Automatic Aseptic Filling Isolator

ZHEJIANG TAILIN BIOENGINEERING CO., LTD

Automatic Aseptic Filling Isolator

Automatic Aseptic Filling Isolator AFL Series

Aseptic Filling Isolator adopts a three chamber design, consisting of transfer chamber, filling chamber and capping chamber, and is equipped with integrated Vaporized Hydrogen Peroxide sterilization system to sterilise the chambers together or separately.Customisation is possible. It adopts modular assembly and automated production to improve the efficiency of aseptic preparation production.
At the same time, it can solve the risk of contamination during the filling process of aseptic preparations and ATMPs.

Applications

- It is used to isolate and protect the critical processes of aseptic filling, corking and capping of preparations, minimising the risk of contamination from the external environment during the filling process.
- The Aseptic Filling Line Isolator is a custom designed cGMP Class A/ISO 5 environment isolator system, designed for batch pharmaceutical production of injectable products for preclinical and clinical trial studies.

Features

- Sterility Assurance: Ensure highest air quality in isolated environments

- H14 HEPA for air intake and exhaust
- Integrated Vaporized Hydrogen Peroxide sterilization system and accurate VH_2O_2 concentration and saturation control technology
- Inflatable seals made of silicone in compliance with GMP
- Fully enclosed chambers to avoid direct contact
- Real time monitoring the sediment bacteria, velocity, differential pressure, humidity, temperature

- Energy Saving: Can be placed in a Class D environment to reduce operating costs; Reduced energy consumption throughout the operating cycle with sustainable low-voltage inverter-controlled ventilation fans

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- Automated Leak Testing: Equipped with a automated leak test system, each chamber is individually leak tested according to ISO10648-2, leakage rate is less than 0.5% volume/hour at 2 times working pressure

- Glove Integrity Testing: Integrated automated glove integrity tester(GIT series) that performs an independent leakage test on each glove mounted on the isolator according to ISO 14644-7; Capable of detecting holes down to 100μm diameter

- Data Management: Integrated control of the isolator from an IPC

- With multi-level login access control, audit trail and e-signature functions, in compliance with the FDA21 CFR Part11
- Real-time recording of the entire filling process, complete and traceable data

- Ergonomics: Excellent ergonomics ensure the most comfortable working conditions for operators, maximising operational efficiency and reducing the risk of accidents, eliminating unplanned downtime and improving quality.

- Easy to Maintain: Integrated control module. Allows direct access to all maintenance. Allows secure and private communication via the Internet and remote access to help, updates and maintenance anytime, anywhere.

- Customisable: Customized and modular designed

- For radioactive, toxic, bacteriological particles, a non-contact, safe-change bag-in/bag-out(BIBO) filter system is available (optional)
- DPTE rapid transfer system (optional)
- Aseptic liquid through-wall connection system (optional)
- Highly efficient catalytic external decomposition of VH_2O_2 to achieve lower safe emission concentrations(optional)
- Highly efficient catalytic internal decomposition of VH_2O_2 provides rapid decomposition up to 1ppm for safe discharge into the background environment of the isolator (optional)

Air flow: Vertical unidirectional laminar flow	VH_2O_2 Leakage: ＜1ppm (around the isolator during sterilisation)
Cleanliness Level: GMP Grade A	Control System: Siemens PLC control,12" Siemens industrial panel PC
Sterility Assurance Level: ≥6-log kill	Noise: ＜75dB(A)
Lighting: LED lamp, 500lux	Power Supply: AC380V/50Hz
Airtightness: leakage rate is less than 0.5% volume/hour at 2 times working pressure	

*Size can be customized

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