

Cobetter Lifecube™ PB Single-use Powder Bag



Cobetter Lifecube™ PB single-use powder bag is designed for the preparation and transportation of dry powder culture medium, buffer solution, active raw materials, excipients and other products in biopharmaceutical process. Compared with the traditional process, it is cleaner, safer and more efficient.

Benefits

- Ease-of-use and process visibility
- Sealed by clamp to prevent the material from contacting the environment.
- Standard sanitary connections in 2 in., 3 in., 4 in., 6 in. or 8 in.
- 3 L to 50 L capacities as standard

Quality Assurance

- 100% integrity test
- ISO 9001 quality management system
- Passes USP <88> Class VI and USP <87>
- Animal Component Free and of Non- Animal Origin
- Complies with FDA 21 CFR

1. Topene™ T300 Film

1.1 Film Process

Cobetter Topene T300 blown film designed for biological processes is composed of ULDPE (ultra-low density polyethylene) with low extractability, low precipitation, good chemical compatibility and biological safety.

The Topene T300 film has an ultra clean inner surface, good environmental stress resistance, tear resistance, rubbing resistance, tensile resistance, chemical stability and biological safety, which can be applied to biopharmaceutical processes such as powder bag or configuration and storage of buffer and medium.

Film Process	Film Cooling	Production Environment
Blown film	Vacuum water ring	The environment of film inner layer is over ISO class 5. The environment of film outer layer is ISO class 7.

Characteristic	Co-extrusion Film Blown Equipment
1. The film is extremely clean because the inner layer is not in contact with the workshop environment. 2. The physical strength of the film is excellent because it is stretched horizontally and vertically during the processing.	

1.2 Physical Properties

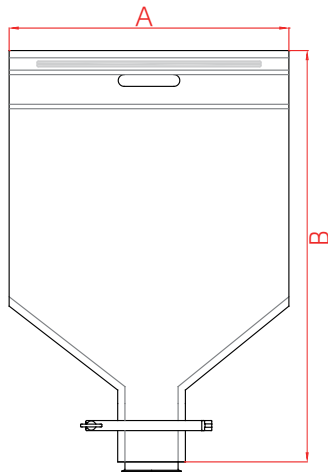
Item	Value (After gamma sterilization, > 25 kGy)	Procedure
Material	ULDPE	
Operation Temperature	-20 °C to 60 °C	
Thickness	300 μm	
Sterilization	25-45 kGy	
Tensile-Strength	Transverse > 10, Longitudinal > 10, MPa	YBB00072005-2015
Heat Seal Strength	> 20 N/15 mm	YBB00072005-2015
Water Vapor Transmission Rate	< 1 g/(m ² · day)	YBB00072005-2015
Oxygen Permeability	< 4000 cm ³ /(m ² · day · bar)	YBB00072005-2015

1.3 Regulatory Compliance

Item	Procedure	Value (After gamma sterilization, > 25 kGy)
Particulate Matter	USP <788>	Particulate matter in the product eluent meets the requirements in USP <788> for large volume parenterals.

Item	Procedure	Value (After gamma sterilization, > 25 kGy)
Bacterial Endotoxin	USP <85>	Aqueous extraction contains < 0.25 EU/mL as determined by Amebocyte Lysate, USP <85>.
ISO10993-4 Hemolytic	ISO 10993-4	The product will not cause hemolysis or erythrocyte coagulation.
USP <87> Cytotoxicity	USP <87>	Meet the requirement of USP <87> In Vitro Biological Reactivity Test.
USP <88> Biological Reactivity	USP <88>	Meet the criteria of the USP <88> Biological Reactivity Test for Class VI plastics.
Indirect Food Additive	21 CFR 177 – 182	The fluid contact component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177 – 182.
Animal Derivative Content	FDA 21 CFR 189.5 EMA/410/01 rev.3	Products do not contain animal derived components and are free from TSE risk.
Quality Assurance	ISO 9001:2015	These products are manufactured in a facility which adheres to ISO 9001:2015 Practices.

2. Ordering Information

Volume	Part No.	Sanitary Outlet	Size A (mm)	Size B (mm)	Package	Diagram of dimensions
3 L	PB2D03L2NSA1	2"	400	550	Sterile	
	PB2D03L3NSA1	3"	400	550		
	PB2D03L4NSA1	4"	400	500		
5 L	PB2D05L2NSA1	2"	400	650	Sterile	
	PB2D05L3NSA1	3"	400	650		
	PB2D05L4NSA1	4"	400	600		
15 L	PB2D15L2NSA1	2"	400	850	Sterile	
	PB2D15L3NSA1	3"	400	850		
	PB2D15L4NSA1	4"	400	800		
30 L	PB2D30L3NSA1	3"	560	1050	Sterile	
	PB2D30L4NSA1	4"	550	1000		
50 L	PB2D50L3NSA1	3"	560	1200	Sterile	
	PB2D50L4NSA1	4"	600	1150		

* For more customized solutions, please consult Cobetter technical team.

Sales and Technical Assistance

 86-571-87704359 (English)
86-571-87704270 (Japanese)
 86-571-87704256
 sales@cobetter.com



Cobetter Filtration Equipment Co., Ltd

 13-18 / F, Building 1, Zicheng International Innovation Center,
No.39 Jincheng Road, Xiaoshan District, Hangzhou 311215, China
 Cobetter Park, Heshang New Material Industry Park,
Xiaoshan District, Hangzhou, 311265, China

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