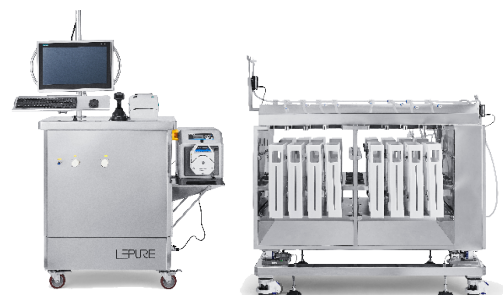


Bulk filling System

With the rapid development of biopharmaceutical industry in China, the demand for proteins, vaccines, antibodies and other drugs is increasing year by year. More and more pharmaceutical enterprises begin to pay attention to fluid management, and liquid filling is a very important part of fluid management. The bulk filling system independently developed by LePure Biotech makes a high-speed filling come true in a fully automatic way. The use of single-use technology greatly reduces the investment in fixed assets in the early stage, and reduces the comprehensive production cost while improving the production efficiency. The equipment is simultaneously equipped with high-precision peristaltic pump and weighing module to achieve a high-precision filling with error controlled within 1%. The bulk filling system is applicable to the filling of antibody, cell/gene therapy, vaccine and other liquids.

Applications

- Large volume liquid filling
- Medium filling
- Buffer filling
- Bulk filling

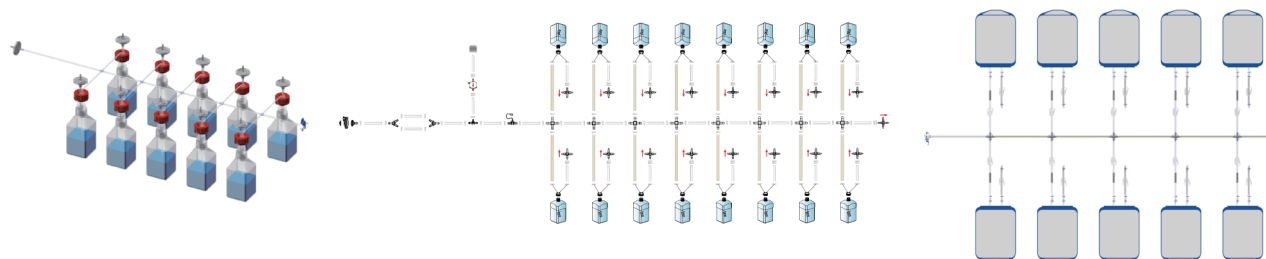


Advantage

- Strong scalability, the volume of filling ranges from 5 ml to 250 L, customized selection, meeting different customer needs
- Suitable for the filling of buffer, drug substance and final product
- Customized pipeline assembly system with high compatibility
- High-performance hardware configuration, modular design, enhanced data security and integrity, and stable system operation
- Automatic data backup, data storage in multiple locations, three-level authority, audit trail, supporting electronic signature, and meeting the requirements of GAMP 5 and part 11 of FDA CFR21
- Supporting the interaction and data transmission of multiple control software and multiple communication protocols
- Providing multiple configurations and upstream and downstream process solutions

Functions and characteristics

The tubing assembly is combined with the bulk filling. The single-use tubing assembly service is provided at the time of bulk filling to reduce manual operation in the filling; Each individual pipe can be equipped with a sterile connector and sterile disconnecter; The tubing can be put into use quickly after pre-irradiation sterilization. Manifold bags or bottles are available for liquid filling and storage.



With the bulk filling solution provided by LePure Biotech, only one control unit is needed to realize fast and accurate filling from 5 mL to 250 L; Besides, the reserved interfaces of the control units of multiple filling brackets can be easily connected through wireless networks, without the need for hardware transformation; Later system upgrade, modular design of requirements and customization of any specification of bracket; And a variety of standard alternative brackets types are available to achieve quick response and quick delivery upon acceptance of custom requirements.



The formula function is available in the system to edit your process conveniently and quickly. After the formula operation, a QR code label independently developed by LePure Biotech will be output, which will be pasted on the storage bag for information reading with a barcode scanner in the next process, so as to reduce the probability of manual writing errors and lay a good foundation for digitization realization of subsequent equipment.



Technical Parameters

Bulk filling system

Technical specification	Specific parameters
Control cabinet size (L*W*H)	1860*490*1030 mm
Material	SS304
Maximum volume after filling	5 mL-250 L
Maximum filling quantity	20, more specifications customizable
Tubing connection	Pre-assembly sterilization
Valve (type, control mode, quantity)	Pneumatic/electric, pinch valve, with customizable quantity
Pump (optional type and model)	Any commercialized pump and pump head
Meet the standard	Comply with FDA 21CFR Part 11 audit trail and electronic signature requirements
Control system	Siemens S7 1500 series CPU + WinCC
Communication protocol	Optional arbitrary field bus
Power supply	AC 220 V 50 Hz 1 phase
Printer	Non-adhesive label printer
Sensor	Mettler load cell, with optional online integrity test function

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