

# Liner Bag

# Mixing Bag

## Overview Information

Specification	19L-200L Can be customized Less than 19L, We do not recommend using liner bag
Manual	ULDPE Film or SEBS FILM
Operating Temperature	No more than 45°C
Packaging	One-layer packaging (Default)
Sterilization	Gamma irradiated (25 ~ 40 kGy)
Shape	Cylindrical or square customize according to your existing support container

## Features

- More economical than closed bags
- Open type makes it easy to put in large quantities of material quickly
- Multi-mode top match the pipe, and extract the material from port
- Model can be customized with bottom port
- Port mouth can be tied up with can reduce the cross-impact or cross-pollution

## Application

- Media Preparation
- Buffer Preparation
- Short-term storage and transport for cell harvest fluid
- Short-term storage for purified intermediate product
- Scrap during purification

## Supporting Products

- Round plastic bucket with cover
- Square folding box
- Supporting mobile base
- Overhead Stirring Mixing System



## Overview Information

- Neumo offers 1L-2500L mixer bags
- Contains a central magnetic impeller assembly
- Inline control and monitoring of pH, conductivity and temperature. Avoid the risk of contamination associated with reusable test and reduce operator time
- ULDPE fluid contact layer
- A disposable impeller is welded into the bottom of the bag assembly that mounts to the motor drive assembly via direct magnetic coupling
- The magnetic engagement between motor and disposable impeller imparts high torque and fast mixing capability to the system
- Efficient, low shear general purpose mixing with a wide range of applications and shear sensitive solutions

## Features

- Highly customized bags are available
- Different size of top port for powder transfer
- Easy installation and direct access during filling, sampling and draining
- 1L-2500L bags are available
- Consistent process validation data with sustainable, reproducible and reliable data
- ✓ European Pharmacopoeia conformity analysis
- ✓ USP Class VI
- ✓ ADCF
- ✓ Reproducible and reliable data for Extractable and Leachable (E&L)
- ✓ Particulates Test
- ✓ Mixing effectiveness verified

## Application

- Variety of applications\_ from buffer and media preparation to downstream steps and final formulation
- Medium preparation
  - Buffer Preparation
  - pH adjustment
  - Resuspension
  - Chromatography pooling
  - Homogenization of protein solutions
  - Homogenization of vaccine adjuvants
  - viral inactivation
  - Intermediate storage and pooling
  - Ultrafiltration / diafiltration (UF/DF)
  - Final formulation
  - Cell harvest



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# 2D Bag

## Overview Information

Specification	50ml-50L Can be customized Over 50L, we recommend 3D bags
Operating Temperature	-45°C to +60°C +60°C
Packaging	Double layer packing (Default)
Sterilization	Gamma irradiated (S25 ~ 40 kGy)

## Features

- Good physical strength, chemical & biocompatibility
- High transparency which is conducive to process
- For various types of solution storage and transport in biopharmaceutical process
- Size & tubes can be customized which are suitable for a variety of process

## Application

- Storage and transport small scale Buffer & Media & Stock solution
- Collect for purification components
- Used for mixing appropriate amount of liquid
- Used in some ADC reaction mixing process

## Supporting Products

- Transfer tray
- Multy-tier Bracket



# 3D Bag

## Overview Information

Specification	50L-2000L Can be customized Less than 50L, we recommend pillow bags
Operating Temperature	-45°C ~ +60°C
Packaging	To separate packaging
Sterilization	Gamma irradiated (25 ~ 40 kGy)
Shape	Cylindrical or square Customize according to your existing support container

## Features

- Good physical strength, chemical & biocompatibility
- High transparency which is conducive to process judgments
- Can meet the various types of solution storage and transport in biopharmaceutical process
- Size & tubes can be customized which are suitable for a variety of process

## Application

- Storage and transport small scale Buffer & Media & Stock solution
- Transfer cell harvest fluid
- Collect for purification components
- Used for mixing appropriate amount of liquid
- Used in some ADC reaction mixing process

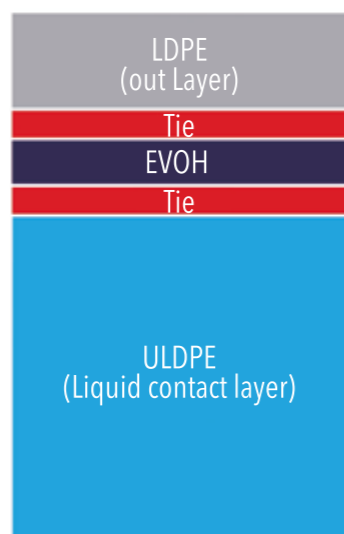
## Cell Harvest Liquid Transfer

- Support product
- Round plastic bucket with cover
- Square folding box
- Supporting mobile base



## 5-layer co-extruded film

- Fil thickness: 0.325mm
- Inner Layer: ULPDE
- Low Leachables & Extractables
- ADCF



## Regulatory requirements

Evaluation items	Guideline
Hemolysis	ISO 1010993-4
Cytotoxicity	ISO 1010993-5
Implantation test	ISO 1010993-6
Irritation and Sensitization test	ISO 1010993-10
Acute Systemic Toxicity test	ISO 1010993-11
Bacterial Endotoxins-LAL test	USP <85>
Biological reactivity testing, in vivo, class VI	USP <88>
Plastic Containers	
European Pharmacopoeia test, Ch 3.1.5	USP <661>

## Regulatory requirements

Items	Test Results (Before/ After)	Guideline
Haze	7 / 7 %	ASTM D-1003
Clarity	97 / 97 %	ASTM D-1003
Transmittance	93 / 93 %	ASTM D-1003
Tensile strength at break	14 / 13 Mpa	ASTM D-882
Elongation at break	280 / 300 %	ASTM D-882
Elastic Modulus	370 / 350 %	ASTM D-882
Cold temperature resistance	-45 / -45°C	ISO 8570
Density	0.9g	ASTM D-792
water vapor transmission rate	0.35 / 0.32 (g/(m <sup>2</sup> .day)) (23°C, 100% RH)	ASTM F-1249
Oxygen permeability	<0.05/<0.05 (cm <sup>3</sup> /(m <sup>2</sup> .day.bar)) (23°C, 0% RH)	ASTM D-3985
Carbon dioxide permeability	<0.2/<0.2 (cm <sup>3</sup> /(m <sup>2</sup> .day.bar)) (23°C, 0% RH)	ASTM F-2476

## 5-PE film products

- Pillow Bag
- 3D Bag
- Liner Bag
- Mixer Bag
- Bioreactor bag