ISOTEC
FULL CONTAINMENT SYSTEM

The isolator is a system which allows to handle products and carry out activities fully isolated from the surrounding department or cleanroom.

The threefold effect is the operator, product and environment protection.

ISOTEC systems are able to maintain cleaning requirements, and sterility if needed, inside the containment rooms as well as protect both operator and environment from highly toxic products.

ACCIAIO INOX AISI 316L | Ex | CFR 21 ANNEX1 | EN 14664 | CE | MADE IN ITALY

Tecninox develops designs and provides isolation systems ever more sophisticated thanks to a constant cooperation with pharmaceutical, hospital, chemical, cosmetic and food sectors.

A specific design ensures total containment and safety during those processes involving API components, leading all production to positive results.

ISOTEC line is set up to meet all requirements both with positive pressure (human cells multiplication, aseptic procedures, sterility test, weighing, dosing, fractionation, packing and transfer) and with negative pressure (fractionation, weighing, grinding, micro grinding and transfer).

ADVANCED ISOLATOR TECHNOLOGY FOR SAFE AND EFFICIENT PROCESSING

Isolation technology is essential in pharmaceutical and healthcare applications to prevent contamination and protect operators, products, and the environment.

Benefits of using isolators

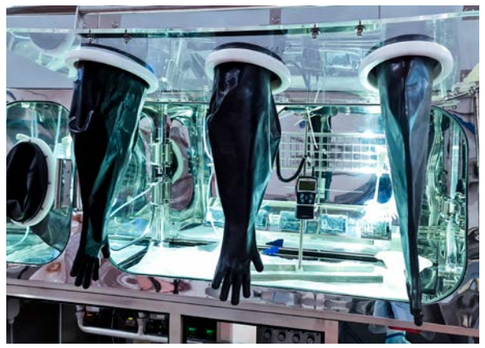
- Guaranteeing product sterility: isolators prevent microorganisms from entering the aseptic processing area or escaping from a contained process, reducing the risk of product contamination.
- Ensuring consistent product quality: isolators help to maintain a controlled environment, which can improve product quality and consistency.
- Improved operator safety: Isolators protect operators from exposure to hazardous materials, such as HPAPIs.
- Reduced environmental impact: Isolators prevent the release of HPAPIs into the environment, protecting the environment and the public.

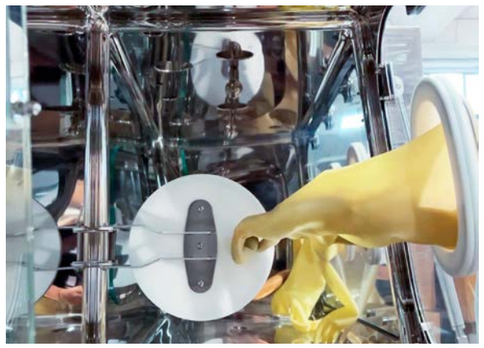
ASEPTIC PROCESSING

Isolation technology is a critical component of aseptic processing, ensuring the sterility of pharmaceutical products. It creates a physical barrier between the product and the environment, preventing contamination.

Tecninox Isolator Key benefits:

- Reduced risk of contamination: isolators are designed to prevent microorganisms from entering the aseptic processing area, reducing the risk of product contamination.
- Increased product quality: this equipment helps to maintain a controlled environment, enhancing product quality and consistency.
- Improved operator safety: Tecninox safety paramount in isolator design, manufacturing and operations is a personal protection from exposure to hazardous materials, such as High Potent Active Pharmaceutical Ingredients (HPAPIs).





TECNINOX PROCESS OPTIMIZATION

- Process-centric design: isolators and RABS design are based on a deep understanding of customer process and requirements to develop the conceptual design of the unit
- 3D Modeling and Mock-up is the result of the integration of process requirements and ergonomic issues
- Air Flow Simulation represents the third step of design to check the efficiency of the ventilation and HVAC systems to achieve an efficient contamination and containment control within the unit
- Tecninox Risk-based Approach to Feature Selection
- Quality Risk Management is an essential study to check that all risk related with process and personal behavior are mitigated by unit design and SOPs
- The integration of our design team and Customer experts is the key to achieve a Quality by Design, QbD unit.

TECNINOX COMMON DESIGN FEATURES

- Each unit is manufactured to the highest GMP quality and it has mirror polished chambers with ultra-safe inflatable gasket protected doors.
- PLC controller able to produce fully validatable process reports.
- A large range of configurable options is available to fully meet user requirements
- Both the fascia paneling and loading systems are bespoke designed to optimize both throughput and surface cleaning procedures

COMPLIANCES

The units have been designed primarily for pharmaceutical and healthcare usage and meet all the requirements EU GMP, FDA GMP and associated pharmacopeia as well as all applicable EN standards and directives and international norms

- ISO 14644-1: This standard provides requirements for the classification of in cleanrooms and controlled environments.
- ISO 14644-7 air cleanliness: This standard provides guidance on the monitoring of air cleanliness in cleanrooms and controlled environments.
- ISO 10648-2: This standard provides requirements for the design, construction, and performance of isolators used in aseptic processing.
- EU GMP: These regulations set forth the good manufacturing practices (GMP) that must be followed by pharmaceutical manufacturers in the European Union.
- FDA GMP: These regulations set forth the GMP that must be followed by pharmaceutical manufacturers in the United States.

TECNINOX ISOLATOR RANGE

- RABS (Restricted Access Barrier Systems): this barrier system provides a physical and dynamic barrier between the product and the background environment where the operators are staying in a grade B area (EU GMP Annex 1)
- Isolators with aseptic processing: these isolators maintain a separate air supply and are designed for aseptic processing including validatable chemical surface bio-decontamination.
- Containment Isolator: for handling High Potent Active Pharmaceutical Ingredients (HPAPI) powders is the state-of-the-art solution for protecting the operator, the environment, and the product during sampling, weighing and production phases.
- Healthcare Isolator: those isolators are designed to perform pharmaceutical compounding of sterile medicinal products, but it can also be used for the preparation of other types of drugs, such as antineoplastic and hormonal drugs. Our Isolators can be used in the manufacturing process for ATMPs. They help to ensure the safety and the quality of these products, and they protect operators and the environment from exposure to hazardous materials.

OPTIONS AND CUSTOMISATION

- Customized products.
- ATEX execution.
- CFR 21 Annex 1 compliance

ISOTEC PRESSURE (–)	ISOTEC PRESSURE (+)
HOSPITAL	
Cytotoxic drugs fractionation	Human cells multiplication
Cells marking	Aseptic procedures
PHARMACEUTICAL	
API dispensing	Sterility test
Grinding	Weighing
Weighing	Transfer
Transfer	
Drug substances handling	
CHEMICAL	
API dispensing	Sterility test dispensing
Weighing	Dispensing
Transfer	