BIOMATRIX
LIFE SCIENCE

# Sterility Test Isolator

# CellExpress-ST3

## 1. About BioMatrix

Our full process isolators assure high containment synthesis and formulation of pharmaceutical and biopharmaceutical compounds from small-scale manufacturing to full-scale production. We have the understanding and expertise of every type of process equipment such as reactors, filters, dryers, ANFD, tray dryers, mills, blending and sieving. We are proud to provide total integration and operation within our process isolators of any piece of process equipment to suit your requirements.

BIOMATRIX's vast experience includes full manufacturing installations such as clinical trials, analytical isolator, lab and kilo-lab isolators for ADC, HPAPI and cytotoxic products. PSL Isolators and Glove Boxes are all compliant with Good Manufacturing Practice (cGMP) and are designed in accordance with the required local and international regulations.

## 2. Overview of Sterility test isolator

Sterility test isolator is designed and produced for the sterility test of aseptic products. It is highly integrated with equipment and instruments, easy to operate, shortens the disinfection and sterilization time, etc., greatly saves the overall test time, minimizes the sample circulation time between production and testing, and provides good environmental control to minimize false positive interference during aseptic testing.

Sterility test isolator in a limited laboratory environment provides a low-cost, efficient clean inspection environment, ensures the product sterility requirements, and ensures the sterility test and aseptic operation of the product sterilization function.

## 3. Description of Sterility test isolator

| S/N | Item | Description | Num. | Remark |
|---|---|---|---|---|
| | **Function Introduction** | | | |
| 1.1 | Pressure and airflow pattern | Buffer chamber: 20-50pa<br>Operation chamber: 50-100pa<br>Airflow pattern: laminar flow | 1 | BIOMATRIX |
| 1.2 | Sterilization | Biological challenge test was carried out in the chamber, and Bacillus stearothermophilus with typical resistance was killed by 6 log. | 1 | Validation test |
| 1.3 | Isolator leakage rate | Leakage test (pressure holding test), which is automatically performed through HMI. The leakage rate is ≤ 2.5 x 10-3 vol/hr.<br>Each chamber can be tested independently. The isolator can be tested as a whole as well. | 1 | BIOMATRIX |
| 1.4 | Cleanliness | Class A, self-purification time shall not exceed 10 minutes. | 1 | BIOMATRIX |
| 1.5 | Differential pressure monitoring system | Differential pressure sensor:<br>Operation chamber: On-line monitoring of HEPA filter pressure difference of air supply.<br>Operation chamber: on-line monitoring of chamber pressure difference. | 4 | Dwyer |
| 1.6 | Door system | Intelligent door control system, interlock design.<br>All operations are carried out through HMI, with 3-level password authority. | 1 | BIOMATRIX |
| 1.7 | Alarm system | Sound & lighting alarm:<br>Pressure, pressure difference, temperature, humidity alarm.<br>Monitoring and alarm of high/low VHP concentration. | 1 | SIEMENS |
| 1.8 | Noise | Noise generated during normal operation or | 1 | BIOMATRIX |

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|---|---|---|---|---|
| | | maintenance of the equipment is ⩽75dB (1m away from the equipment, human ear height). | | |
| 1.9 | Data traceability | Key parameters can be monitored in real time, recorded, printed directly or uploaded remotely. | 1 | SIEMENS |
| | **Main structure** | | | |
| 2.1 | Dimension | Isolator is designed with two chambers and to be operated at one side.<br>Ext. Size: L2250×W750×H2200mm.<br>Ext. Size of buffer chamber: L550×W550×600mm.<br>Ext. Size of operation chamber:L1600×600×800mm. | 1 | BIOMATRIX |
| 2.2 | Material | Interior of isolator: SUS316L, T= 4.0mm.<br>Other parts: SUS304 with spraying. | 1 | BIOMATRIX |
| | Door system | Wing opening front door for operation chamber, equipped with air support structure. Opening angle ≥ 90, can be opened and closed by a single person.<br>Tempered glass for door, T=15mm<br>Glove ring and glove system installed on front door. | 3 | BIOMATRIX |
| | Glove | Operation chamber: 3 gloves, 8-inch oval glove ring, White POM material | 3 | BIOMATRIX |
| | | 8-inch CSM gloves | 3 | Piercan or North (USA) |
| | Trolley | Material transfer trolley, made of SUS316L material. Used for loading and transferring products. | 1 | BIOMATRIX |
| | | Pole, hook, etc. | 1 | BIOMATRIX |
| | **Ventilation system** | | | |
| 6.1 | Blower | Providing air supply and exhaust.<br>Air supply blower: provide air supply to meet velocity requirements of laminar flow.<br>Exhaust blower: for air exhaust (including the residual removal of hydrogen peroxide disinfectant). | 4 | EBM |
| 6.2 | Air supply filter | Air supply filter: liquid tank-type HEPA filter (H14), with high-efficiency PAO generating and testing port reserved. | 2 | Wuxi criticality |
| 6.3 | Exhaust filter | Exhaust filter: Dry HEPA filter (H14), combined with manganese dioxide decomposition medium, can effectively decompose hydrogen peroxide residue. | 2 | BIOMATRIX |
| | **Controlling system** | | | |
| 7.1 | Operation system | SIEMENS S7-700ie series, with RJ45 interface and supports TCP/IP protocol. | 1 | SIEMENS |
| 7.2 | Touch screen | Touch screen: 7 inches, highly integrated system:<br>● Operation of isolator<br>● Isolator parameter setting<br>● Isolator permission setting<br>● Isolator door control management<br>● VHP sterilization system<br>● High and low VHP concentration alarm setting | 1 | SIEMENS |

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|---|---|---|---|---|
| | Online monitoring | ● Dynamic GMP class A environment monitoring (particle counter is optional, connection port is reserved as standard)<br>● Online velocity monitoring<br>● On-line pressure difference monitoring<br>● On-line monitoring of high and low concentration of hydrogen peroxide | 1 | D.P: Dwyer (USA); Velocity: Kriwan (Germany) |
| | **Sterilization system** | | | |
| 9.1 | Hydrogen peroxide Sterilization system | Integrated VHP sterilization system.<br>Isolator and sterilizer are integrated in a PLC system to avoid wrong operation and human intervention.<br>The isolator has the intelligent sterilization reservation function, which greatly improves the sterilization batch. | 1 | BIOMATRIX |
| 9.2 | Hydrogen peroxide Decomposition system | On-line decomposition system of hydrogen peroxide residue can effectively reduce residual hydrogen peroxide concentration. After ventilation, the residual concentration in the chamber is less than ＜1ppm. | 1 | BIOMATRIX |
| 9.3 | Hydrogen peroxide Concentration sensor | Buffer chamber and operation chamber all meet on-line monitoring of high and low concentrations of hydrogen peroxide. | 1 | VAISALA (Finland) |
| | Alarm system | ● Velocity exceeding the standard alarm<br>● Pressure difference alarm<br>● Hydrogen peroxide concentration alarm<br>● Door opening alarm | 1 | BIOMATRIX |
| | **Optional Devices** | | | |
| 11.1 | Gloves Integrity tester | On-line glove integrity tester, supplied with wireless printer. | 1 | BIOMATRIX |
| 11.2 | Sterility test pump | Straight line installation of pump pipe, automatic pipe clamping, memory of process parameters. | 1 | BIOMAI |

**4. List of utilities**

| S/N | Item | Function | Scope/capacity |
|---|---|---|---|
| 1 | Power | Equipment power supply | Single phase / Three-phase,5kw |
| 2 | Air supply | Isolator internal air supply | Indoor air inlet:<br>Clean air circulation condition: 500$m^3$/h;<br>Sterilization and residue removal condition: 2000 $m^3$/h |
| 3 | Air exhaust | Circulate exhaust and residual discharge of isolator | Outdoor exhaust:<br>Clean air circulation condition: 500 $m^3$/h<br>Sterilization and residue removal condition: 2000$m^3$/h |

| S/N | Item | Function | Scope/capacity |
|---|---|---|---|
| 4 | Clean compressed air | Isolator internal dehumidification,<br>Clean air purging of isolator | 6 Bar, dew point: -20℃ |

## 5. Main Parts

| No. | Contents |
|---|---|
| 1. | Pressure difference monitoring |
| 2. | HMI, touch screen system |
| 3. | Buffer chamber |
| 4. | VHP generator system |
| 5. | Printer |
| 6. | Air inlet |
| 7. | Air outlet |
| 8. | HEPA filter & blower |
| 9. | Glove port |
| 10. | Operation chamber |
| 11. | Electrical system |
| 12. | Waste liquid collection system |