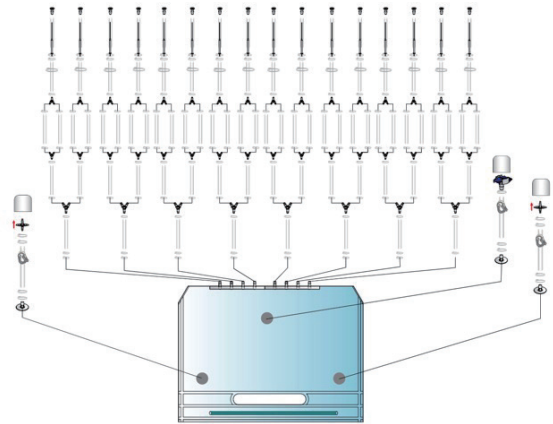


Filling bag

Aseptic filling is the last and most important part of the entire biopharmaceutical production, and the result of aseptic filling directly affects the yield of the final drug. The disposable filling bag can be modularly adapted to the filling equipment, and compared with the traditional stainless steel filling tank has the advantages of flexible and convenient installation, small space occupation and pre-validation. The client does not need to repeat cleaning and sterilization, reducing operational steps and saving time and costs. Lepure uses ultra-clean production process to ensure the cleanliness of disposable pouches, 100% customizable product design to fit different filling equipment and filling process, and professional technical support team to provide strong technical support for the product.



Typical applications

In the production process of biological products, it is mainly used for the aseptic filling of preparations.

Product Features

- Flexible and easy installation
- Pre-validation, pre-installation, pre-sterilization, reducing operational steps
- No risk of cross-contamination

Advantage

- Pre-rinse process brings excellent particulate control to products
- C+A environmental control for improved product cleanliness
- A variety of product designs to choose from, adapted to various types of filling machines
- A wide range of filling bag sizes and shapes can be designed to suit different production batches
- Pre-rinse process delivers excellent particulate control
- Localized production, short delivery time, flexible and customizable
- Professional technical support team can analyze, evaluate and match the actual formulation process according to customers

Technical specification

Physical Parameters

Testing Standards	Test Items	Test Results
ASTM-D6988	Film thickness test (μm)	Pass
ASTM-882	Tensile strength (Mpa)	Pass
ASTM-F1306	Puncture strength (N)	Pass
ASTM-D1709	Falling dart impact (J)	Pass
ASTM-F392	Kneading performance (pcs)	Pass

Biocompatibility

Testing Standards	Test Items	Test Results
USP<87>	In vitro biological response	Pass
USP<88>ClassVI	In vivo biological response	Pass
USP<661>	Physical and chemical properties testing of plastics	Pass

Performance Testing

Testing Standards	Test Items	Test Results
USP<788>	Insoluble Particle Test	Pass
USP<85>	Bacterial endotoxin test	Pass
USP<790>	Visible foreign body test	Pass
In-house methods	Integrity Testing	Pass
USP<643>	TOC Test	Pass
USP<645>	Electrical conductivity test	Pass
ASTM F88	Heat seal strength test	Pass

Ordering information

Category	Configuration Information
Isolator	BETA bag (Optional)
Bag volume	2L-50L (U-HP, FI)
Liquid inlet line connection method	Aseptic connectors, thermoplastic tubing
Respirator	Air Filter
Filling line	1-16 sticks
Filling Needle	ID Min0.5mm, Max7.0mm

Note: 100% flexible and customizable, ask your regional sales manager for details