



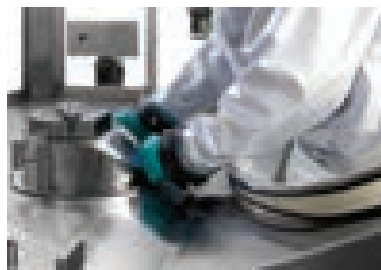
extract
TECHNOLOGY

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ENGINEERED ASEPTIC SOLUTIONS

Sterility Testing Isolator



Extract Technology's Sterility Test Isolators are designed to allow operators to perform sterility testing in an aseptic environment providing assurance of process integrity. They also provide a controlled means of loading and removing the processed product and waste materials from the Isolator enclosure.

This system provides a cost-effective alternative to the "multi-isolator" approach to sterility testing and is ideal for those customers with limited laboratory space whilst benefiting from the ability to provide rapid decontamination.

Over the past decade, the use of Barrier Isolator systems for aseptic applications has increased dramatically. Our Sterility Testing isolators allow operators to perform sterility testing on different quantities and sizes of products in a safe, contained manner and they have basically eliminated false positive tests. Our systems have the option of using our "Pharmaport" glove ports, bespoke glove ports or halfsuits.

Design Advantages

- Ergonomic design
- EU GMP compliant design
- Full process equipment integration of Millipore Steritest® Unit or Sartorius Sterisart®NF
- Different pressure regimes available within each chamber
- Integrated Hydrogen Peroxide Decontamination
- Independent gassing of individual chambers
- Bespoke racking and storage to suit the application
- Recirculation laminar flow airflow system or turbulent airflow systems available providing ISO 5 classification
- Easier process separation
- Energy efficiency

FOR MORE INFORMATION ON STERILITY TESTING ISOLATORS CALL
+44 (0) 1484 432 727 OR EMAIL info@extract-technology.com

Process Description:

SAMPLES TO BE TESTED AND ALL ASSOCIATED SUPPLIES AND EQUIPMENT REQUIRED FOR TESTING ARE LOADED INTO EITHER THE ISOLATOR MAIN CHAMBER VIA A HINGED WINDOW OR A TRANSFER AIRLOCK. WHEN LOADING IS COMPLETED, THE ISOLATOR MAIN CHAMBER AND/OR AIRLOCK CAN BE DECONTAMINATED WITH VAPORISED HYDROGEN PEROXIDE.

The decontamination process is conducted by a hydrogen peroxide generator (supplied separately), which communicates with the Isolator PLC. By communicating with the generator when the decontamination cycle is complete, the Isolator will automatically switch to a "rapid aeration" mode to purge the Isolator of the hydrogen peroxide vapours. When aeration is complete, the Isolator switches to run mode and is ready for sterility testing.

The samples can then be membrane filtration tested by using the optional Millipore 316L Integral Steritest system integrated into the floor of the isolator. Once testing is completed, the exposed media samples and refuse will exit either via the Isolator main chamber hinged window or a transfer airlock.



CLIENT SPECIFICATION

One of the European sites of a global speciality pharmaceutical company approached Extract Technology to design and manufacture a Sterility Test Isolator based on their knowledge and proven expertise in this area. The Client specification for the Isolator included:

1. Providing an easy method of loading prior to the commencement of the Sterility Testing process via the open front of the Isolator or via the Transfer chamber.
2. Viable and non viable monitoring system
3. To create and maintain a sterile ISO 5 environment with unidirectional airflow.
4. To provide a controlled means of removing processed samples and waste materials from the Isolator enclosure without compromising the internal environment.
5. Integrated Bio Decontamination System.
 - The Sterility Test Isolator designed and manufactured at Extract Technology included two chambers, a main chamber that will be used for Sterility Testing and a second chamber that will be used as a transfer chamber. Each chamber can be individually gassed to allow continual processing.
 - Four gloveports in the main chamber gave the operator maximum ergonomic comfort and space to carry out the test process providing sufficient room for product storage and a Millipore Steritest unit.
 - The Client opted for a full scale wooden mock up of the Isolator and visited Extract Technology to participate in an operation and process review in the factory which was carried out successfully.

Our Sales and Engineering staff will work closely with you to design the optimum system to meet your needs. Extract Technology Limited offers complete in - house design, mock-ups, engineering, fabrication, installation and onsite start up services.

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