

ASEPTIC FILLING RIGID WALL ISOLATOR

The construction of an aseptic processing suite for Small - Scale or Clinical - Size batches has been a time consumption & expensive project. Now a days the products are proteins and therefore highly susceptible to microbial contamination, hence the regulatory body are devising and enforcing increasingly stringent requirements for environmental and process control in aseptic processing.

GroyneTech Isolator Technology provides better contamination control, with reducing the project time lines, Increases the environmental quality and Reduce the operating cost.

GroyneTech Aseptic Filling Isolator design with re-circulation system, maintaining a pressure inside +200Pa to +250Pa is having Unidirectional Air Flow of 0.20 to 0.45 meter per second, installed at ISO8 ROOM (Grade D/C).

GroyneTech Aseptic Filling Rigid Wall Isolator are designed to have LEAK tightness that contain within them a qualified controlled environment, at variance with the surrounding conditions.

GroyneTech Aseptic Filling Rigid Wall Isolator will be decontaminated using vapour hydrogen peroxide (VHP) generator.

GroyneTech Aseptic Filling system is a FOUR - Head system, cable of filling 40 - 100 vials/min. depending on the type and volume of the container.

GroyneTech Aseptic Filling system process vials for filling & having a station for stopper (fully or partially) and cap (aluminium with plastic flip - off).Purging station are also placed at before & after filling to have low level of residual oxygen before stopper placement in vials.

MECHANICAL FEATURES:

- Contact part of ISOLATOR & Filling system is SS316L
- NON-Contact part of ISOLATOR & Filling system is SS304L.
- Inlet & Outlet HEPA filters are integrated with 99.97% efficiency for 0.3 micron particles.
- Integration option for Mobile Vial transfer isolator to Filling Turntable.
- Filling head integrated with "Peristaltic Pump" of make: Watson Marlow.
- Integration option of Stoppers / Aluminum Caps transfers to hopper (by RTP or Sterile Linear Bag) closely.
- Integration option for Mobile Vial transfer after partially stopper for LYO.
- Integration option for VHP generator for decontamination.
- Integration of CG - Screen below the Inlet HEPA filter.
- Special Mouse Hole with High Air Flow for exit of vials for next process of operation.
- Easy & Fast changeover of respective change parts with quick time.

DESIGN HIGHLIGHTS:

- System Design & Control with Siemens Make PLC with 10" Color Touch Screen, Software complying with GAMP.
- Siemens make Variable Frequency Drive for air-recirculation control during operation with constant positive pressure & Once through control during aeration phase of VHP decontamination cycle.
- Differential Pressure Transmitter for air pressure control inside the chamber.
- RH/Temperature transmitter placed at return line to have better monitor of RH and Temperature during process.
- Air Velocity Sensor placed over critical area (Filling Head) to have better monitor of air velocity during process.
- Auto synchronization of Peristaltic Pump speed with Filling Speed.
- Integration option for non-viable particle and microbiological monitoring.
- Alarms for BREACH Condition & Safe Transfer Port with continuous Linear Bag.

SPECIAL EFFECTS (OPTIONAL) :

- Auto synchronization with infeed & outfeed machine
- GroyneTech Glove Integrity Tester.
- Interfacing of VHP generator, Online Particle Counters with TCP/IP protocol.
- 10" IPC with SCADA with 21 CFR PART 11
- Heating facility to maintain RH during VHP cycle.
- Online Weighing at Pre & Post filling of vials during process with record.

