFI

Storage & Distribution System is required to store and distribute the PW / WFI within the plant. The system ensures stringent quality parameters of Pharmaceutical / Biotech industry. The distribution system is a closed loop system. Closed loop system ensures integrity of the PW & WFI. The entire Storage & Distribution System parameters are monitored & controlled with the help of instruments & equipments mounted on Distribution Skid.





APPLICATIONS

PW / WFI Storage & Distribution System is required for

- Purified Water / WFI Storage
- Distribution of Purified Water / WFI
- For Sanitization of PW Tank & Distribution Loop
- Controlling Microbial Load in WFI / PW
- Rejecting High Conductivity PW / WFI
- Sterilization Process Management WFI Tank & Distribution Loop

FEATURES

- PW and WFI Storage Tanks are manufactured as per cGMP guidelines and ASME VIII, DIV 1 standard
- Storage tanks can be plain, jacketed or limpet type. Jacketed and limpet tanks are provided suitable rockwool / glasswool insulation and AISI 304 stainless steel cladding
- If required, provision of electric heating can also be provided with suitable insulation & cladding
- Process nozzles will be flushed sanitary flange type
- To make sure optimum cleanability, all tanks are Riboflavin tested
- PW / WFI tanks are provided with necessary accessories for reliable operation
- IPC & PLC based fully automated plant complies with 21 CFR Part 11 & GAMP 5
- Fully drainable sanitary pumps are selected to maintain minimum velocity of 1.2 m/s in the return line at peak load consumption
- Two pumps (Duty / Stand by) are provided to ensure continuous hassle-free operation along with swing arm assembly for changeover
- Distribution skid is provided with instruments to monitor parameters like temperature, conductivity, pressure, flow rate, velocity and also TOC count
- Distribution piping is designed for minimum dead leg criterion of < 1.5 D
- Distribution Loop tubes are semi seamless tubes as per ASTM A270
- All contact parts MOC is AISI 316L Stainless Steel and electro polished to less than 0.4 Rasurface finish and Non-Contact parts are AISI 304 Stainless Steel
- The Distribution loop is designed for 100% drainability by maintaining the minimum slope of 1:100
- All weld joints in the loop are orbital welded using high purity (99.99%) argon gas and can be inspected by boroscopy machine
- Complete set of documentation and certificates to ensure compliance with regulatory authority. We provide DQ, OQ, IQ, FAT & SAT. Also assist client to develop PQ



LIQUID ORAL MANUFACTURING PLANT

The Liquid Oral Manufacturing Plant is also known as Syrup Manufacturing Plant. Sugar and water are loaded to the Sugar Syrup Vessel either manually or with the vacuum system. Here, sugar syrup is prepared using stirrer & electrical / steam heating at required temperature. If required, activated carbon can be used to make sugar syrup crystal clear. Sugar syrup is transferred to manufacturing Vessel by vacuum or by pump through basket filter. After processing in manufacturing vessel the product can be homogenised with the use of homogeniser. Homogeniser has inbuilt pumping facility which can provide desired multiple passes in recirculation mode. Finally the transfer pump discharges the final product to the storage vessel through zero hold up filter press.

FEATURES

- Available in various batch capacities from 50 litres to 20,000 litres
- Complete plant is designed & manufactured as per cGMP & ASME BPE guidelines
- All vessels are vacuum rated and hence can be sterilized
- Bottom entry stirrer can be provided to restrict overall height
- All Tanks are provided with necessary accessories for reliable performance
- Pre-mix Vessel can be provided if process demands
- IPC & PLC based 21 CFR part 11 complied fully automatic control panel with online printing facility
- Working platform and ladder with railing in AISI 304 stainless steel
- All connecting pipelines, fittings, valves and contact parts are of AISI 316 stainless steel and are electro-polished and crevice free
- Sugar Melting Vessel and Manufacturing Vessel can be provided with jacket or limpet coil for steam heating. If required, provision of electric heating can also be provided. All Vessels are provided suitable rockwool / glasswool insulation and AISI 304 stainless steel cladding
- Loadcell is provided for volumetric measurement
- Spray ball is provided in all vessels for online CIP
- Complete set of documentation and certificates to ensure compliance with regulatory authority. We provide DQ, OQ, IQ, FAT & SAT. Also assist client to develop PQ



THE PLANT CONSISTS OF

Sugar melting vessel	Inline homogenizer
Manufacturing vessel	Top / bottom entry stirrer
Storage vessel	Inter connecting piping
Online sugar syrup pre filter	Transfer pumps
Vacuum system for transfer of sugar & sugar syrup	Working platform
Zero holdup filtration unit	PLC based control panel



STERILE VESSELS

Sterile vessels are required to manufacture liquid injectable products. We adhere to stringent manufacturing processes and follow cGMP / ASME BPE guidelines to manufacture the Sterile Vessels. Manufacturing and Holding Vessels are accompanied with suitable high grade filtration to get the final product. The Vessels are designed to achieve online CIP & SIP. Sterile vessels are provided with necessary accessories, high grade instruments and PLC based control panel to monitor and control the process of manufacturing to utmost integrity.





APPLICATIONS

Sterile Vessels are required for

- LVP Manufacturing
- SVP Manufacturing
- Manufacturing specialized Products likes Blood Plasma / Protein Refolding / Crystallizer etc.
- Manufacturing Nasal & Ophthalmic Products
- Manufacturing of any Kind of Liquid Sterile Products
- Manufacturing Vaccines & Serums

FEATURES

- Zero dead leg aseptic design of bottom outlet valve
- Zero dead leg aseptic design of sampling valve
- Calibrated full view glass for the blending vessel
- Volume monitoring by load cells
- Process Automation
- IPC & PLC based 21 CFR part 11 complied fully automatic control panel with online printing facility
- Aseptic connection and flanges to avoid product contamination
- Inbuilt CIP-SIP System or Separate CIP-SIP System can be provided
- Agitator : Bottom driven agitator (Electrical & Magnetic)
- Functionally : Cleaning in place, Sterilization in place, Fermentation process with temperature control, pH control, DO control
- Jacket with Pressure gauge, Safety Valve, Vent, Chilled water supply & return, Drain, Circulation pump with heat exchangers for fine temperature control



POINT OF USE HEAT EXCHANGER (POU HE)

Point of Use (POU) heat exchangers are primarily used for the instant cooling of Water for Injection (WFI) and Purified Water (PW) directly at the dispensing point. In the process thermal energy is transferred from a hotter fluid to a cooler fluid without the two fluids mixing.

Sterinox POU HE (Point of Use Heat Exchanger) mechanical and process design ensures sanitary design with high strength against sudden thermal shocks and avoids cross-contamination.



APPLICATIONS

- Point of use cooling of WFI (Cool from 80-85°C to 25-40°C)
- Point of use for heating of PW (heat from 25°C to 80-85°C)
- Water for Injection (WFI)
- Clean steam condensing and sub-cooling
- Temperature control of high purity product
- Process fluid cooling or heating

FEATURES

- Flow Range: 100–4000 LPH
- Designed and constructed to achieve 100% drainability and available with DTS (Double Tube Sheet) construction
- Designed and manufactured as per ASME BPE and cGMP guidelines, meeting USP, EP, BP and IP standards
- Complete set of documentation and certificates to ensure compliance with regulatory authority
- All heat exchanger tubes will be seamless quality.
- PLC / HMI or PLC / IPC – SCADA with 21 CFR Part 11 compliance full automatic control panel with online printing facility.



CIP (Clean in Place) SYSTEM & SIP (Sterilization in Place) SYSTEM

CIP system is required to clean the equipments in place. The CIP process is generally customised as per the client requirements. CIP system has wide ranging applications. The system can be built with storage tanks and also tankless system can be provided to suit the client requirements.

SIP system are required to sterilise plants and equipments in place. The SIP process are designed to ensure maintenance of sterilisation temperature and pressure during the entire sterilisation cycle.

If required combo plant for CIP & SIP can be built. Both systems has wide ranging applications like in Pharma & Biotech industry, Dairy, Food & Beverage industry.





FEATURES

- CIP / SIP System is provided with instruments to monitor parameters like temperature, conductivity, pH and TOC
- The system is designed and constructed to comply with ASME BPE & cGMP.
- CIP / SIP systems are integrated with high grade instrumentation and PLC based automation to control and monitor the operations with highest level of integrity yet user interface remains simple and easy to understand. If required SCADA system can also be incorporated.
- Various options can be provided to achieve sanitisation temperature, like jacketed tank, tank with electric heaters and Double Tube Sheet type Heat exchangers can be provided
- CIP system are designed to make sure it passes riboflavin test
- Inter connecting piping is designed for minimum dead leg criterion of < 1.5 D
- Fully drainable design by proper arrangement of equipments and by maintaining the minimum slope of 1:100 for inter connecting piping
- All piping weld joints are orbital welded using High Purity (99.99%) Argon Gas and can be inspected by boroscopy machine.
- GAMP 5 sentence
- Complete set of documentation and certificates to ensure compliance with regulatory authority.

AUTOCLAVES & STERILIZERS

Sterinox Systems offers a comprehensive range of sterilization solutions designed for Pharmaceutical, Biotechnology, Healthcare, Medical Device, and Food industries. Our sterilizers are engineered to deliver reliable sterilization performance, product safety, regulatory compliance, and operational efficiency. Designed and manufactured in accordance with cGMP and international standards, our systems are available with advanced automation, validation support, and customized configurations to suit diverse process requirements.



APPLICATIONS

Sterinox Autoclaves & Sterilizers are widely used for:

- Pharmaceutical Manufacturing
- Biotechnology Facilities
- Injectable Manufacturing (LVP & SVP)
- Vaccine Production
- Ophthalmic & Nasal Products
- Medical Device Manufacturing
- Laboratory Applications
- Food & Beverage Industry
- Hospitals & Healthcare Facilities

FEATURES

- Designed and manufactured as per cGMP and international regulatory guidelines
- PLC / HMI based fully automatic control system with optional 21 CFR Part 11 compliance
- Uniform temperature distribution for validated and repeatable sterilization cycles
- Advanced monitoring and control of temperature, pressure, and process parameters
- Energy-efficient design with optimized utility consumption
- Available in manual, semi-automatic, and fully automatic configurations with PLC / HMI / SCADA with 21 CFR PART 11
- Stainless Steel AISI 316L product contact parts with hygienic construction
- Robust and compact design for reliable long-term operation
- Customized chamber sizes and process configurations available
- Complete set of documentation and certificates to ensure compliance with regulatory authorities
- DQ, IQ, OQ, FAT & SAT documentation provided, along with support for PQ development
- Low maintenance design with user-friendly operation and maximum process reliability

TYPES OF STERILIZERS

- Steam Sterilizer (Autoclave)
- Steam-Air Sterilizer
- HPHV Sterilizer
  (Hydrogen Peroxide Vapor Sterilizer)
- Dry Heat Sterilizer
- Superheated Water Spray Sterilizer
- Closure Processor
- ETO Sterilizer (Ethylene Oxide Sterilizer)

OUR PRODUCT RANGE

sterinox

Non-Sterile Process Vessels

- Coating Solution Preperation Vessel
- Vacuum Impregnated System
- Soft Gelatin Manufacturing Plant
- Liquid Oral Plant
- Ointment Plant
- Paste Manufacturing Plant
- Gel Manufacturing Plant
- CIP System

Sterile Process Vessels

- LVP Manufacturing Setup
- SVP Manufacturing Setup
- Special Application Sterile Vessels
- CIP / SIP System

Water Systems

- PW Generation
- Vapour Compression Distillation (WFI Generation)
- Multi Column Distillation (WFI Generation)
- PW/WFI Storage & Distribution
- Pure Steam Generation with Distribution
- Point of Use Heat Exchanger (POU HE)
- Ultrapure Water Generation with Storage & Distribution

Sterilizers

- Steam Sterilizer
- Steam Air Sterilizer
- HPHV Sterilizer
- Dry Heat Sterilizer
- Super Heated Water Spray Sterilizer
- Bung Processor

OUR PRESENCE



OUR CLIENTS

ATLAS VETERINAIRE · Dr.Reddy's · acme · amneal PHARMACEUTICALS · arthropharm pty ltd · BDH Industries Ltd. · BION HEALTHCARE · GUFIC BIOSCIENCES LIMITED

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