



Isolator

Technology Introduction

Possible contamination due to exposure of clean-room environment or personnel to process media can be unacceptable in high toxic applications. An Isolator unit under light vacuum (100 Pa) that provides uncompromised and continuous isolation of its interior from the external environment is necessary in this case.

Isolator types:

API Isolator

- Dispensing & Sampling Isolator
- Reactor Charging Isolator
- ANFD Discharge Isolator
- Centrifuge Isolator
- Reaction, Distillation, Filtration & Drying Isolator

Formulation Isolator

- Granulation Isolator
- QC Isolator
- Milling & Sieving Isolator
- Pack off Isolator

Benefits

- Operator safety
- Uncontaminated process media
- Alarms and safety measures in case of breach

Applications

- Handling Cytotoxic drugs, Oncology drugs etc



Features

1. Laminar airflow
2. Rugged SS 316 build
3. Containment breach alarm, low pressure and high pressure alarm, filter choked alarm etc.
4. Interlocked door system
5. Push-push type safe changeable HEPA filters
6. PLC controlled, Digital pressure controller to maintain a constant pressure.
7. Integrated Clean In Place / washable to reach every corner of chamber
8. Integrated Weighing Scale, Nutsche Filter, Vacuum Tray Dryer, Continuous liner port and Drum loader
9. Oxygen monitoring / Nitrogen inertization
10. Turbulent airflow
11. ISO 14644-1: class ISO 5
12. Complete Documentation – FDS, DQ, FAT, IQ, OQ, OMM, Leak test, Lux, Noise, Air change, Filter integrity, Glove test, OEL etc.
13. Integration with RTP for safe and rapid transfer
14. Split Butterfly valve for safe transfer of material.

OEL (Occupational Exposal Limits) Categories

Categories	Hazard Description
OEL 1	Harmful, and / or low pharmacological activity
OEL 2	Harmful, and / or moderate pharmacological activity
OEL 3	Moderately toxic and / or high pharmacological activity
OEL 4	Toxic and / or very high pharmacological activity
OEL 5	Extremely toxic and / or extremely high pharmacological activity

Pharmaceutical Positive Isolators

Whenever product protection is desired with respect to moisture / oxygen / creating inert working atmosphere / sterility etc, the Positive pressure Isolators are the solution. This Isolator works at higher pressure than atmospheric condition and is hermetically sealed system.

The blower / air handling system works on complete / partial recirculation wherever and whenever required, depending on the type of operation.

Positive pressure isolator is generally for Sterile Operation Applications. Sterility test Isolators are also integrated with VHP (Vapourised Hydrogen Peroxide) generator. With VHP cycle, the hazardous bacteria decontamination can be carried out.

These Isolators are classified under ISO 5 (Class 100 Grade A).



Applications

- Sterility testing
- Sterile transfer
- Sterile filtration
- Sterile loading and unloading of vials into lyophilizers
- Sterile Compactor and filling lines



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