Decontamination Transfer Chamber

Brinda
PHARMA TECHNOLOGIES PVT. LTD.

Decontamination Transfer Chamber

Product Function Description

The decontamination transfer chamber allow monitoring material, tools, or bags with stoppers etc. to be transferred quickly between cleanrooms of different classes – C, B or A according to cGMP.

Fast and reliable microbiological surface decontamination is achieved using vaporized hydrogen peroxide (H2O2).The integrated LAF recirculation system guarantees the pressure cascade between the rooms and sterility is ensured also after the gassing process.

All safety-relevant functions are constantly monitored electronically.

The Main Structure Of The Pass Box

- The construction is created entirely in stainless steel AISI 316L, with a coarseness of Ra<0.6 for the processes surface parts and with materials compatible with vaporized hydrogen peroxide, for the other parts.
- Toughened safety glass, T=15mm.
- The inner room can be equipped as required with shelves, storage frames and trolleys

Operating System

Dedicated electronics with an operating panel for the control of the pass box, in laminar flow functioning mode and in sterilization, the software is comprised of the following functions:

- Mode of work selection (laminar flow /sterilization).
- Work cycle parameters selection
- Prints data.
- Visual alarms.
- Continuous visualization of the VHP concentration.
- Sterilization cycle.
- Conditioning of the atmosphere and the load, in ambient air temperature and humidity
- Delivery of the sterilization and achievement of the sterilization concentration
- Maintenance of the concentration for the set-up time.

Traceability

As the most important requirement of traceability, a paperless recorder is used to record real time parameters, store parameters, and export data and other working conditions.

Important parameters are monitored and may be recorded; they can be either directly sent to a printer (option) or stored on a remote PC (option).

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Leak Test

The chamber performs a separate fully automatic leak test prior to the decontamination cycle.

Automatic leak testing procedure for the bio-decontamination airlock and for the whole work area.

- Leak tightness is guaranteed.
- High protection of operator and environment.

At the beginning of each working routine the following steps will be automatically gone through.

According to ISO-14644-7 and ISO-10682-2 regulations, leakage tests are determined according to the requirements. Automatic leak test is carried out through PLC system, and clear results are obtained. If the technical requirements of leakage rate don't meet the requirements, the subsequent transmission chamber cannot be sterilized.

Shut-off valves will be provided to permit leak testing by pressure decay. These valves will be fitted ahead of the inlet HEPA filters and after the exhaust HEPA filters.

Inflatable Seal System

The open windows and doors are sealed by an inflatable seal, and the windows and doors are made of silicone rubber, which is certified by the pharmaceutical industry.

When inflating, set pressure relief valve and pressure gauge to avoid the clean compressed air overcharging, when the pressure is insufficient, the alarm is carried out through the pressure gauge.

When running, design the safety valve, keep the constant pressure of the inflatable seal ring, the seal pressure will be monitored at all times, and the alarm system is equipped. The mechanical parts that protect the window seal are also used to ensure the safety of the failure.

Door of Chamber

The door opening of the transmission and operation chamber is controlled. The operation log must be formed through the PLC system in order to open the door system.

When the door is opened or locked, transfer will not be able to enter the cabin run or, conversely, the same disinfection mode), when the transfer tank circulating disinfection, also cannot open the door.

The inner and outer doors of the Transfer hatch will be interlocked, so that only one door (of the two) can be open at any time.

Vaporized Hydrogen Peroxide Gas Generator

The hydrogen peroxide generator is integrated with the chamber, vapors distribution and control system to provide automatic sporicidal gassing for the mode selected. It has the ability to use a number of different common bottle types, with the potential to execute dozens of cycles without the need for replenishment.

The generator will be provided with the hydrogen peroxide sensor to measure the peak vapors concentration during the disinfection cycle.

The VHP sterilization cycle involves 4 phases:

- Dehumidification
- Conditioning
- Sterilization
- Aeration

The above steps are performed automatically through the transmission of the cabin PLC system without human interference.

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Filters

To comply with the requirement of the air quality inside the work chamber, High Efficiency Particulate Air Filter (HEPA) H14 are used. These filters act as a particle barrier between the isolator and the surrounding room. The air in the work chamber is double filtered.

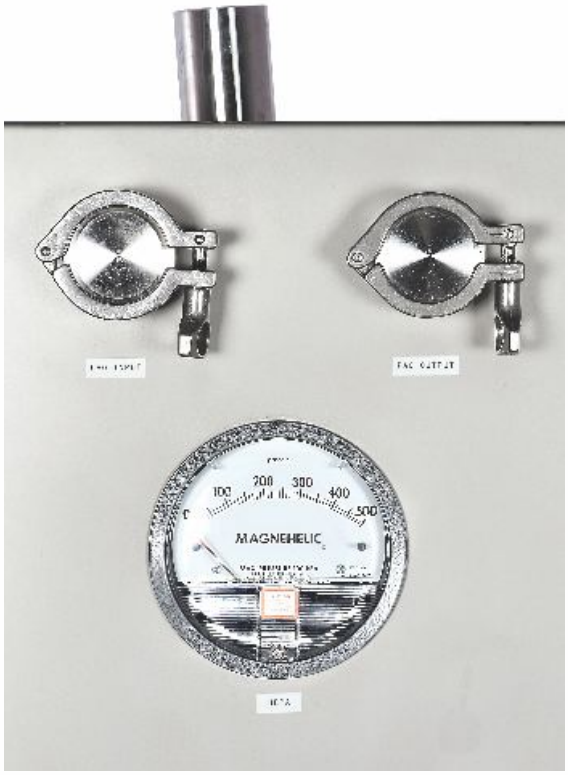
The relative environment of the transfer chamber is a positive pressure system, and the air distribution is laminar flow. Fresh air is collected from the high level area (B level) or HVAC system, and the unidirectional laminar flow is formed through HEPA (H14).

The retention rate of H14 HEPA filter is according ISO14644: retention rate > 99.995% at 0.3μm， The filter integrity test is done in compliance with ISO14644.

After the sterilization is completed, the automatic residue process is performed through the HMI, and the MnO2 filter can effectively degrade the hydrogen peroxide and discharge the cavity.

Shelves

The shelves are made of stainless steel 316L and are used for an efficient loading of the basic isolator. They are installed at the back wall of the work chamber. A shelve consists of 3 load surfaces with the dimensions 210 mm x 700 mm. The distance of a load surface between the top and the middle shelf is 140 mm, between the middle and the bottom shelf 250mm.



Illumination

A fluorescent tube illuminates the work chamber and is placed on the outside of the front door and can be replaced during production. The color of the tube is day light white.

Hydrogen Peroxide Sensor

Hydrogen peroxide sensor, high concentration (max. 1000ppm)

This option consists of a probe for high H_2O_2 concentration measurement in the work chamber.

The sensor is placed inside the circulating air section.

Technical Data

Type	DTC-600	DTC-800	DTC-1000
External Dimension W*TH*H (MM)	1150*620*1800	1350*820*1800	1150*1020*2000
Pass chamber (Internal Dimension) W*TH*H(MM)	600*600*600	800*800*800	1000*1000*1000
Weight	150kg	250kg	350kg
Air distribution	laminar flow	laminar flow	laminar flow
Air classification	Class A Class A	Class A Class A	Class A Class A
Air inlet HEPA	100 m^3/h, G4+H14	150 m^3/h, G4+H14	200 m^3/h, G4+H14
Air outlet HEPA	100 m^3/h,MnO2 Filter	150 m^3/h, MnO2 Filter	200 m^3/h, MnO2 Filter
Leak rate per hour	< $2,5x10^{-3}$	< $2,5x10^{-3}$	< $2,5x10^{-3}$
PLC system	All operations are performed by PLC.		
Differential pressure sensor	On-line monitoring HEPA filter, chamber pressure difference		
VHP sterilization system	Isolation Machine System integrates VHP Sterilization System		
Weighing sensor	On-line monitoring of the consumption of hydrogen peroxide to ensure a complete sterilization cycle		
Hydrogen peroxide concentration sensor	The highest concentration of hydrogen peroxide in the on-line monitoring chamber		
Compressed air/nitrogen	6 bar		
Power supply	220V (1Ph+N+PE), 50/60Hz, 2KW, 16A TN-S		

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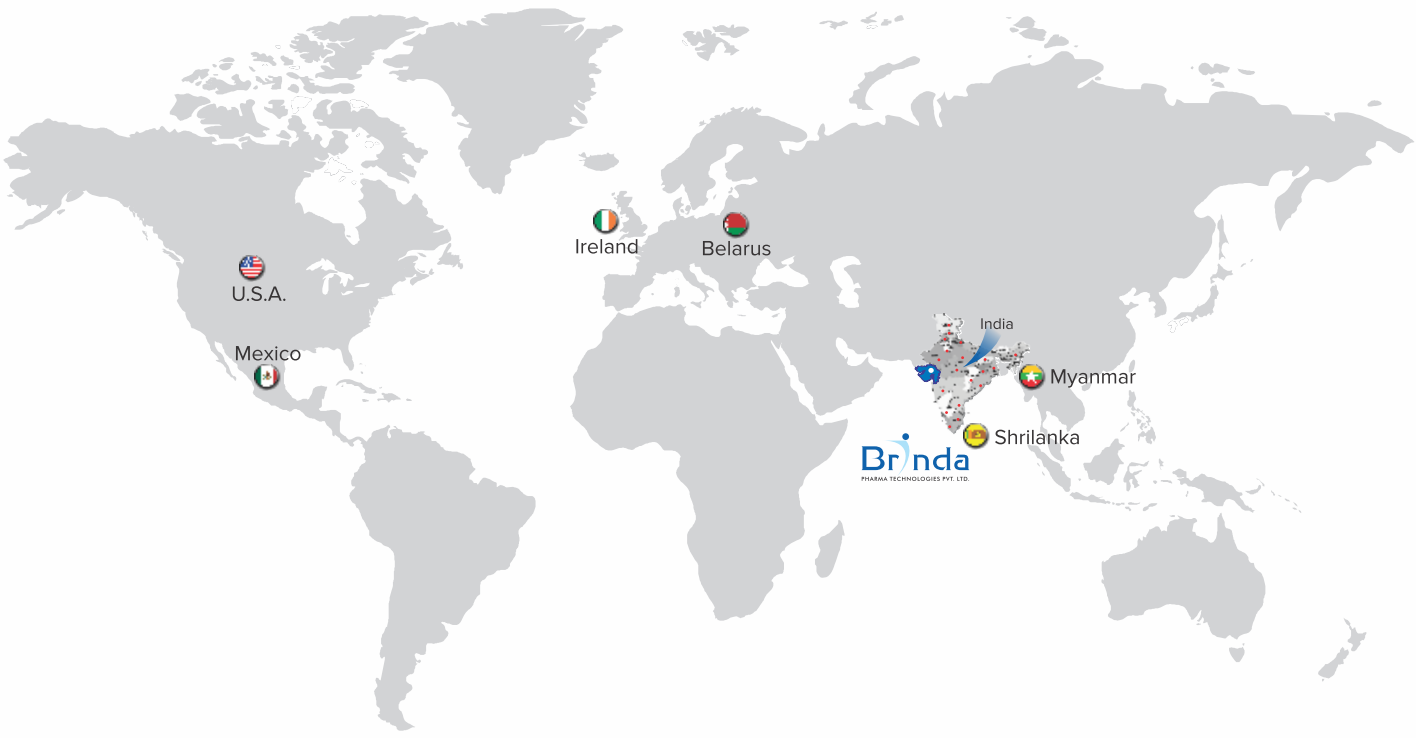
Global Presence



Brinda Pharma Technologies Pvt. Ltd.

33, Jaylaxmi Industrial Estate, Opp. Anup Engineering,
Nr. C.M.C. Odhav, Ahmedabad - 382415. Gujarat, India.

Tele/Fax : +91-79-22891289

Email : sales@brindapharma.com | brindapharma@yahoo.co.in
web : www.brindapharma.com