Sterile Isolator

The most widespread application of isolators is in the pharmaceutical industry, as drug research and production processes require an additional physical barrier to isolate operators from the sterile production environment and protect products from contamination.

Common processes such as dispensing, weighing, batching, crushing, sampling, etc. can be performed in a positive pressure sterile isolator.

Isolators are generally used in conjunction with the operation chamber and pass box, or can be used separately. The airflow design and flow direction of isolator are similar to those of biosafety cabinet, except that the isolator cabinet is fully enclosed under positive pressure, while the Class II biosafety cabinet is semi-enclosed by negative pressure, and the Class III biosafety cabinet is fully enclosed by negative pressure. These cabinets are designed according to their functions. The isolators can be large or small, and most of the functions and sizes are customized to the user's needs.

In the use process, the operating samples and equipment are transferred to the operation chamber through the pass box, then the pass box door is closed, and the experimenters operate through gloves.



The sterile isolator is mainly used for sterile production and testing. VHP sterilization system can be configured and customized according to customer's requirements. The airtight isolator is mainly used to completely separate personnel from the production process during operation to avoid contamination or cross-contamination of products. Sterile inspection and microbiological inspection are carried out to ensure the authenticity of test results and protect the safety of operators. The main structure of the chamber is made of stainless steel and tempered glass, with hard chamber structure and laminar or turbulent flow, in line with Class A standard when in static state.

Sterile Isolator

Advantages

The inner chamber adopts laminar flow (turbulent flow) air supply, and the airflow shape is professionally designed to ensure the purification level;
Monitor the pressure, temperature, and air speed of the internal chamber in real time, and automatically control and adjust them;
Integrate LOG sterilization program, with the microbial killing rate reaching Log 6 or higher;
The isolator airtightness is tested in strict accordance with ISO14644-2 standard.
Waste can be immediately and quickly discharged from the work area through the RTP, aβ valve, to ensure a clean environment inside the isolator (optional);
Support PLC control with touch screen operation and key operation interlocking control, to effectively prevent misoperation;
Monitor key parameters in real time, and store data and charts for easy export and printing;
The online detection system of dust particles, the online sampling system of airborne microbe and the online detection system of hydrogen peroxide concentration can be integrated as required;
Online glove leak detector can be equipped;
The product can be customized according to customer needs.

Glove Leak Detector

It is a special equipment used for testing the leakage rate of gloves/cuffs for isolation systems (barrier isolation systems);
The data cannot be modified and can be integrated into the production reports in real time;
Complies with computer verification, with audit trail function;
Provides ergonomic operating handle, enjoying unique and compact appearance;
Adopts unique airtight design;
All materials meet medical grade and food grade requirements;
Supports three-level user management.

Product accessories and parameters

Productmodel	TKSAGE-ISO2050(S2)	TKSAGE-ISO2450(S3)	TKSAGE-ISO3150(S4)	TKSAGE-ISO3150(W8)
Overall dimensions:	2050*850*2480	2450*850*2480	3150*850*2480	3150*1100*2480
Glove station:	2gloves	3gloves	4gloves	8gloves
Air distribution	Laminar flow			
Chamber airtightness	Comply with ISO10648-2 standard requirements, and EU and FDA regulatory requirements.			
Door system	Interlocking system			
Filter	G4 primary-efficiency filter + H14 high-efficiency filter			
Control system	PLC intelligent control system (industrial PC, Siemens S7-1200 PLC, three-level permission control, electronic signature, audit trail)			
Intelligent monitoring	Differential pressure of isolator chamber /HEPA differential pressure Air speed at the air outlet/Leakage rate per hour Gas concentration/Temperature and humidity			
Pressure testing	±80Pa			
System integration	Online monitoring of temperature and humidity/air speed/hydrogen peroxide concentration/particles/airborne microbe, etc.			
Leakage rate per hour	<0.5% Vol/hr			
Power supply	220V/5KW			