

Our **Industrial Sterilizers** operate on EO gas mixture cylinders. They can work with all sterilant gas mixtures ranging from 20/80 EO/CO<sub>2</sub> mixture to 90/10 EO/CO<sub>2</sub>. However, we promote rich mixture sterilizers which work on 90/10 EO/CO<sub>2</sub> as it has distinct advantages. It should be noted that all these sterilant mixtures are flammable combinations, therefore, all components and wiring that is a part of the equipment to be placed in the hazardous or the gas area should be of flameproof design. Although 90/10 EO/CO<sub>2</sub> is a rich EO mixture, most medical device manufacturers as well as spice manufacturers all over the world prefer it as it provides distinct advantages over lean mixtures like:

- 1) Cycle is in vacuum hence the risk of leakage of gas from chamber which is a distinct possibility in lean mixtures is almost nonexistent.
- 2) Lower gas consumption kg to kg – hence saving in gas cost.
- 3) Reduced exposure time – hence cycle time is lessened and also residuals are lesser.
- 4) Lower possibility of failure of cycles as stratification of gas which takes place when leaner mixtures are used is avoided.

We offer **Industrial Sterilizers** for the MEDICAL DEVICE INDUSTRY with the sterilization process validatable as per EN ISO 11135 - 2014

**Standard Sizes – 54, 72, 96, 128, 200, 250, 300, 400, 500, 750 cubic feet and more.**

We offer **Industrial Sterilizers** for the Bio Burden Reduction for the Herbal Products and Spices Industry. The sizes of these chambers can be customized as per the batch size.

**Standard Sizes – 128, 200, 250, 300, 400, 500, 600, 750, 900, 1250 cubic feet and more.**

## **CHAMBER CONSTRUCTION**

The chamber shell is manufactured from Mild Steel or Stainless steel 304 and reinforced with carbon steel structural members from the outside. A full cubical jacket made of carbon steel is provided for efficient chamber heating. The internal surfaces are ground and polished to a rough matte finish or painted with epoxy paint. The chamber is designed for a pressure equal to 20 psig and is constructed in accordance with relevant Indian Standards.

## **DOOR**

The door can be manually operated, hinged type with a radial arm design with pleasing looks or can be hydraulic operated sliding door.

## **DOOR GASKET**

The door gasket is made of moulded silicon rubber, chosen for its excellent sealing abilities and long durability and is of a single piece design.

## **CHAMBER INSULATION**

The chamber is insulated and sheathed with aluminum creating a pleasing appearance. The sheathing, combined with the insulation, creates an excellent thermal barrier to reduce the heat load into the installed area. The sheathed insulation is an impact resistant surface, which prevents damage and allows for easy maintenance.

## **CHAMBER HEATING SYSTEM**

We will provide the chamber with a hot water circulation through jacket running around the chamber. A separate tank having adequate heating and storage capacity is provided and the heated water is circulated throughout the chamber periphery with the help of circulation pumps (two nos.).

## **MECHANICAL EQUIPMENT AND VALVES**

We will use sturdy & reliable mechanical components in the assembly of the equipment. This includes valves, pumps, regulators, etc. Components are chosen to simplify calibration, maintenance, replacement and servicing.

## **AUXILIARY EQUIPMENT**

The following items are part of the ETO sterilizer:

### **VACUUM PUMP**

A vacuum evacuation system suitable for operation in hazardous area is provided to evacuate the chamber to 26" Hg. The system is sized to evacuate a dry, empty chamber in less than 30 minutes. The vacuuming is controlled automatically through stainless steel valve.

### **FILTERED AIR INLET/BREAK**

An air inlet filter assembly shall be provided to enable vacuum break at the end of vacuum pulses. The assembly shall include the filter housing, a 0.2-micron removable filter cartridge

### **ETO VAPORIZER**

A specially designed gas evaporator suitable for operation in hazardous area will be provided to ensure that the gas enters the chamber in Vapor State only. The gas is conditioned automatically to a predetermined temperature by maintaining the vaporizer temperature at a preset level. A special provision is made to ensure that the EO goes into the chamber in gaseous form only and the automation system controls the gas flow if it senses that the EO may pass in liquid state.

## **HUMIDITY & HUMIDITY MONITORING**

A Steam generator made from S.S. 304 along with the humidity monitoring sensor will be installed to monitor the humidity levels. The monitoring of humidity will be done only during conditioning and prior to the release of ethylene oxide (EO) + CO<sub>2</sub> mixture in the chamber.

### **GAS CIRCULATION SYSTEM**

To ensure evenness of gas flow inside the chamber, a provision is made using automatically operated valves to ensure that each portion of the chamber gets adequate gas according to the settings made in the automation system which can be adjusted at site. This makes for a safer alternative than a circulation fan/system inside the chamber which due wear and tear and the use of rotating parts in the presence of flammable E.O. gas could be a hazard.

### **GAS VENTILATION SYSTEM (OPTIONAL)**

To reduce the exposure of ethylene-oxide to the workers, the sterilization chamber is equipped with a ventilation connection suitable for operation in hazardous area. This connection is fitted at the top of the chamber, as far away from the unloading / sterile door as practical. When running a cycle, the connection is closed, by a vacuum and airtight butterfly-valve. After a cycle, when the door is opened, the valve opens and a signal is given to operate the exhaust fan. Fresh air is now sucked from the unloading door, where people are working, through the load and out to the ventilation system. This further aerates the material and ensures lower residues. An exhaust hood should also be provided which will work in tandem which ensure that any gas near the door will be sucked away from the operators. The exhaust fans, exhaust ductings, the exhaust hood and wall connections to this system shall be provided by the customer.

### **GAS DIFFUSOR (OPTIONAL)**

A specially designed pneumatically operated gas diffuser suitable for operation in hazardous area will be provided to ensure that the gas going out of the system if it is being let out into the air will be diluted before it is let out to the atmosphere. This system is coupled to the automatic system and is energized whenever the gas is being exhausted. A compressed air source providing about 100 psi @ 5SCFM (**in customer scope**) is required along with this unit. This unit ensures nil or extremely low ppm levels around the gas exhaust area. This unit sucks in the gas, diffuses it and then lets it out into the atmosphere. This unit can also be coupled with the gas scrubbing unit for added protection.

### **ELECTRONIC WEIGHING SCALE (OPTIONAL)**

An electronic weighing scale suitable for operation in hazardous area, of suitable capacity will be provided to measure the quantity of the sterilant gas mixture while charging the chamber. The weighing scale shall be coupled to the control system to monitor the amount of gas going in the chamber.

## **AUTOMATION CONTROL SYSTEM**

The sterilizer is controlled using dedicated automation controller that will control the entire automatic cycle of sterilization. All the parameters required for the cycle can be set and are monitored continuously.

The control system monitor plant utilities and informs the operator if any utilities are missing or are needed as per the chosen cycle's requirement. If any utility essential for operation of the selected cycle becomes unavailable, the loss of any monitored parameter during cycle will generate an audible and visual alarm to alert the operator of the malfunction.

Some of the standard features programmed into system:

- a. Program Selection Mode- Ten Individual Cycle Programs with half cycle validation processor – in all 20 different cycles.
- b. Multiple Password Security system.
- c. Setting of various parameters to alter cycle with process control limits.
- d. In built aeration facility and safety from overpressure and leakage.
- e. Touch screen controls
- f. Dot matrix Printer based recording system.
- g. Electronic Chartless Recorder.

The setup menu allows the operator to select from pre-programmed cycles to establish specific operating parameters for the selected cycle. Each cycle consists of segments or phases. Once all preparations are complete, the operator can then select a cycle for performing. The operator does not need to program the unit again and again for the same cycle. Once programmed the cycle will be repeated till any modification is desired.

The controller advances the system through these required phases of the selected cycle, as the conditions for each portion are completed. According to the cycle selected, the cycle advances through necessary segments as the conditions to complete each segment are achieved. During a cycle, the operator display will show the current process values such as chamber temperature and pressure alongwith other parameters as and where applicable and all the parameter values will recorded on a printer.