The line can fill vial sizes from 2ml to 250ml at speeds of up to 200 vials per minute depending on size.

Change parts for the following fills/vial sizes are included with this line:

| | | |
|---|---|---|
| 3ml | x | 13mm |
| 5ml | x | 13mm |
| 10ml | x | 20mm |
| 20ml | x | 20mm |
| 50ml | x | 20mm |
| 240ml | x | 28mm |

IMA PHARMA

## DESCRIPTION OF EQUIPMENT COMPONENTS

### BOC Edwards Vial Washing Machine, Model CRW-1

Serial #: C351410

This is a compact rotary washing machine with 12 vial holders, (arms). The 35" diameter rotary table moves the vials to the vial holders. When filled, the machine indexes to the first washing station where the vials are inverted. There are 10 stations available for a variety of washing functions. The 10 stations are divided into 3 separate washing zones. This unit has a single file infeed system along with single vial holders. Equipped with automatic low pressure shut down / overload protection, missing vial detection in the cassette and low water temperature.

Other features include external, as well as internal washing and air blowing, fixed nozzles for filling, tri-clover connection, passivated 316 stainless steel, self-draining system, (no "dead" water). Class 100 Laminar Airflow unit sits above the outfeed and is constructed as follows: Surface of the unit covered by HEPA filter having an efficiency higher than 99.999% at 0.3 µ m particle DOP. 304 stainless steel construction, integrated fluorescent lights, pre-filter pollution indicator and flexible curtains. Rated at up to 300 vials per minute depending on size. Vial Range: 2ml to 1000ml.

### BOC Edwards Steriline Depyrogenating Tunnel, Model ST-7

Serial #: L020TU

This is a laminar flow depyrogenating tunnel designed to depyrogenize ampoules, vials and syringes with a continuous process throughout the length of the tunnel. Local class 100 Laminar Airflow units located over tunnel infeed. This unit consists of three chambers:

1) The inlet chamber with its laminar flow unit keeps clean the transfer of glassware from the washing machine to the hot chamber, dries and preheats glassware and protects from the hot air back flow coming from the hot chamber;
2) The hot chamber subjects the glassware to the thermal cycle for the depyrogenation;
3) The cooling chamber cools the glassware to the suitable temperature to be discharged into the sterile isolator.

Features of the Depyrogenating Tunnel:

- Contact parts are 316 stainless steel or FDA approved plastics;
- Polished internal finish for maximum heat reflection;
- Class 100 environment in all tunnel sections, or better;
- Laminar flow above infeed and cooling down zone;
- Tunnel frame, welded, 304 stainless steel, hermetically sealed;
- Dual stainless steel frame in sterilizing chamber with insulated lining;
- Stainless steel conveyor with separate variable speed drive;
- Uniform distribution of air through HEPA filters;
- Adjustable container infeed and discharge opening;
- Belt speed adjustment with digital read;
- Adjustable air control baffles to adjust air pressure and airflow in different areas of the tunnel.
- Heating elements for sterilizing the cooling chamber by means of dry heat;
- Cooling chamber insulation to provide protection at temperatures up to 230°C;
- Insulated airtight door at the tunnel exit, equipped with high temperature resistant inflatable gaskets to protect the isolator during the cooling chamber sterilization and to enable the isolator to be sterilized without any leak and VHP to the tunnel.

During the depyrogenating heat cycle, the filtered hot air temperature reaches 200°C in the chamber. Once complete, the cooling chamber sterilization cycle commences and the following occurs:

- The airtight door closes and the insulated gaskets inflate;
- The cooling water heaters start;
- The cooling chamber temperature rises to the predefined set point.

The tunnel is equipped with an automatic discharge bar to fully discharge the glassware at the end of the process. Range of glassware: 1ml to 1000ml.

## BOC Edwards 8 Head Time/Pressure Inline Filling System, Model ILF8-RS/TP

Serial #: C351430

This system is designed for aseptic filling and rubber stoppering. Its time/pressure filling provides for particle free filling, increased sterility assurance level and ideal filling conditions. The filling module controls the actual filling process and can be divided into two parts; a needle bridge which holds the filling needles and a filling section which controls the filling process itself. Vials are fed by the through conveyor into an indexing unit and at each position the presence of a vial is detected. If no vial is present, filling will not start and the indexing unit returns to its start position. All vials pass through a check weighing module to weigh empty vials before filling and then to weigh them when filled.

The filling nozzles lower (bottom up fill) into the vials and rise with the product level as filling proceeds. Machine can also be set for submerge filling where the needle tips keep contact with the liquid during filling, and fixed position filling when high speeds are required in combination with side spraying. Once filled, the indexing unit opens for discharge to allow the next set of empty vials to be filled.

Features of the 8 Head Inline Filling System:

- Heavy duty 304 stainless steel machine frame;
- Dedicated drive for vial indexing unit;
- No vial, no fill;
- Bottom-up fill;
- Reject station;
- Nitrogen flushing;
- Check weighing;
- Manifold;
- Product supply piping with tri-clamp connection;
- Aeration valve;
- 8 pinching devices;
- Temperature sensor;
- Silicone tubing.

## BOC Edwards Rubber Stopper Inserting Machine

This is a versatile machine capable of handling rubber stoppers and vials up to 500ml at production speeds of 50-500 stoppers per minute.

Comes equipped with a rotating turret to transport the rubber stoppers and a mechanical stopper low particle unscrambling system, model FM2 all under vacuum. The turret is provided with a vial dedicated star wheel with 12 sealing heads. These heads release a rubber stopper from the hopper chute end while passing.

Features of the Stopper Inserting Machine:

- No vial - no stopper;
- Low stopper level signal;
- No stopper - machine stop;
- Nitrogen flushing;
- Open design for HEPA filter laminar flow protection;
- Upstream and downstream communication with filling and capping machine.

Comes equipped with a Reject Module designed to divert all vials that are "off specification" and include instructions for "off specification" vials such as:

- vial not closed;
- stopper too high;
- vial weight out of tolerance;
- filling weight out of tolerance;
- empty vials.

## BOC Edwards Aluminum Capping Machine, Model SC2-6

Serial #: C351450

Machine is constructed entirely of stainless steel and is designed for clean-room operation where it fold seals aluminum caps onto vials. Comes equipped with an infeed star wheel for the vials to pick up a cap from the chute and then be transferred to the 6 head sealing unit to seal the caps onto the vials. This machine can handle vials from 2 ml to 250 ml. Once vials are capped, they go to a tray loading module for final inspection/packaging.

Features of the Capping Machine:

- Adjustable top pressure of the sealing heads;
- Adjustable side pressure of the sealing rollers;
- Mechanical cap orienting with low particle generation;
- High seal performance;
- No vial – no cap;
- No rubber stopper – no cap;
- Low cap level signal;
- No cap – machine stop.

## La Calhene Isolators (2)

Filler - Model 13.1, Serial #: 1717
Accumulation - Model 13.2, Serial #: 1718

Designed for the elimination of the human airborne generation of microorganisms by removing operators from the process. Provides a controlled environment to assure aseptic processing conditions i.e. temperature, pressure, relative humidity, airflow, make-up air balancing and the elimination of product contamination.

Features of the Isolators:

- Compact and modular design;
- Good ergonomics and easy access through a single front window;
- Same isolator design to process vials, bottles, syringes and cartridges;
- Suitable for “Ready to Use” (RTU) materials supplied in nest & tub, or materials supplied in bulk;
- For aseptic and aseptic-toxic products. Operation under positive or negative pressure;
- Easy and safe HEPA filters replacement from the front side;
- One single isolator construction shell which surrounds filling machine frame with a continuous joint-less base;
- Integrated DPTE® solutions for materials transfer in & out of the isolator;
- Ideal for small scale clinical trials as well as for mass production;



## Ancillary Equipment

Included with the line is all ancillary equipment used to support the LaCalhene isolators in order to ensure decontamination and a sterile environment. Ancillary equipment includes the following:

- 6 Sifat Blowers;
- 3 Cooling Coils;
- 3 HEPA Filter Boxes;
- 12 Hayward 12” Diameter Valves;
- All other valves, piping, sanitary (tri-clover) clamps and fittings.