cobetter®
filtration

Lifecube® Single-use Bags

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The iconic starting point of the single-use system was that in the 1980s when pharmaceutical companies began to use plastic capsule filters in small scale. In the 1990s, sterile 10-inch capsule filters (pre-sterilized by gamma irradiation) entered people's vision. At the same time, disposable plastic bags began to be used in the pharmaceutical process and developed rapidly, with the emergence of 2D and 3D single-use plastic bags of different types and volumes. Not only used in storage of liquids, today single-use bags also cover the entire biopharmaceutical process including upstream cell culture, downstream buffer mixing and storage, and storage of the final product. The comprehensive advantages of the single-use system are as follows.

· Single-use system eliminates the risk of cross contamination and greatly improves safety.

· No need for cleaning and sterilization in place. The annual production batches of the production workshop in the same scale are greatly increased, and the production efficiency is greatly improved.

· Reduced the cost of QC and cleaning verification.

Cobetter Lifecube® single-use bags are exclusively designed by Hangzhou Cobetter Filtration Equipment Co., Ltd. The entire manufacturing process of Cobetter Lifecube single-use bags from raw material storage to product packaging is completed in the ISO Class 8 clean zones. Cobetter establishes and continuously maintains the company's quality assurance system in accordance with the requirements of ISO® 9001:2015 quality management system and cGMP. All the products are manufactured under strict quality system to ensure stable and reliable quality. Cobetter Lifecube® can help you achieve simpler process, greater process efficiency and productivity, easier verification and safer products.

Features

- The film has low level of extractables and leachables, good physical strength, chemical compatibility and biocompatibility
- Meets the requirements of various storage and transfer applications in the biopharmaceutical process.
- Flexible design bags and tubings for all different applications.

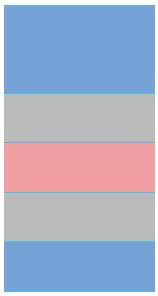
Typical Applications

- Buffer and media preparation, storage and transfer
- Preparation of bioreactor feeds
- Purified components collection
- Storage of purified intermediates
- Stock solution storage and transfer

Lifecube® Film

Specifications

The film of Cobetter Lifecube® single-use bags is composed of five layers. The thickness, materials and performance of each layer are given below.



0.23 mm	**ULDPE** Fluid contact layer, ultra-low density polyethylene	Low extractables & leachables, broad chemical compatibility and biological safety.
0.01 mm	**Tie** Bonding layer	
0.02 mm	**EVOH** Gas barrier layer, ethylene vinyl alcoho	Minimizes gas transfusion
0.01 mm	**Tie** Bonding layer	
0.05 mm	**LDPE** Outer layer, low density polyethylene	Protective layer

Film Specifications

Physical Property	Value (Before / after gamma sterilization, 25 kGy)	Procedure
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	
Break at Cold Temperature	below 45 °C / below 45 °CISO 8570	
Density	0.9 g/cm3 ASTM D-792	
Water Vapor Transmission Rate	0.35 / 0.32, g/(m2·day) (23 °C, 100 % RH)ASTM F-1249	
Oxygen Permeability	< 0.05 / < 0.05, cm3/(m2·day·bar) (23 °C, 0 % RH)ASTM D-3985	
Carbon Dioxide Permeability	< 0.2 / < 0.2, cm3/(m2·day·bar) (23 °C, 0 % RH)ASTM F-2476	
Particle Shedding	Particulate matter in the product eluent meets the requirements in USP <788> for large volume	
Bacterial Endotoxin	Aqueous extraction contains < 0.25 EU/mL as determined by Limulus Amebocyte Lysate (LAL),	
Physicochemical Test for Plastics	Meet the requirements of USP <661> physicochemical tests for plastics.	
ISO 10993 4 Hemolysis	Meet the requirement of ISO 10993 4 in direct contact with the human blood.	
USP <87> Cytotoxicity	Meet the requirement of USP <87> In Vitro Biological Reactivity Test.	
USP <88> Biological Reactivity	Meet the criteria of the USP <88> Biological Reactivity Test for Class VI plastics.	
Indirect Food Additive	The fluid contact component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177–182.	
Animal Free	Products do not contain animal derived components and are free from TSE risk.	
Quality Assurance	These products are manufactured in a facility which adheres to ISO® 9001:2015 Practices.	

Lifecube® 2D/3D Single-use Bags

Quality Assurance

· ISO® 9001:2015 quality management system
· ISO Class 7 clean zones
· 100% leak testing for Lifecube® 2D single-use bags
· ADCF raw materials
· Meet the FDA Indirect Food Additive requirements cited in 21 CFR 177–182
· Meet the requirement of USP <87> In Vitro Biological Reactivity Test
· Meet the criteria of the USP <88> Biological Reactivity Test for Class VI plastics
· Aqueous extraction contains < 0.25 EU/mL as determined by Limulus Amebocyte Lysate (LAL), USP <85>
· Particulate matter in the product eluent meets the requirements in USP <788> for large volume parenterals
· Verify gamma irradiation dose according to ISO® 11137
· Provide product Validation Guide and Certificate of Quality

Features

· Good physical strength and excellent biological safety
· Integrated bag body designed for Lifecube® 2D single-use bags and less residual liquid
· Double-layer sterile packaging sterilized by 25-45 kGy gamma irradiation
· Local supply. Variable and flexible customized services
· Various and scalable

Typical Applications

· Buffer and media storage and transfer after filtration
· Intermediates storage
· Stock solution storage

Supporting Containers

· Provide 2D supporting transfer frame or multi-layer rack
· Provide 3D supporting transfer carts
· 304 stainless steel
· Optional weighing module
· Flexible customized services

Cobetter provides stainless steel containers suporting Lifecube® single-use bags for customers. Customized stainless steel container carts are also available for customer requirements.

Lifecube® AS Single-use Sampling Bags

Quality Assurance

· ISO® 9001:2015 quality management system
· ISO Class 7 clean zones
· 100% leak testing
· ADCF raw materials
· Meet the FDA Indirect Food Additive requirements cited in 21 CFR 177–182
· Meet the requirement of USP <87> In Vitro Biological Reactivity Test
· Meet the criteria of the USP <88> Biological Reactivity Test for Class VI plastics
· Aqueous extraction contains < 0.25 EU/mL as determined by Limulus Amebocyte Lysate (LAL), USP <85>
· Particulate matter in the product eluent meets the requirements in USP <788> for large volume parenterals
· Verify gamma irradiation dose according to ISO® 11137

Features

· Good physical strength and excellent biological safety
· Integrated bag body and less residual liquid
· Double-layer sterile packaging sterilized by 25-45 kGy gamma irradiation
· Various choices for sampling application
· Local supply. Variable and flexible customized services

Typical Applications

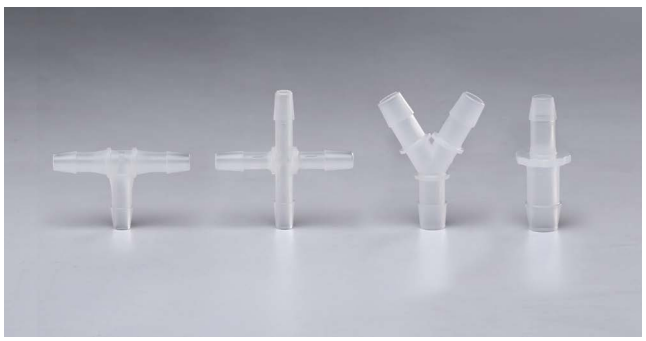
· Sampling with single-use bags
· Secondary sampling from sampling bag
· Store samples after sampling

Lifecube® SA Single-use Assemblies

Quality Assurance

· ISO® 9001:2015 quality management system
· ISO Class 7 clean zones
· 100% leak testing
· ADCF raw materials
· Meet the FDA Indirect Food Additive requirements cited in 21 CFR 177–182
· Meet the requirement of USP <87> In Vitro Biological Reactivity Test
· Meet the criteria of the USP <88> Biological Reactivity Test for Class VI plastics
· Aqueous extraction contains < 0.25 EU/mL as determined by Limulus Amebocyte Lysate (LAL), USP <85>
· Particulate matter in the product eluent meets the requirements in USP <788> for large volume parenterals
· Verify gamma irradiation dose of sterile packaging according to ISO® 11137

LifemetaTM SF
Pharmaceutical Grade Connectors



Quality Assurance

· ISO® 9001:2015 quality management system
· ISO Class 7 clean zones
· ADCF raw materials
· Meet the FDA Indirect Food Additive requirements cited in 21 CFR 177–182
· Meet the requirement of USP <87> In Vitro Biological Reactivity Test
· Meet the criteria of the USP <88> Biological Reactivity Test for Class VI plastics
· Aqueous extraction contains < 0.25 EU/mL as determined by Limulus Amebocyte Lysate (LAL), USP <85>
· Particulate matter in the product eluent meets the requirements in USP <788> for large volume parenterals

Features

· Polypropylene material. Can be sterilized by gamma irradiation at 25-45 kGy or autoclaved 30 minutes at 126 °C
· Withstand vacuum pressure at room temperature to 5.5 bar
· Cobetter self-producted with short delivery time