

Cytotoxic Anticancer



 **TECNinox**[®]

*Your partner
in process technology*



The isolator is designed to manipulate liquid with Cytotoxic compounds. They are designed for the situation where operator, product and environmental protection from dangerous effects due to uncontrolled diffusion of air-transported contaminants is requested. At the same time they avoid any biological interference of the environment on the product during its handling.



High Tech containment

COMPOUNDING AND DISPENSING ISOLATOR

This isolator is designed for Vessel reaction charge (Compounding) or for Bin charge (Dispensing). In both cases the high activity product is introduced in the chamber through a pre-chamber.

In the main chamber the operator discharges the product into the bin or in the vessel.

In Compounding isolator the reaction vessel is positioned on a loading cell in order to dose the required active ingredient with precision. In this case the working surface of the isolator will be provided with a special gasket that doesn't interfere with the weighing but assures the required containment level.

In Dispensing isolator, the working surface will be provided with a "containment valve" to load the BIN lower positioned.

The chamber is made in AISI 316L stainless steel with continuous welding and high bending radius. Waste through RTP port or linear bag. Filtration of exhaust air with double H14 Hepa filters safety changeable. Filtration on inlet air (or nitrogen) with 0,2 microns cartridge filter or Hepa filter. Indicators of filter pressure loss.

Frontal screen fixed or openable, made with safety laminated glass. Predisposition for WIP (Washing in place).



Essential characteristics:

- Minimized personnel intervention.
- Completely suitable for in line CIP and SIP (cleaning/sterilization in place).
- Sterile filters for gases and fluids (IT in-line).
- Use of an isolator made in AISI 316L with high bending radius.
- Design free of dead leg area.
- Minimization of product losses by the use of block valves and valve ring.

Essential process requirements

By using the latest components and valve technology and the latest state-of-the-art manufacturing concepts we ensure to meet the rigid safety bonds that shall be foreseen for the operator handling the active principle that is critical when it is in the solid powder shape. The R2 (slurry tank) reactor is fitted with a bottom propeller agitator, a heating and cooling system jacket and many other useful follow-up links for the preparation process. In the R2 reactor a concentrated solution of the active principle is prepared with WFI; then it is transferred (pressure or vacuum) to the second R1 main reactor.

In the R1 reactor the final preparation phase takes place in order to obtain the final quantity of product. Then the product is filtrated and transferred to the filling machine.



CIP/SIP

An essential part of high-quality production of cytotoxic compounds is an integrated CIP/SIP system. The whole installation has been designed for the execution, before and after production, of sterilization and cleaning phases per unit such as R1, R2, transfer/filtration line till the filling machine. In fact sterilization and cleaning phases foresee the same steps also for the piping circuit that strictly concern the connection of the preparation plant to the filling machine and the filling machine itself. The process is managed by an independent PLC/SCADA system that permits the automatic control and the monitoring of all phases.

Automation

System control options range from simple, manual push-button control to full programmable logic controller (PLC) based SCADA options offering a wide range of recipe handling, data acquisition and networking functions. The system complies with all current industry standards like 21CFR par 11. Talk to us. Together, we will find the most appropriate solution to meet your requirements.



Generation
Storage and
Distribution
System for
Purified Media



Blood Plasma



Syrup and
Suspension



Cream
Gel
Suppository



Vaccines



Cytotoxic
Anticancer



Parenteral
Formulation
Compounding



Biotech
Modules
Superskid



Insuline



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