Sterile/Negative Pressure Filling Isolator



Product Description

The sterile/negative pressure filling isolator is mainly used for providing Class A sterile protection for the sterile filtration, filling, capping and other key sterile operating procedures of sterile, highly toxic and highly active preparations, and reducing the risk of environmental pollution in the sterile filling and capping production process. The sterile filling isolator is suitable for filling, capping and sterile solution filtration of sterile drugs, XDC-type conjugated drugs, oncolytic viruses and other products with high toxicity and high activity for trial and pilot R&D.

Product features

The sterile/toxic isolator system is mainly composed of isolator chamber, air filtration system, sterilization system and control system, which provides sterile Class A protection for the equipment inside the isolator and protects personnel from toxic drugs. For the production of sterile/highly toxic and highly active drugs, the isolator technology has the following features:

1. Flexible design: The sterile filling isolator can be flexibly designed according to the process, with matching filtering, dispensing, capping and other functional units;
2. Flexible production: The product can realize the common line production of penicillin bottle and pre-filled needle products;
3. Isolator segment design: The whole line or individual segments can be provided with independent leak testing and VHP sterilization;
4. Pressure gradient design: Each segment is connected by airtight valve, which can adjust the differential pressure independently and set appropriate differential pressure for each segment according to the process, which avoids cross contamination;
5. The product can be integrated with the online environmental monitoring and sampling system of particles and airborne microbes;
6. The sterile filling isolator equipped with RTP barrel/valve transfer device is optional according to supply needs;
7. The wireless glove leak detector can be configured to detect leakage for each glove before production, preventing damage to the internal environment of the isolator from glove breakage;
8. Wash-in-place (WIP) for chamber + clean-in-place (CIP) for air duct can be configured. The isolator bottom plate adopts tilt design, which can facilitate drain after cleaning;
9. Operational risk control confirmation: The Mock-UP wood mold and ergonomic testing confirm that the integrity of the isolator is not damaged, the airflow is not affected, the glove opening location is reasonable, and all interventions have been confirmed before the design of the isolator.
10. A professional validation service team, combined with a set of scientific and perfect validation management system documents proven by the project practice (including but not limited to RA, DQFAT, SAT, IQ, OQPQ, etc.), ensures the product quality and reliable validation results.