sterinox
our quality our power

"There's a way to do it better - Find It"
Thomas Edison

ABOUT US

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

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

INFRA STRUCTURE

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

Sterinox Systems factory is located in Thane district (Near Mumbai). Our factory setup in the span of 6000 Sqft. area with well equipped machinery backed by a dedicated team of well qualified engineers, draughtsmen and skilled workers.

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

VISION

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

OUR CLIENTS

MISSION

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

VALUES

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

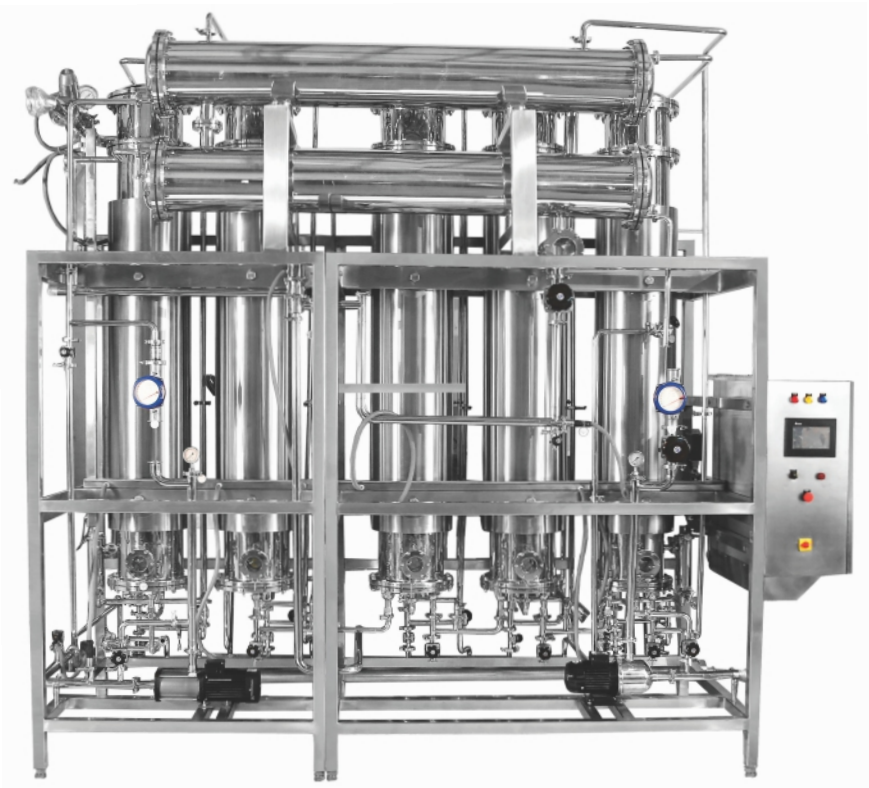
QUALITY

Sterinox Systems strictly adhere 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 peak 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.

OUR PRESENCE

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 utilise this pure steam to produce furthermore pure steam. During this heat exchange process, pure steam condenses. Also 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.



- Capacity varies from 50 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
- PLC based CFR21 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.

PURE STEAM GENERATOR

The Pure Steam Generator (PSG) is used to produce low conductivity pyrogen / endotoxin free sterile steam.

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.

- Capacity varies from 50 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
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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 utilises best instruments and equipments ensuring solid performance and reliability. Sterinox Purified Water Treatment Plants are skid based and designed to accommodate in minimum footprint.

- 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
- 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.

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.

- 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 require 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
- 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 Ra surface 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. The 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.

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

- Available in various batch capacities from 100 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 sterilised
- Bottom entry stirrer can be provided to restrict overall height
- All Tanks provided with necessary accessories for reliable performance
- Premix Vessel can be provided if process demands

- Optimised design and fully automatic PLC based control ensures minimum manual handling and low maintenance cost
- 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 require 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.

STERILE VESSELS

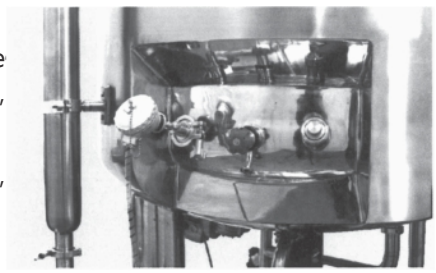
Sterile vessels are required to manufacture liquid injectable products. We adhere to stringent manufacturing processes and follow cGMP / ASME BPE guidelines to manufacture the Sterile Vessels. Manufacturing and Holding Vessels are accompanied with suitable high grade filtration to get the final product. 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.

Key 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
- Operation : Fully Automatic with PLC & HMI / SCADA system
- Steri connection and flanges to avoid product contamination
- Inbuilt CIP-SIP 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

Accessories :

- Spray ball, pressure gauge, foam sensor, pH sensor, Temperature sensor, vent Line, ZDL Bottom outlet port, ZDL Sampling port, Sanitary safety relief valve
- Valve, Acid / Alkali / feed addition lines with sterile four way valve, peristaltic pump, media filter (NFF type)
- Incinerator after exhaust filter



Application :

❖ Sterile Solution	❖ Large Volume Parenterals
❖ I V Fluids	❖ Small Volume Parenterals
❖ Vaccines	❖ Oncology Products
❖ Serums	❖ Ophthalmic

CIP (Clean in Place) System & SIP (Sterilisation 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.

- 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
- Contact parts MOC SS 316L and electro polished to less than 0.4 Ra surface finish.

- 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.
- Automation of the plant comply with 21 CFR Part 11 & control panels are designed as per GAMP 5. The system can have PLC based automation or SCADA based automation with IP
- Complete set of documentation and certificates to ensure compliance with regulatory authority

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