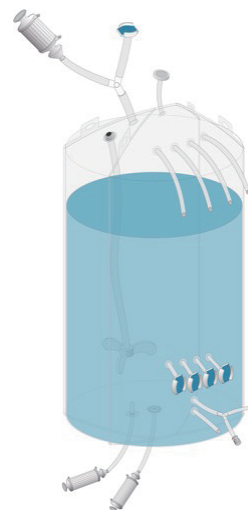


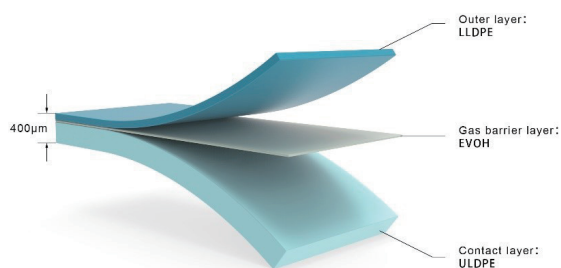
LeKrius® Top stir single use bioreactor bag

LePure can provide customers with a variety of customized bioreactor bag services. Single use bioreactor bags made of LeKrius® film will provide you with an excellent cell culture experience.

LeKrius® have excellent biosafety, chemical compatibility and physical properties to provide biopharmaceutical users with safe, reliable single-use products, covering the full process application of upstream and downstream formulation filling.



Film material information



The film material is three-layer structure. LDPE is the outer layer, EVOH is the gas barrier layer. ULDPE is the liquid contact layer. The total thickness of 400µm. In order to fully guarantee good cell culture performance, the antioxidant Irgafos®168 was not used in the selection of LeKrius® film resins and formulations, and the film formulation was optimized to improve the physical properties of the film, including tensile strength, weldability, puncture resistance, and rubbing resistance.

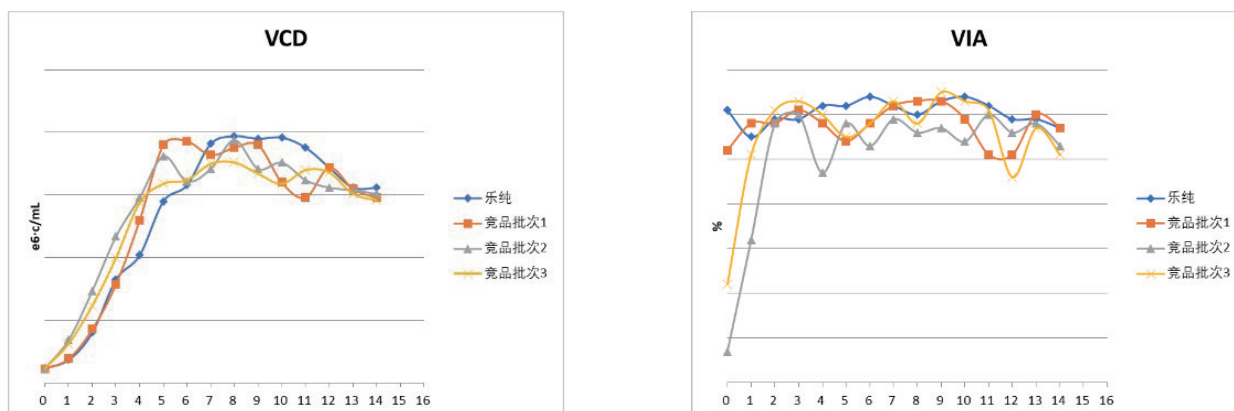
Advantages

- ◎ Perfect replacement can be achieved, stirring and the ventilation effect is consistent after replacement. No modification of process parameters is required after replacement
- ◎ LeKrius® provides better bag body and welding strength, 50mbar still guarantees bag body integrity
- ◎ More mature bag-making process, there are 2000L commercial reaction bag supply cases
- ◎ Each bioreactor bag is tested for integrity before leaving the factory

Application

The LePhenix® single use bioreactor bag has been extensively studied, from cell culture testing to batch to batch stability of membrane materials. The experimental results showed that the LePhenix® disposable bioreaction bag could fully meet the cell culture of HEK293, CHO, SF9 and other cells with excellent performance.

This kind of customized bioreactor bag has been applied to 2000L scale commercial production.



Application Case

This test is the result of cell culture after replacing the competitor's bioreactor bag with LePure's customized up-stirred bioreactor bag. Cell density, cell viability and yield were consistent with those of competing products.

Product Parameter

Art.No.	Maximum/minimum culture volum (L)	Exhaust filter	Stirring diameter (mm)	Blade material	Sparger	Operating pressure
BT050-2K	25/50	0.2µm, 1700cm ² ×1	10.63	PP	178um*360 DHS×1 +Micro Sparger×1	50mbar
BT050-4K	10/50					
BT100-2K	50/100	0.2µm, 1700cm ² ×1	14.6		178um*570 DHS×1 +Micro Sparger×1	
BT100-4K	20/100					
BT250-2K	125/250	0.2µm, 7300cm ² ×1	19.2		233um*775 DHS×1 +Micro Sparger×1	
BT250-4K	50/250					
BT500-2K	250/500	0.2µm, 7300cm ² ×1	25.1		368um*980 DHS×1 +Micro Sparger×1	
BT500-4K	100/500					
BT1000-4K	200/1000	0.2µm, 7300cm ² ×2	32	445um*1180 DHS×1 +Micro Sparger×1		
BT2000-2K	1000/2000	0.2µm, 7300cm ² ×2	39.8	OPEN PIPE×1 +Micro Sparger×3		

Technical specification

Pharmacopoeia compound

Test criteria	Test item	Result
USP<661>	Physico-chemical tests	Pass
E.P.3.1.5	Contact layer polyethylene	Pass


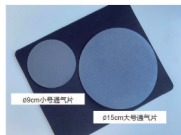




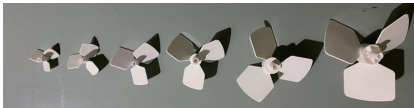

Biocompatibility

Test criteria	Test item	Result
ISO 10993-4	Hemolysis	Pass
ISO 10993-5	Cytotoxicity	Pass
ISO 10993-6	Implantation tests	Pass
ISO 10993-10	Irritation and Sensitization tests	Pass
ISO 10993-11	Acute Systemic Toxicity tests	Pass
USP<85>	Bactivity endotoxins-LAL tests	Pass
USP<87>	Biological reactivity tests, in vitro(Cytotoxicity)	Pass
USP<88>	Biological reactivity tests, in vivo, class VI	Pass
E.P.5.2.8	TSE/BES risk	Pass

Compliance testing

Test criteria	Test item	Result
ASTM F2095-07	Leak tests	Pass
ISO11137	Gamma irradiation	Pass
USP<788>	Insoluble Particles tests	$\geq 10 \mu\text{m}: \leq 10 \uparrow/\text{mL}$ $\geq 25 \mu\text{m}: \leq 1 \uparrow/\text{mL}$
ASTM F1980-2016	Expiration Date	2 Years

Customized accessories

 <p>Gas Filter</p> <p>LePure independently develops 0.2μm gas filters, which can provide 180cm^2 to 13200cm^2 specifications.</p>	 <p>DHS</p> <p>Laser perforation technology to achieve precise aperture.</p>	 <p>Shaft seal</p> <p>Extensive speed and fatigue testing ensures shaft seal integrity during operation.</p>	 <p>Sterile connector</p> <p>Sterile connector for bioreactor bag</p>	 <p>Pressure sensor</p> <p>Available with PENDOTECH or other brand pressure sensors.</p>
 <p>Disposable electrode</p> <p>Disposable electrode solutions are available</p>	 <p>Blade</p> <p>50-2000L specification blade, blade material PP</p>	 <p>Micro Sparger</p> <p>Micro- Provides better oxygen dissolving effect</p>		