

Isolators

Containment Isolator, Aseptic Isolator, Compounding Isolator, Integration of Isolator with equipment.

Containment, Aseptic, Integration

The isolation concept, which is well known throughout the **pharmaceutical industry**, is protecting the process from the Operator and/or the Operator from the process, while protecting the environment. The potency of pharmaceutical chemicals is characterized by OELs in $\mu\text{g}/\text{m}^3$. The lower the value, the more potent the chemical and the greater the level of containment that is required.



Pharmaceutical glove boxes (isolators) are specifically designed to meet the needs of their application.

A large number of pharmaceutical isolators use laminar air flow technology in their design. This feature provides a system that directs the air flow for applications needing low particle counts, while protecting the user from the hazardous material being handled. The pharmaceutical industry utilizes isolators in the packaging of medicine, sterility testing, microbiological agents, potent compounds testing, liquid filling, sterile processing and powder processing.

In addition, glove boxes manufactured for pharmaceutical and nuclear markets have been designed to provide the barriers of protection needed in the handling of hazardous chemicals and/or radioactive material. Barrier isolators (glove boxes) used in the pharmaceutical industry are designed to handle hazardous pharmaceutical compounds, chemotherapy agents and mixtures that can be harmful to the end user.

TYPES OF ISOLATOR

CONTAINMENT ISOLATOR

ASEPTIC ISOLATOR

COMPOUNDING ISOLATOR

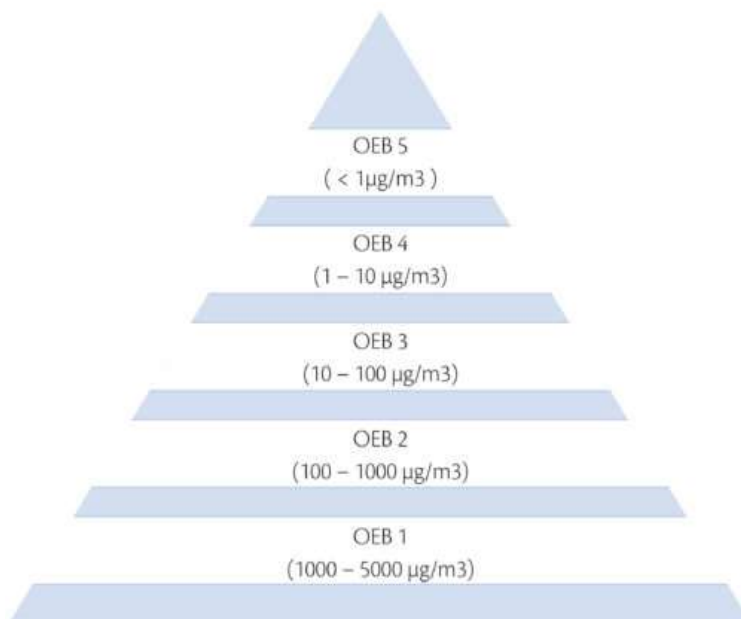
DISPENSING ISOLATOR

FILLING LINE ISOLATOR

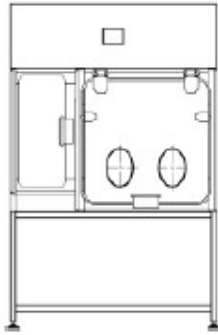
STERILITY TESTING ISOLATOR

CONTAINMENT PYRAMID

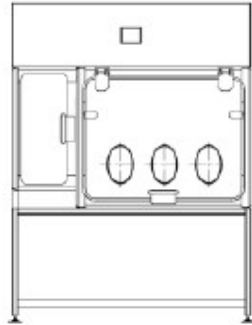
OEL is just one among several different parameters available as international standards in order to measure and classify the toxicity of the active ingredients and of other chemical substances. Operational exposure limit usually refers to inhalation exposure and it is used as an indication of the maximal concentration of the substance in the air at working places that allows no risks for the health. OEL levels change for oral or parenteral exposure. Exposition time is calculated on the basis of eight hours per day (40/h per week) over the entire life span. International guidelines do not indicate a precise requisite as for exposure levels during production.



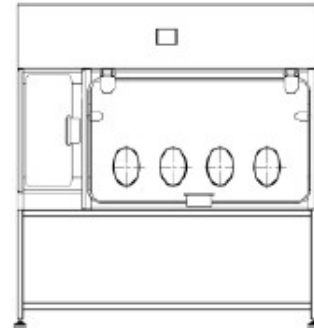
DIFFERENT DESIGN ISOLATOR FOR QUANTITY OF API TO BE HANDLE



2 GLOVE PORT



3 GLOVE PORT



4 GLOVE PORT

STERILE ISOLATOR

Sterile Isolators are focused on protecting the substance and the user. The chamber works under negative pressure in this case, since human health is at stakes along with product/substance protection conditions to ensure full containment.

The system is designed to ensure internal laminar flow to aid in preventing contamination and cross- contamination.

Ravona Aseptic Isolators are made of SS316 construction with full effective cleaning abilities among which are rounded corners, Cleaning in Place (CIP), the surface polish of $Ra < 0.4$.



Aseptic Sterile Isolator

Available Options:

- Preparation for various VHP generators
- Control of blower speed during weighing phase
- BIBO enclosures HEPA filters
- Various illumination wave length
- The complete separation of the internal and external environment results in a surrounding area that can be operated at a much lower classification and consequently lower cost.
- Full cGMP documentation is provided.

Isolator define uses

Isolator Type	Characteristics and Properties
Compounding Aseptic Containment Isolator Aseptic Isolation systems require an environment free from biological hazards and are negatively or positively pressurized.	Negative pressure (when potent substance are used) Laminar flow Isolator. 316L Stainless Steel construction.
Isolators for high-potency drugs	Negative pressure -Turbulent air flow – eliminating cross contamination. 316L Stainless Steel construction.
Isolators for high-potency drugs/ Oxygen/Humidity sensitive compounds. Option: ATEX (EX-Proof and ex proof vent system).	Negative pressure -Turbulent air flow/inert Gas Flow –eliminating cross contamination 316L Stainless Steel construction. Real time oxygen/humidity monitoring.

