

ISOLATION TECHNOLOGY FOR
**PRIMARY PHARMACEUTICAL
PRODUCTION**



Your primary choice.

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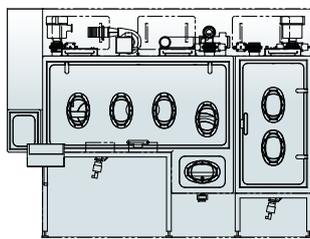
Comecer isolators for primary pharmaceutical production have been conceived for pharmaceutical companies who require high containment level during manipulations of active pharmaceutical ingredients (APIs).

Some types of our isolators for APIs handling:

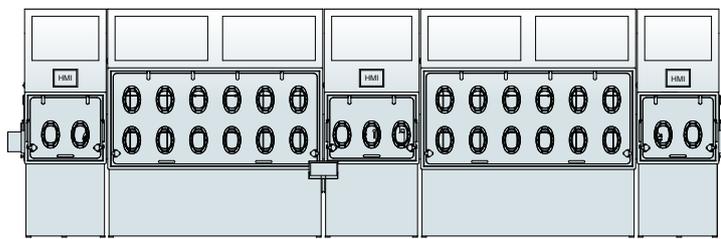
- Dispensing & Weighing
- Milling & Micronizing
- Reactor Charging
- Powder Processing
- Chemical Synthesis
- R&D
- Kilolabo
- Quality Control

A real tailor made approach

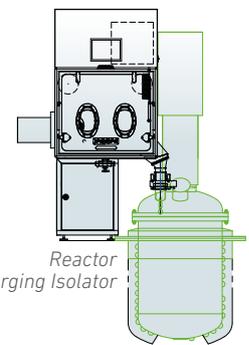
Every single process requires a special attention and a deep understanding of the needs. Therefore the final design is at the end what perfectly fits the customer requirements.



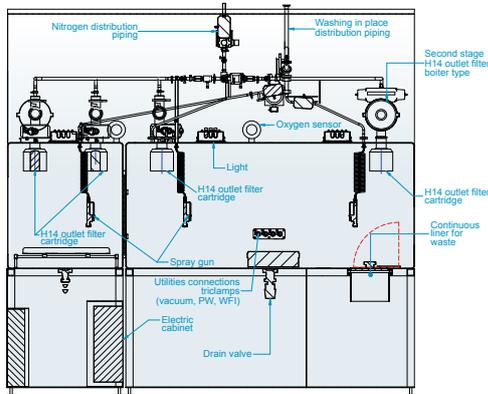
Weighing Isolator



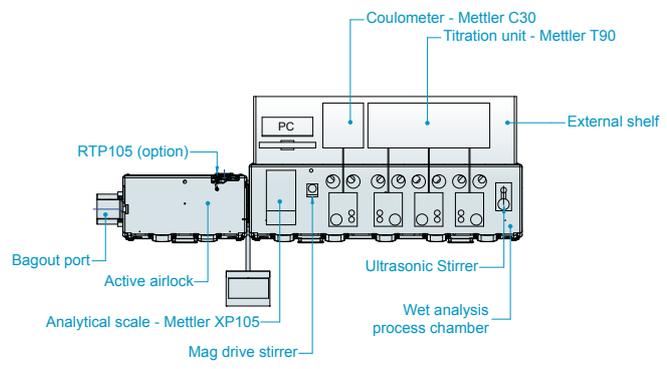
Research & Development Isolator



Reactor Charging Isolator



Dispensing & Weighing Isolator



Quality Control Isolator

Customized internal solutions

Comecer isolators for primary pharmaceutical production can be equipped with racks, accessories and instruments (scales, QC lab instruments, vacuum ovens etc.) in order to answer any specific requirement.



Continuous Liner



Interface Flange



Reactors

Containment: the heart of APIs production

The toxicity of APIs is measured using the OEB/OEL levels. For each of these levels a different containment system is required based also on the process, volume and dustiness of the APIs. Ultimately the isolation technology is the only solution that can guarantee the protection of the operator even in the case of highly toxic products.

OEB:
Occupational Exposure Band

OEL:
Occupational Exposure Level

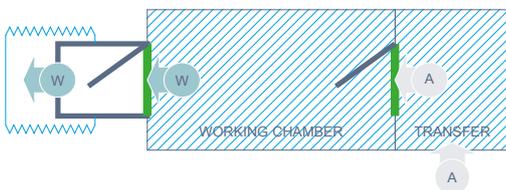
PDE:
Permitted Daily Exposure

| | | | | |
|---|------------|------------------------------------|------------------------|-----------------|
| Isolator Systems | 6 | <0.1 | <1 | Extremely Toxic |
| Isolator Systems or Liner Connecting Systems | 5 | 0.1-1 | 1-10 | Highly Toxic |
| Isolator Systems or Liner Connecting Systems | 4 | 1-10 | 10-100 | Toxic |
| Liner Connecting Systems or Protective Liner Connecting System Trickle Protection | 3 | 10-100 | 100-1000 | Less Toxic |
| Protective Liner Connecting System Trickle Protection | 2 | 100-1000 | 1000-10000 | Almost Nontoxic |
| Open systems with local extraction | 1 | 1000-5000 | >10000 | Nontoxic |
| | OEB | OEL [µg/m ³] | PDE [µg/day] | |

General process cycle

OEB 4/5

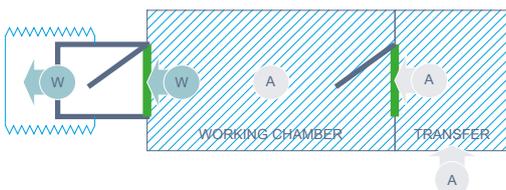
1. Material loading/operation



2. Transfer chamber washing (CIP/WIP)



3. Material loading during operation

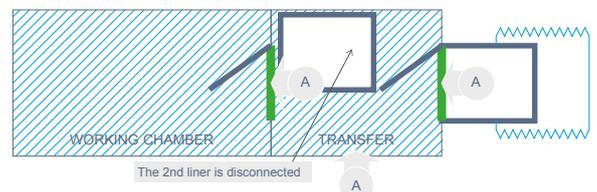


4. Final washing (CIP/WIP)

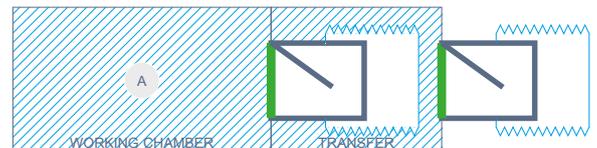


OEB 5+

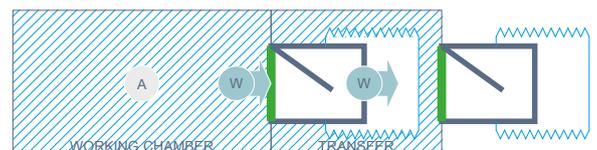
1. Material loading



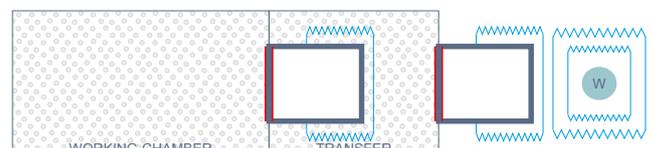
2. Second liner connection



3. Operation



4. Final washing



W Waste

A API: Active Pharma Ingredient

 Contaminated

 Washed

An example: Modular Dispensing and Weighing Isolator

The Modular Dispensing and Weighing Isolator has been conceived to satisfy the requirements related to the handling process of highly toxic API (Active Pharmaceutical Ingredients).

State of the art features

- Stainless steel AISI 316L enclosure with roughness less than 0,4 micron
- Turbulent airflow or laminar airflow
- Inlet/outlet HEPA 14 safe change filters (bag-in bag-out or push-push)
- Nitrogen blanketing system
- Inflatable gaskets
- Washing in place (WIP) / Cleaning in place (CIP)
- Sanitary drain system
- Software CFR21 part 11/GAMP 5 compliant
- PLC control
- Widescreen HMI with user-friendly interface including USB and ethernet port

Further optional

- Instruments integration
- Automatic glove tester (AGT) onboard
- Rapid transfer port (RTP)
- Continuous liner
- Humidity and temperature sensors
- ATEX compliance
- High containment valves (both active and passive parts)
- Paperless graphic recorder
- Others on request

Technical data

| | |
|--|---|
| Material | |
| Shell structure | AISI 316 L |
| Stainless steel finish | external: Scotch-Brite internal: Mirror-Brite |
| Air classification | |
| Main chamber | Class C ISO 8 (at rest) |
| Pre-chamber | Class C ISO 8 (at rest) |
| Working internal pressure | |
| Main chamber | -125/-25 Pa (standard: -75 Pa) |
| Pre-chamber | -125/-25 Pa (standard: -50 Pa) |
| Filters | |
| Main chamber | N°1 H14 cartridge filter (inlet) N°2 H14 filters bag-in bag-out (outlet) |
| Pre-chamber | N°1 H14 cartridge filter (inlet) N°2 H14 filters bag-in bag-out (outlet) |
| Overall dimensions (w x d x h) | 2900 x 850 x 2750 mm |
| Internal dimensions (w x d x h) | |
| Main chamber | 2000 x 600 x 900 mm |
| Pre-chamber | 800 x 600 x 900 mm |
| Net weight | 1300 kg |
| Utilities requirements | |
| Compressed air | 6 bar, 25 nL/min |
| Power supply | 230V (1Ph+N+PE) 50/60Hz 32A TN-S |
| Installed power | 2600 W |

All data refer to the configuration MODULAR DISPENSING AND WEIGHING ISOLATOR (OEB 4/5)



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