



Link to Enable Biotechnologies



About Bio-Link

Bio-Link Biological Applied Technologies (Shanghai) Co., Ltd. (Bio-Link) is a group of technology-driven businesses that provide products and process solutions in the life sciences industry. The company focuses on the development and production of the key processing equipment and consumables for recombinant protein drugs, vaccines, antibodies, cell therapies, gene therapies and other biological products. Bio-Link's portfolio of offerings covers the entire upstream and downstream bioprocess such as cell culture, single-use mixing and storage, protein chromatography, filtration and ultrafiltration, hydration as well as process development and validation service. Bio-Link is committed to provide customers with high-quality, innovative products and solutions, strives to build an efficient, safe and competitive biopharmaceutical supply chain eco-system.

Currently, Bio-Link has 5 major manufacturing sites separately located in the city of Nantong, Lanzhou, Suzhou and Shanghai. In order to provide high quality service to customers nearby, we have set up sales and service centers in Beijing, Shanghai, Guangzhou, Chengdu, Suzhou, Wuhan, Jinan and Changchun. Besides, we established an R&D center in Suzhou, with process development and show site function. To better support the international business, we've set up the subsidiaries both in Germany and Singapore.



 Suzhou R&D Center

Manufacturing sites

- Nantong - Single-use Bioprocessing Manufacturing Site
- Lanzhou - Chromatography Resins Manufacturing Site
- Suzhou - Bioprocessing Hardware Manufacturing Site/Filtration Products Manufacturing Site
- Shanghai - Digitalisation and Automation

Sales network

Beijing, Shanghai, Guangzhou, Chengdu, Changchun, Jinan, Suzhou, Wuhan

Overseas subsidiaries

Germany, Singapore

BIO-LINK

林科制药装备

Nantong Single-use Bioprocessing Manufacturing Site ▶▶

Bio-Link's Single-use Bioprocessing Manufacturing Site is located in Nantong City, Jiangsu Province, with a total area over 27,000 sqm and more than 300 staff. With an investment of US\$30 million, the site has an annual production capacity of 2 million single-use bioprocessing consumables and 10 million injection mold pieces. The Phases I, II and III single-use consumables cleanrooms with total 7,360 sqm have been certified with ISO9001 and ISO13485. The Phase IV of hardware workshop is equipped with a 2,150-square-meter sheet metal shop and a 1,400-square-meter mold workshop. The Phase V of hydration workshop has an annual production capacity of 5 million liters and a 1,400-square-meter validation and analysis center, to provide customers with extractable and leachable validation services.



Phase I Consumables workshop

- Total area/cleanroom: 960 sqm/620 sqm (ISO Class 7)
- Mfg line × 4 (2D/3D/mixing bag)

Phase IV Hardware workshop

- Sheet metal shop: 2,150 sqm
- Mold workshop: 1,400 sqm

Phase II Consumables workshop

- Total area/cleanroom: 3,200 sqm/1,500 sqm (ISO Class 7)
- Mfg line × 12 (storage/mixing/Bioreactor bag)

Phase V Expanded products/ service workshop

- Hydration products: 1,000 sqm (ISO Class 7/GMP)
- Validation and analysis center: 1,400 sqm
- Delivery center: 800 sqm
- Bridging manufacturing service : 2,000 sqm



Phase III Consumables workshop

- Total area: 3,200 sqm
- cleanroom: 250 sqm (ISO Class 6+5)
- Mfg line × 2 (Bag for final filling / drug substance)
- Automated bag manufacturing workshop: 150 sqm (ISO Class 7)
- Injection mold workshop: 500 sqm (ISO Class 7)
- Full servo Injection molding machine



Lanzhou Chromatography Resins Manufacturing Site ▶

Located in Lanzhou City Gansu Province, Bio-Link's chromatography resins manufacturing site covers 7,000 square meters and cost more than US\$15 million investment. With around 100 employees, the base is responsible for the development and production of purification and cell culture products such as chromatography resins and microcarrier. At present, the base has one 500L and one 1,000L chromatography resins production line and a well-equipped quality control lab, certified with ISO9001:2015. The site produces dextran-based matrix, agarose-based matrix and hydroxyapatite chromatography resins by working on five chromatography principles (size exclusion chromatography, ion exchange chromatography, hydrophobic interaction chromatography, affinity chromatography and multimodal chromatography). The site has a planned production capacity of 80,000 liters per year.

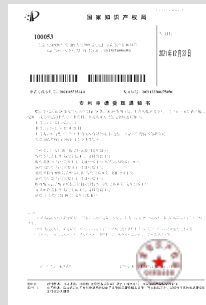


Chinese "Core" Chromatography Resins

Bio-Link Group has an experienced technology R&D team with innovation capability and mindset of independent intellectual property protection. The development of chromatography resins involves the innovative green chemical balling process, coupling mode, and ligand.

Features of the continuous production process of the new agarose microspheres

- Without toxic and harmful solvents
- Available for continuous production, achieving preparation and separation at the same time
- Easy to scale up, with no need for cleaning or quick cleaning
- With low requirements for place of origin, reducing the dependence on the original place of raw materials and processing of agarose



Patent application for protein A variant



Freedom to operate (FTO) analysis report of protein A variant



Building A Systematic Resin Production Quality System

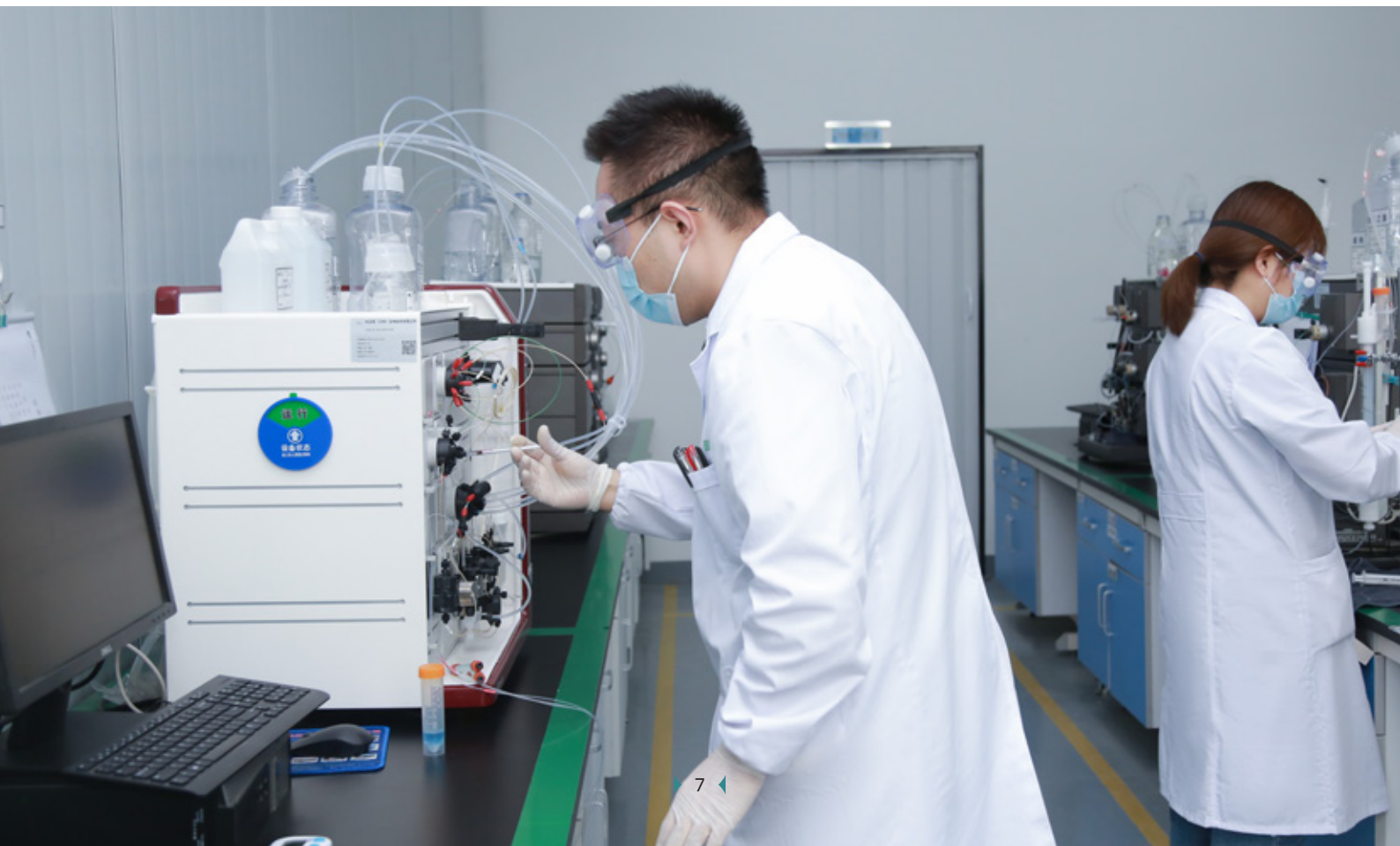


1,015 controlled documents



ISO9001:2015 Certificate

Class I	Quality manual (company code - QM - 4-digit serial number)	1
Class II	Procedure documents (company code - system document code - 4-digit serial number)	20
Class III	Standard operating procedures (instructions, RSF documents, specifications, work instructions, management system, external documents, etc.)	581
Class IV	Related records (reports, labels, records, forms, etc.)	413



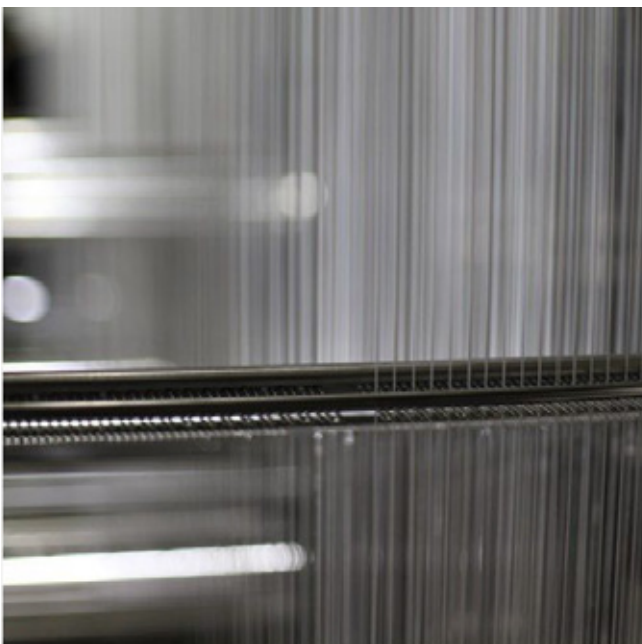
Suzhou Filtration Products Manufacturing Site ▶

This site covers about 6,000 sqm, with more than 100 staff and a completed operation system including film production, hollow fiber column packaging, product function and quality testing, packaging and transportation, etc..

A technical team led by senior experts is responsible for the film development and optimization, to enable the products with sustained competitive advantage.

The company has been certified with ISO13485. All products are produced in the cleanrooms of ISO Class 7 under strict quality control and inspection system.

We have successfully launched TFF hollow fiber column products, and with the pipeline to develop cassettes and virus removal products.



Suzhou Bioprocessing Hardware Manufacturing Site ▶▶

This site covers an area of 6,000 sqm with more than 100 staff, which mainly focus on the large scale bioprocessing hardware devices manufacturing. The product development, production and validation in this site are compliant with ISO9001. All equipment is processed and assembled under strict quality control and assurance system.



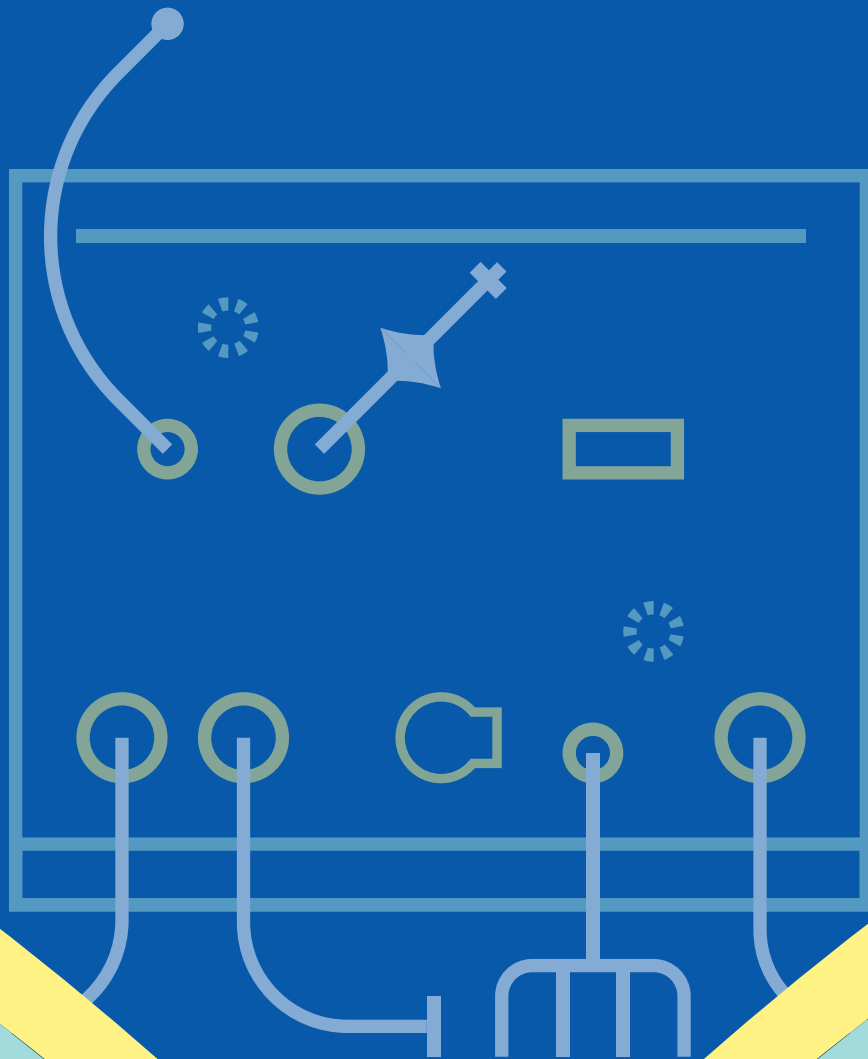
Bio-Link R&D Center ▶▶

The Bio-Link R&D Center is located in Suzhou City Jiangsu Province, covering 3,000 square meters.

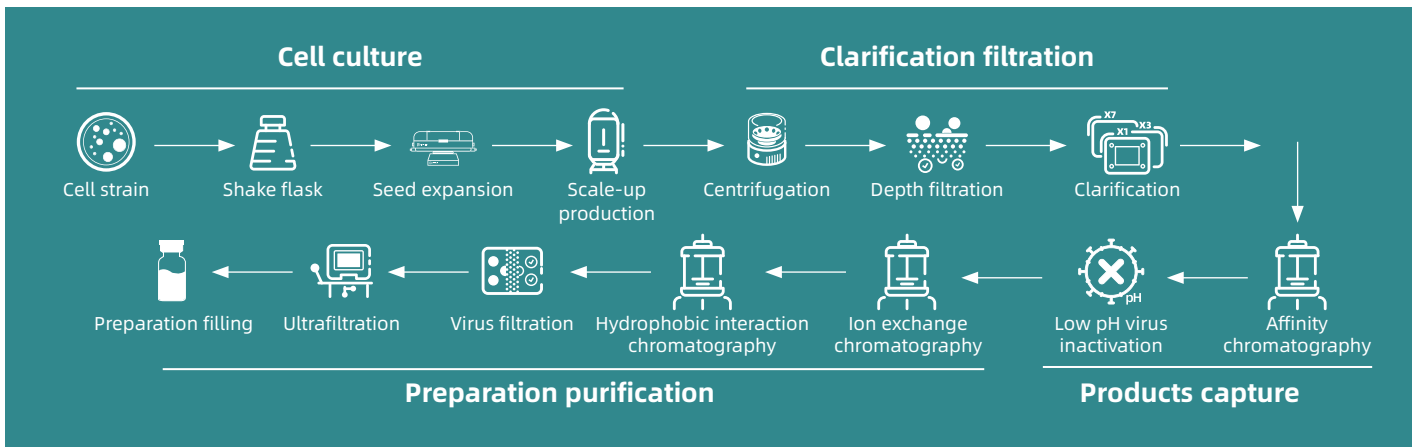
It consists of **R&D department**, **a show site**, **an application center**, **a scientific instrument research lab**, **a machinery and equipment area**, and **other functional areas**. The R&D center will enable Bio-Link to further develop its upstream and downstream innovative products and solutions, While continuing to promote process innovation and expand the product portfolios. Bio-Link aims to foster an ecosystem where the company's growth will be driven by its R&D innovation, manufacturing and service capabilities.



Product Overview



Chinese "Intelligent" Bioprocessing Solutions ▶▶



Fluid management	▶ Mixing and storage hardware and consumables (M/P/S/C/customized)	▶ Storage bottle (PC/PS)	▶ Assembling components
Hydration products	▶ Water for injection	▶ Buffer/Process liquid	▶ Customized products

- ### Upstream cell culture
- ▶ Wave hardware
 - ▶ Wave bag
 - ▶ SU Bioreactor hardware
 - ▶ SU Bioreactor bag

- ### Downstream protein chromatography
- Chromatography hardware:
- ▶ Manual column
 - ▶ Dynamic column
- Chromatography resins:
- ▶ Size exclusion chromatography
 - ▶ Affinity chromatography
 - ▶ Multimodal Chromatography
 - ▶ Polymer

- ### Downstream clarification filtration
- ▶ Filtration hardware
 - ▶ Capsule filter

Product validation and process development



Fluid Management



NovaLinX® RNase-free Disposable Consumables ▶▶

mRNA, a new generation technology platform that is expected to change traditional ways of vaccines and monoclonal antibodies development and manufacturing. Due to its short R&D cycle, simple production process, strong immunogenicity and high safety, mRNA has the potential to be widely applied in various fields such as vaccines for infectious diseases, tumor immunology and recombinant protein.

Ribonucleases (RNase), a class of nucleic acid hydrolases that are widely found in animals and plants. Due to its "ubiquitous" nature, it is necessary to take multiple and complex clean-ups to eliminate the effects of RNase in the mRNA production process, which greatly reduces the production efficiency and compromise product quality. Meanwhile, the process validation and verification of RNase removal are also time-consuming and labor-intensive. Therefore, RNase-free disposable consumables are highly welcomed by mRNA manufacturers using single-use bioprocess technology for production. In addition, RNase level within those consumables shall be inspected before release and can be verified post-use without damage.

Master bag + Innovative design of double satellite bags

- Identical materials/production environments of master bag and satellite bags, consistent gamma irradiation conditions
- Supplier: Satellite bag 1, for releasing RNase-tested products
- Customer: Satellite bag 2, for pre-use or post-use RNase inspection



QC

- 100% light table inspection
- 100% bag integrity test (pressure decay)
- 100% RNase test release (0.005pg/uL)



Production environment

- RNase level Monthly inspection
- Endotoxin Daily inspection
- Subvisible particle Daily inspection



Validation items

- RNase testing equipment IQ/OQ/PQ
- RNase testing kit
- Shelf life validation



Pending PCT patent application

Used by well-known mRNA manufacturers

Single-use Storage Products >>

2D storage bag and matched containers

BioHub® 2D storage bag



Bag chamber volumes: 5 mL ~ 50 L
Multiple fitting & tubing configurations
Optional films for customization

Matched containers for 2D storage bag



Plastic & stainless steel trays



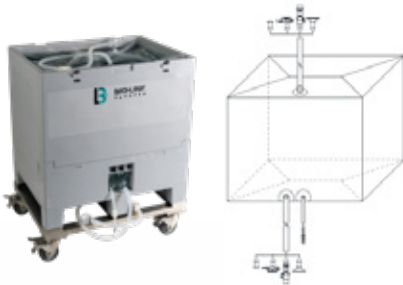
Cryopreservation case



Stainless steel bracket

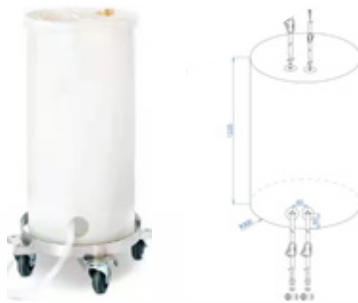
3D storage bag and matched containers

BioHub® Cubic foldable plastic bin + Matched storage bag



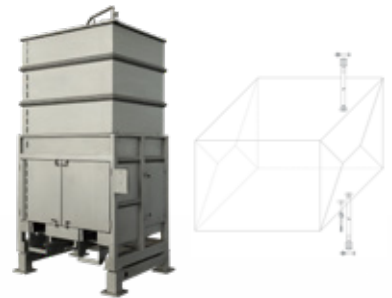
Volume: 50/100/200/250
500/1,000L

BioHub® Circular plastic bin + matched storage bag



Volume: 50/100/200/300/500 L

BioHub® Stainless steel bin + matched storage bag



Volume: 50/100/200/400/500/650 L
1,000/2,000/3,000L

*Compatible with a variety of fittings and tubings with a flexible choice of film options for customization

Single-use Storage Products >>

BioHub® BM Single-Use Magnetic Mixing System



MX10/50/100/200/400/500/650/1000/
2000/3000

BioHub® UM Open Top-Driven Mixing System



MX10/50/100/200/500/1000/2000/2500/
/3000

BioHub® DS Single-Use Desktop Mixer



2L/5L/10L/15L/20L

BioHub® Sterile Welder



BioHub® Sterile Sealer



10L/20L

Single-use Needle Sampling Bag/Bottle ▶▶

Needle sampling bag



Volume: 50, 100, 250, 500, 1,000 mL
 Configuration: single-needle, single-bag;
 single-needle, 5-bag
 Fitting type: needle sampling valve
 (single-needle/dual-needle)

Needle sampling bottle



Volume: 20, 50, 125, 250 mL
 Configuration: single-needle, single-bottle;
 single-needle, 5-bottle
 Fitting type: needle sampling valve
 (single-needle/dual-needle)

Sampling base



TC50 series/In gold series/In line series/
 customized series

BioHub® Single-use Storage Bottles ▶▶

BioHub® single-use storage bottles are designed exclusively for storage and transportation of liquids in biopharmaceutical. In addition, multiple cap configurations can provide a variety of choice for customer to meet their specific fluid management demand.

- Volume: 5 mL to 20 L
- Cap without tubing: Regular, 2-port, 3-port
- Cap with tubing: C-Flex tubing, silicone tubing
- Autoclave, Presterilized by gamma irradiation
- Comprehensive regulatory compliance and validation documents
- Available at – 80 to 120 °C



Sterile Disconnection Plier ▶▶

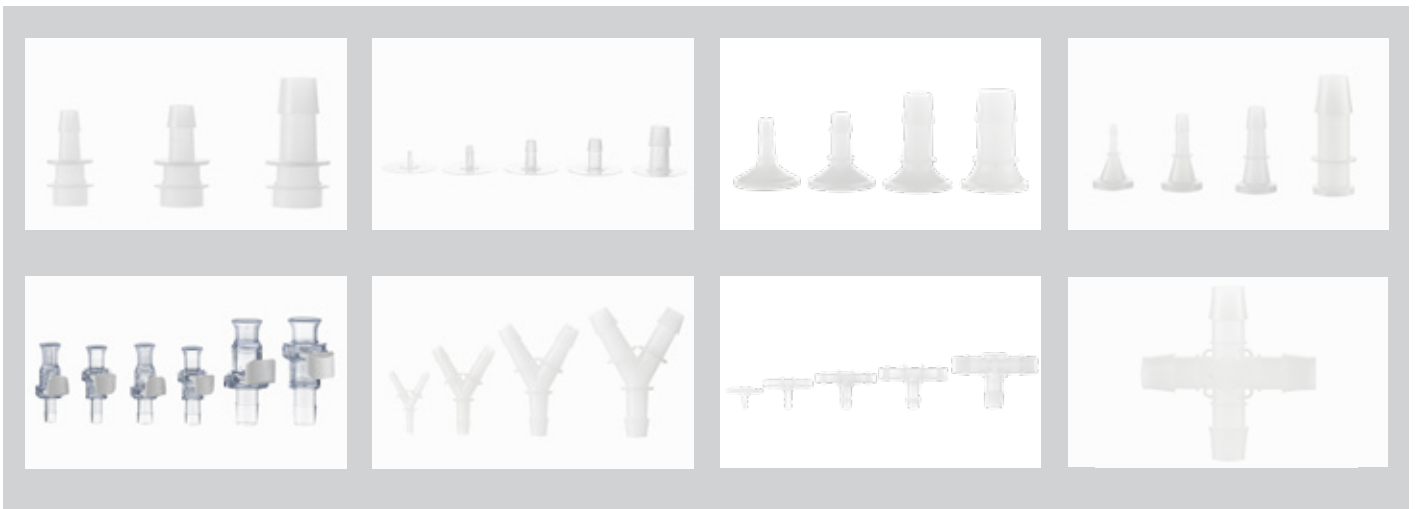
Validation items:

- Jaw life test
- Tubing disconnection test
- Disconnection appearance test
- Integrity test
- Strain relief test
- Burst pressure test
- Sterile barrier test



BioHub® PVDF Fittings ▶▶

These high-quality and reliable fittings are developed in response to the fast changes in the drug development and pharmaceutical manufacturing markets. We supply flexible and easy-to-use fittings for pipeline assembly, filter assembly, tank connection, liquid aliquoting, and many other applications. BioHub® fittings are available with a variety of straight connectors, reducers, tees (Y- and T-shaped), crosses, flange covers, clamps, and tri-clamps.



Systematic raw material and components validation system ►►

The validation system for raw material and components aligns with the BPOG standard.

<p>01 Biocompatibility</p> <ul style="list-style-type: none"> • USP <87>/USP <88>: biological activity • ISO10993-4: hemolysis • USP <85>: bacterial endotoxin (large infusion) • USP <661>: physicochemical properties (pharmaceutical packaging materials) 	<p>02 Physical properties</p> <ul style="list-style-type: none"> • USP <788>: particles • ASTM requirements (F392, D882, F88): mechanical performance • ASTM requirements: O₂/CO₂/vapor transmission rate • Temperature stability at - 80 to - 70 ° C • pH stability test (+ 0.2) 	<p>03 Chemical compatibility</p> <ul style="list-style-type: none"> • Buffer, salt, lipid, organic solvent, amino acid, strong acid (2M HCl), strong alkali (3M NaOH), surfactant, disinfectant, etc. • Appearance, integrity, mechanical properties, degradation and adsorption of contact solvents, etc. 	<p>04 Extractables</p> <ul style="list-style-type: none"> • BPOG: extractable test • Strong acid (0.1M H₃PO₄), strong alkali (0.5N NaOH), organic solvent (50% CH₃CH₂OH), high-concentration salt (5M NaCl), surfactant (1% PS-80), water, and other solvents tested at different temperatures
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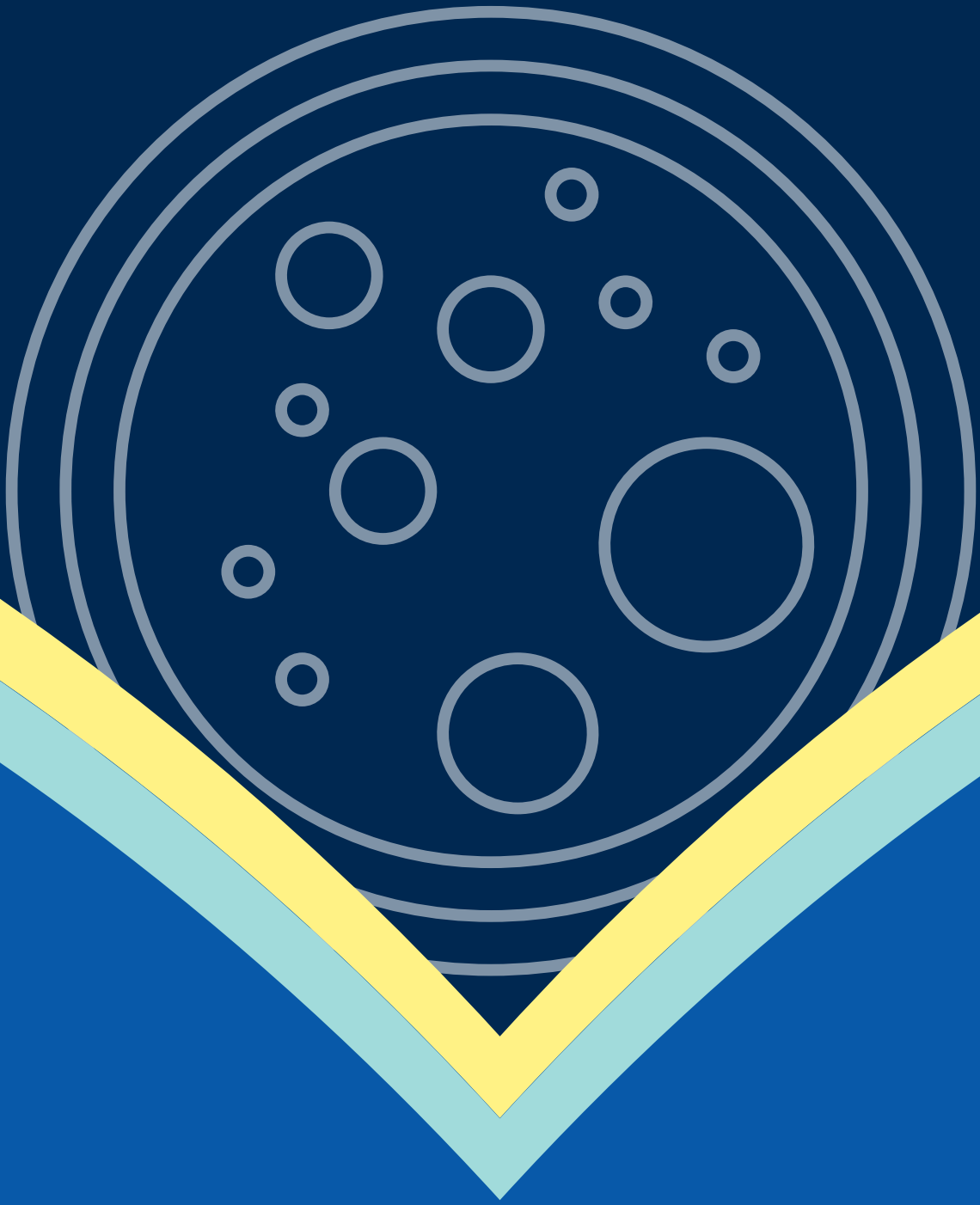
DMF Filing ►►

The single-use multi-layer co-extrusion bag produced by Bio-Link has been approved for DMF filing of the US Food and Drug Administration (FDA DMF filing no.: 037110). It is classified as Class III DMF - pharmaceutical packaging material, covering the single-use storage bag, mixing bag, cell bag, and filling bag produced by Bio-Link.

This means that the customers using Bio-Link's products can refer directly to the DMF filing materials in their regulatory submissions to the FDA for new drug registration, without the need to provide specific information about raw materials and excipients.

 DEPARTMENT OF HEALTH AND HUMAN SERVICES		Food and Drug Administration Silver Spring, MD 20993
DMF 037110	DMF ACKNOWLEDGEMENT	
BIO-LINK PHARMACEUTICAL APPLICATION SYSTEM (JIANGSU) CO., LTD. Attention: SHI WEI, JURIDICAL PERSON NO.1 BOJINXIANG, CHENGBEI ROAD (ETDZ) RUGAO CITY, NANTONG, JIANGSU PROVINCE, CHINA		
Dear Shi Wei,		
The Food and Drug Administration acknowledges receipt of the following Drug Master File (DMF) submission:		
<u>DMF NUMBER ASSIGNED:</u>	037110	
<u>DATE OF SUBMISSION:</u>	MAY 10, 2022	
<u>DMF TYPE:</u>	III	
<u>SUBJECT (TITLE):</u>	SINGLE-USE BAG WITH MULTILAYER CO-EXTRUSION FILM	
<u>Holder:</u>	BIO-LINK PHARMACEUTICAL APPLICATION SYSTEM (JIANGSU) CO., LTD.	
<u>Submitted by:</u>	BIO-LINK PHARMACEUTICAL APPLICATION SYSTEM (JIANGSU) CO., LTD.	
<u>AGENT:</u>	NONE	

Upstream Cell Culture Products



CytoLinX® WB Single-Use Rocking Bioreactor

Item	Description	Range
Hardware	SIEMENS PLC	
Interface	13.3" tablet computer; PC optional	
Compliance	Compliant with 21 CFR PART 11	
Wave Bioreactors 0.3-25L		
Tray	10 L, 20 L, and 50 L trays (optional)	0.3 L - 25 L (working volume)
Agitation	Rock rate	2-40 rpm
	Rock angle	2-12°
Temperature control	Electric heating blanket	RT-40°C (65°C)
Gas flow control	Air mass flow controller x 1	Overlay, 0-2 lpm
	O ₂ mass flow controller x 1	Overlay, 0-2 lpm
	CO ₂ mass flow controller x 1	Overlay, 0-1 lpm
Pumps	Watson Marlow variable speed pump x 2	0-150 rpm
	Pt100 temperature electrode x 1	0-80 °C
Sensors	pH electrode and fiber x 1 (optional)	6-8 pH
	DO electrode and fiber x 1 (optional)	0-100 %
	Load cell x 1	0.2-30 kg
	Pressure sensor x 1	0-0.3 bar

设备信息

日期	时间	状态	来源	站名	备注
2023-02-12	08:17:04	报警上屏	PUMP3	报警	PUMP3
2023-02-12	08:15:50	报警上屏	PUMP2	报警	PUMP3

操作记录

2023-02-12 08:18:02	用户名 [Engineer] 材料, 20瓶 接种培养基液量= 瓶次, 流量=固定
2023-02-12 08:18:29	用户名 [Engineer] 材料, 20瓶 接种培养基液量= 瓶次, 流量=固定
2023-02-12 08:18:22	用户名 [Engineer] 材料, 20瓶 接种培养基液量= 瓶次, 流量=固定
2023-02-12 08:18:07	用户名 [Engineer] 接种培养基, 接种尺寸 接种培养基液量= 10 L, 流量=50 L

CytoLinX® WB Cell Bag 2 L to 50 L ▶▶

Validated items

Loading capacity (+ tray)

Drop test

Simulated transport test

Bag pressure test (operation pressure: 0.1 bar)

Operational temperature and pH ranges

Mbag temperature test at 40-70 ° C

Routine test for cell bags as per USP <788>

Establishment/Test of pH & DO calibration validation methods

Bacterial endotoxin

Invisible particles

100% visual inspection

USP <87>

USP <88>

BSE | TSE

Post-cleaning test of subvisible particles on the sieve (water, 0.1N NaOH)

Welding process; supplemented with 1,400C welding tension validation (on the tray)

Packaging illuminance

pH & DO manufacturing illuminance

In-process QC

No tooling leakage

Validated items

USP 661 TOC

Leachable report (pH DO Perfusion bag)

Gamma irradiation

Endurance limit mixed test (10 days, 240)

Physical and chemical compatibility tests of 1,400C film, leachable report

Accelerated aging test of bags

Test of dye leakage



CytoLinX® BR Series Single-use Bioreactor ▶

Item	Options	CLX BR-50	CLX BR-200	CLX BR-500	CLX BR-1,000	CLX BR-2,000
System parameters						
working volume (L)		20 - 50	40 - 200	100 - 500	200 - 1000	400 - 2000
Height to diameter ratio (H/D)		2.5:1 or 1.5:1	1.5:1	1.5:1	1.5:1	1.5:1
Bag lifting device and installation ladder					√	√
Accessory parameters						
pH conventional electrodes	single-use/ Arc electrodes	1-3	2-3	2-3	2-3	2-3
DO optical conventional electrodes		1-3	2-3	2-3	2-3	2-3
PAT tools	pCO ₂ / cell density	0-2	0-2	0-2	0-2	0-2
Gas mass flow controller (MFC)	Optional gas and range	4-6	4-6	4-6	4-6	4-6
Integrated pump unit	Series 1,3,and 5	2-4	2-4	2-4	2-4	2-4
Reserved port for external pump unit	Series 5,6,and 7	0-4	0-4	0-4	0-4	0-4
Weighing module		1	1	1	1	1
Tail gas heating jacket	Optional size	2-4	2-4	2-4	2-4	2-4
Reserved port for external weighing						
Temperature control unit (TCU)	Air-cooled or water cooled	5 KW	5 KW	5 KW	10 KW	10 KW
Control unit						
Hardware	SIEMENS PCS 7 (DCS, compliant with ISA 88)					
Display	19" touch screen display,mouse and keyboard conforming to appropriate protection class,and built-in UPS					
Compliance	Compliant with 21 CFR PART 11					
Consumables						
Sparger	Micro,medium,and large bubble size options available	Micro+large or medium+large bubble size design in the standard product				
Tubing	Customizable tubing length	The tubing length in the standard product is sufficient for post-installation welding requirements				
Tail gas filter	Optional size	4.5"	6.7"	6.7"	10"	10"



Microcarrier Puredex® Cyto-1

Puredex® Cyto-1 is a type of microcarrier based on cross-linked dextran matrix with positively charged groups. It can provide a broad adhesion surface for cells, thereby increasing cell density and achieving high yields. Such microcarrier makes it possible to change the way adherent cells are cultured, while making it easier to optimize the cell culture process to reduce costs and increase efficiency. Puredex® Cyto-1 microcarrier can be used for the culture of a variety of host cells, including 293 cells, Vero cells, and CHO cells.

With these unique properties, Puredex® Cyto-1 microcarrier has become an indispensable material in today's extremely demanding upstream cell culture process, and plays an important role in the fields of biopharmaceuticals such as antibodies, vaccines, nucleic acids, enzymes, and recombinant proteins.

Features of microcarrier Puredex® Cyto-1

Puredex® Cyto-1 adopts the biocompatible cross-linked dextran matrix, exhibiting excellent cell culture performance:

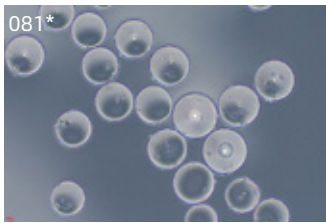
- **Inert material:** Provide a solid and reliable adhesion surface for cell culture.
- **Resistance to stirring:** Provide more room for optimizing cell culture parameters.
- **Optimized specific surface area:** Make it possible to further increase the yield.
- **Transparent appearance:** Help to observe the cell adhesion on the surface under microscope.

Technical specifications of microcarrier Puredex® Cyto-1

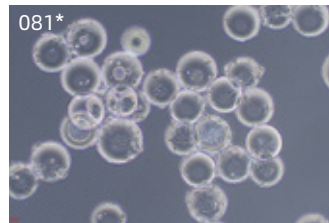
Name	Description
Matrix	Cross-linked dextran
Ligand	N-N-Diethylaminoethyl
Average particle size	190 μm
Specific surface area	4000 cm ² /g dry weight
Number of microspheres	4 × 10 ⁶ cm ² /g dry weight
Swelling coefficient	20 mL/g dry weight
Operational pH range	2-12
Tolerable temperature range	4-135 °C
Chemical stability	All commonly used aqueous solutions and 75% ethanol

Growth chart of suspension culture in microcarrier Puredex® Cyto-1

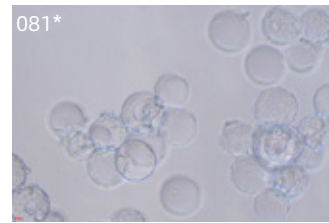
Growth status: At different time points (4, 24, 48, and 72 h) after inoculation, observe the adhesion and growth of MDCK cells in each microcarrier sample by microscope.



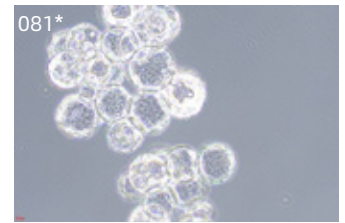
Bio-Link microcarrier 081* (4 h)



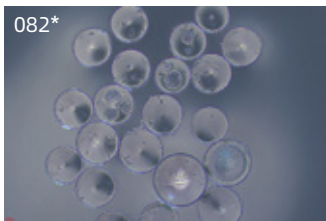
Bio-Link microcarrier 081* (24 h)



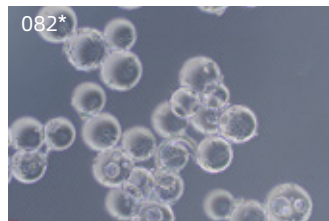
Bio-Link microcarrier 081* (48 h)



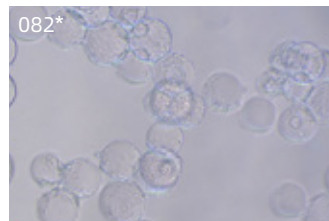
Bio-Link microcarrier 081* (72 h)



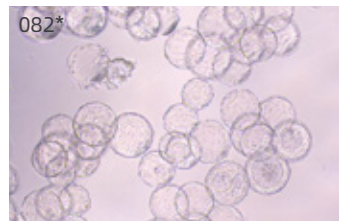
Bio-Link microcarrier 082* (4 h)



Bio-Link microcarrier 082* (24 h)



Bio-Link microcarrier 082* (48 h)



Bio-Link microcarrier 082* (72 h)

Downstream Protein Chromatography Products



Chromatography Hardware — Chromatography System ▶

- All the key components are from the first-in-class suppliers worldwide, which traceable material certificates to ensure the stability and safety of equipment.
- Siemens PLC, industrial computers, and the software based on ISA88 structure are used.
- This system supports electronic signature and electronic recording, which meet the requirements for audit trail in GAMP5 and 21 CFR Part 11.
- Support hierarchical alarm management, three-level permission management, and data backup and restoring.
- The process tubing is made of 316L, with the inner surface polished $Ra < 0.4 \mu m$, in line with ASME BPE standard.
- The data interfaces for SCADA system are reserved, enabling the integration of production data of MES system, so as to facilitate users' design of automatic plant in the future and support the upgradable DCS system (PCS7, Delta V, etc.) .



Chromatography Hardware — Manual Column ▶

Column chromatography separation is a very common method for separation and purification in drug development and large-scale production, which is widely applied in various steps of separation and purification. To meet the needs for purification of our biopharmaceutical customers, we have designed the ChromLinX® series column for common biopharmaceutical chromatography applications. This column is easy to install, simple to use, safe and reliable.

Features of ChromLinX® series column:

- The column is made of glass, which offers a clear view and makes it convenient to observe the position of the column bed (comparing with the outer wall calibration tail of the column to determine the bed height) and gel level status.
- With hygienic design, meeting GMP requirements.
- Simple and easy to manually adjust the head height and lock the seal ring by rotating the screw.
- Easy to maintain and repair.
- A side outlet is reserved at the bottom for easy connection with valves and tubings.
- With horizontal screw handle meeting ergonomic requirements, which is easy to operate.
- Optional diameters: 70, 100, 140, 200, 300 mm
- Optional heights: 500, 750, 950 mm
- Optional pore diameters of sieve: 10 and 23 μm

Available support documents:

- Quality certificates
- Material certificates
- Instructions



Chromatography Hardware — Dynamic Column ▶▶

ChromLinX® Auto series column:

- The column is made of acrylic material, with a clear view and visible column bed position
- With hygienic design, meeting GMP requirements
- Made of safe materials, meeting regulation requirements
- Supporting scientific design without dead ends for cleaning
- Compatible with various resins
- Optional inner diameters: 450, 600, 800, 1,000, 1,200 mm
- Available heights: 620mm
- Optional pore diameters of sieve: 10 and 20 μm

Supporting documents:

- IQ/OQ validation documents
- Quality certificates



ChromaX® Chromatography Resins ▶▶

Chromatographic method	Product category	
Size exclusion chromatography	<ul style="list-style-type: none"> • Chromstar 4FF/6FF • Chromstar CL-4B/CL-6B • Chromstar 4B/6B 	<ul style="list-style-type: none"> • Geldex PG series • Puredex® G series • Puredex® LH-20
Ion exchange chromatography	<ul style="list-style-type: none"> • MaXtar Q/DEAE/S • MaXtar Q/SP HR • MaXtar Q/SP HR XL • Q/SP Chromstar BB • O/DEAE/SP/S/CM Chromstar FF 	<ul style="list-style-type: none"> • Q/DEAE/SP/CM Chromstar HP • Q/SP Chromstar XL • Q/SP Chromstar BB XL • DEAE Puredex® A50 • CM Puredex® C25
Affinity chromatography	<ul style="list-style-type: none"> • Antibody purification • Histidine-tagged proteins purification • Immobilized metal ion affinity chromatography 	<ul style="list-style-type: none"> • GST-tagged proteins purification • Other types
Hydrophobic interaction chromatography	<ul style="list-style-type: none"> • MaXtar Phenyl (HS)/(LS) • MaXtar Butyl/Octyl • MaXtar Phenyl/Octyl/Buyl HR • Phenyl Chromstar 6FF (HS)/(LS) 	<ul style="list-style-type: none"> • Octyl/Butyl Chromstar 4FF • Butyl-S Chromstar 6FF • Phenyl/Butyl Chromstar HP
Multimodal chromatography	<ul style="list-style-type: none"> • MaXtar MMC • MaXtar MMC HR • MaXtar COLL 700 • MaXtar COLL 400 	<ul style="list-style-type: none"> • Maxtar MMA • Maxtar MMA HR • BaronCHT type I • BaronCHT type II
Polymer chromatography	<ul style="list-style-type: none"> • Maxgo series 	

Size Exclusion Chromatography ▶▶

Chromstar FF

- High-flow velocity chromatography resin based on an agarose-based matrix
- With weak non-specific adsorption and good chemical stability
- Suitable for the separation of polysaccharides, recombinant proteins, viruses, and other large molecules

Chromstar

- Chromatography resin based on an agarose-based matrix
- With organic solvent resistance and good chemical stability
- Suitable for the separation of polysaccharides, recombinant proteins, nucleic acids, and other large molecules

Puredex®

- Chromatography resin based on a dextran-based matrix
- With organic solvent resistance and good chemical stability
- With various separation ranges and multiple particle sizes for component separation

Chromstar CL

- Chromatography resin based on an improved agarose-based matrix
- With organic solvent resistance and good chemical stability
- Suitable for the separation of polysaccharides, recombinant proteins, nucleic acids, and other biomolecules, or determination of QC molecular weight

Geldex PG

- High-resolution chromatography resin based on an improved agarose-based matrix
- With weak non-specific adsorption and good chemical stability
- Suitable for the separation of various biomolecules, including polypeptides, polysaccharides, recombinant proteins, nucleic acids, viruses, etc

Puredex® LH-20

- Chromatography resin based on a dextran-based matrix
- Substituted by hydroxypropyl, suitable for aqueous or organic phase, with good chemical stability
- Suitable for the separation of natural products and other substances with small differences

Ion Exchange Chromatography ▶▶

MaXtar HR

- High-resolution chromatography resin based on an improved agarose-based matrix
- With organic solvent resistance and good chemical stability
- Suitable for fine separation

Chromstar BB

- Chromatography resin based on an improved agarose-based matrix
- With high flow velocity, low back pressure, and high binding capacity, easy to scale up linearly
- With organic solvent resistance and good chemical stability

Chromstar HP

- High-resolution chromatography resin based on an agarose-based matrix
- With weak non-specific adsorption and good chemical stability
- Suitable for fine separation

Puredex®

- Chromatography resin based on a dextran-based matrix
- With organic solvent resistance and good chemical stability

MaXtar

- Chromatography resin based on an improved agarose-based matrix
- With organic solvent resistance and good chemical stability
- Suitable for fine separation

MaXtar HR XL

- Chromatography resin based on an improved agarose-based matrix with ultra-high binding capacity and high resolution
- With both high binding capacity and high resolution, presenting excellent cost performance
- With organic solvent resistance and good chemical stability

Chromstar FF

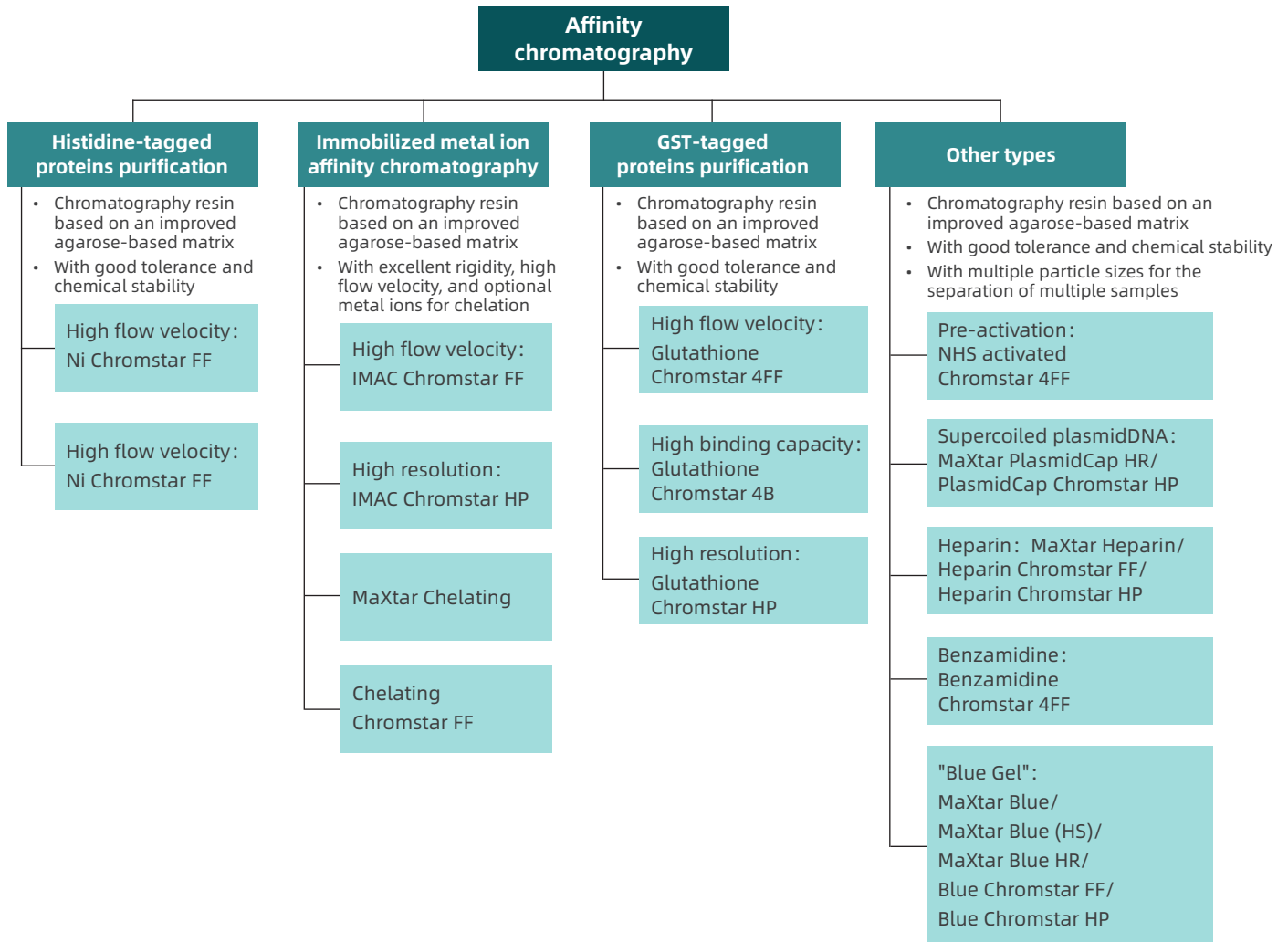
- High-flow velocity chromatography resin based on an agarose-based matrix
- With weak non-specific adsorption and good chemical stability
- Suitable for capture

Chromstar XL

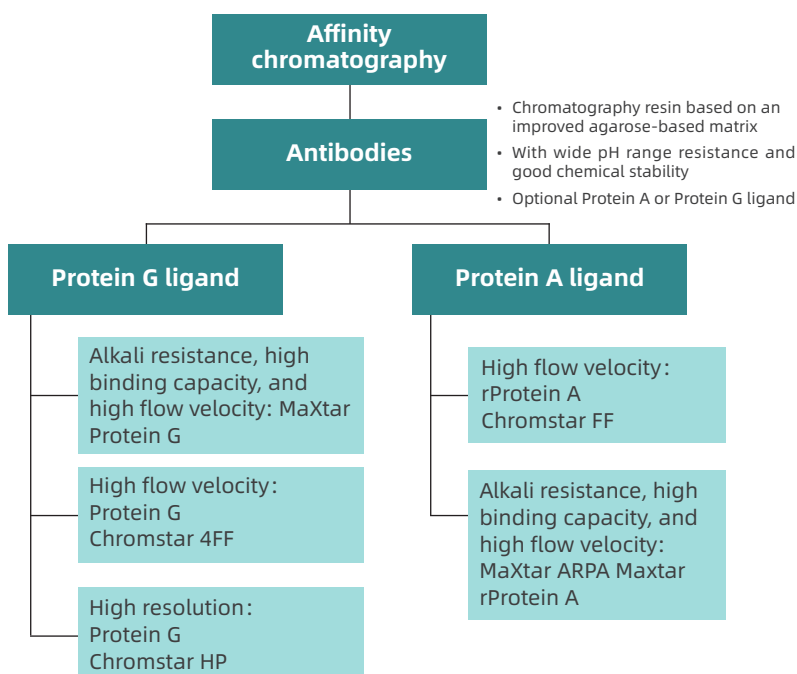
- Chromatography resin based on an agarose-based matrix with ultra-high binding capacity
- With organic solvent resistance and good chemical stability



Affinity Chromatography ▶▶



Antibody Affinity Chromatography ▶▶

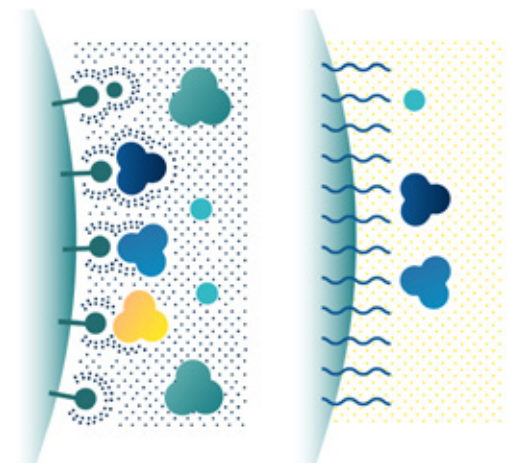


Protein A affinity resin: MaXtar ARPA

- Independent intellectual property right:** Patent no. 202111572524.4
- High dynamic binding capacity:** It adopts innovative ligand coupling process and human blood-derived IgG as the sample, with a dynamic binding capacity (DBC) of about 68 mg/mL.
- Excellent alkali resistance:** It adopts the protein A ligand with high alkali resistance. In each cycle, 0.5M NaOH is used for CIP treatment for 15 min. After 200 cycles, its DBC still retains more than 90% of the original capacity.
- High-proof pressure mechanical performance:** It uses the MaXtar series of high-performance agarose-based matrix of Bio-Link, which can provide better rigidity and operate at higher flow velocity than traditional agarose-based matrix.
- Safe and stable supply:** The maximum production capacity per batch is 1000 L.

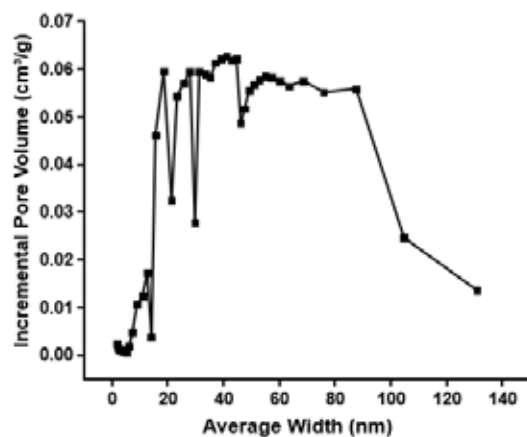
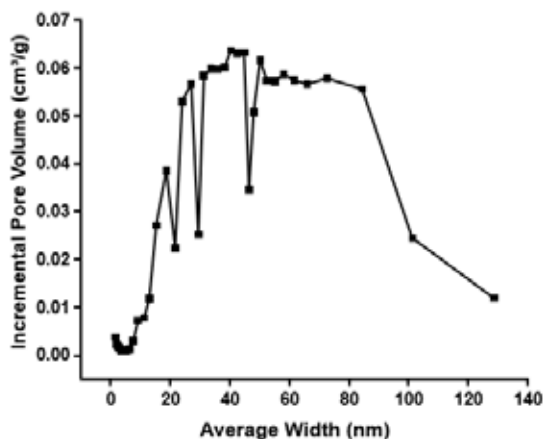
Hydrophobic Interaction Chromatography ▶▶

Category	Features
MaXtar	<ul style="list-style-type: none"> High-flow velocity chromatography resin based on an improved agarose-based matrix With excellent rigidity, high flow velocity, low back pressure, easy to scale up With resistance to high-concentration salt, wide pH range, and organic solvents, and with good chemical stability
MaXtar HR	<ul style="list-style-type: none"> High-resolution chromatography resin based on an improved agarose-based matrix With both high resolution and high flow velocity With resistance to high-concentration salt, wide pH range, and organic solvents, and with good chemical stability
Chromstar FF	<ul style="list-style-type: none"> Chromatography resin based on an improved agarose-based matrix With resistance to high-concentration salt, wide pH range, and organic solvents, and with good chemical stability
Chromstar HP	<ul style="list-style-type: none"> Chromatography resin based on an improved agarose-based matrix With resistance to high-concentration salt, wide pH range, and organic solvents, and with good chemical stability



Multimodal Chromatography ▶▶

Product	Features
MaXtar MMA	<ul style="list-style-type: none"> High-flow velocity chromatography resin based on an improved agarose-based matrix With wide range resistance and good chemical stability Composed of multiple groups with different properties: amino groups, hydrogen bonds, and hydrophobic groups
MaXtar MMC	<ul style="list-style-type: none"> High-flow velocity chromatography resin based on an improved agarose-based matrix With wide range resistance and good chemical stability Various optional ligands available, presenting the combined separation effect of multiple chromatography principles
MaXtar COLL	<ul style="list-style-type: none"> With a double-layer structure, where the outer shell is an improved agarose-based passivation layer and the inner core coupled with a ligand of both hydrophobic and positive charge adsorption With wide range resistance and good chemical stability Suitable for the separation of viruses and other large biomolecules



MaXtar COLL pore diameter test results via BET method

ChromaX® BaronCMT Hydroxyapatite Multimodal Chromatography ▶▶

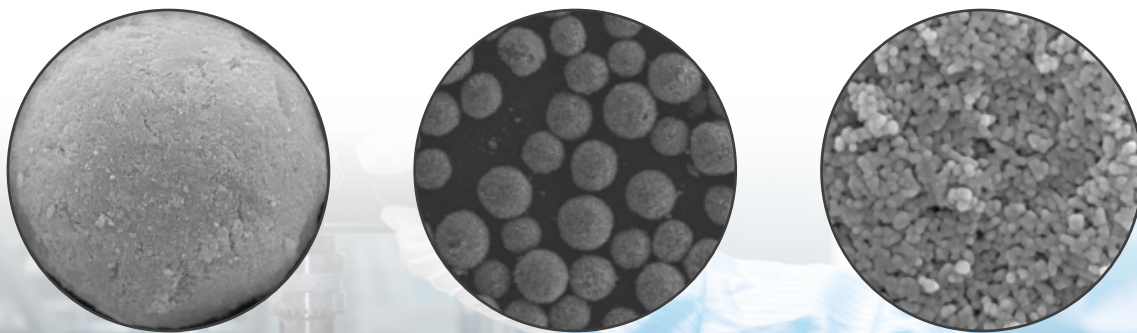
[Ca₁₀(PO₄)₆(OH)₂] is an inorganic pure-phase chromatography resin which is sintered at high temperature into spheres. It has the same crystal structure as that of bone hydroxyapatite, with stable spherical structure and uniform particle size. Multiple modes of interaction exist between hydroxyapatite and biomolecules, which enables two mechanisms of separation simultaneously, i.e. the cation exchange and the calcium metal affinity. The cation exchange can be realized mainly due to the negatively charged phosphate group on hydroxyapatite. Meanwhile, the carboxyl clusters and phosphoryl moieties on biomolecules can bind more strongly to the calcium site on hydroxyapatite through the metal affinity mechanism. Due to these unique separation mechanisms, hydroxyapatite has become an indispensable chromatographic medium suitable to be utilized in the extremely demanding downstream processes nowadays, playing an important role in the biopharmaceutical fields including antibodies, vaccines (bacterial polysaccharides, pneumoniae polysaccharides, viruses, etc.), nucleic acids, enzymes and recombinant proteins.

The ChromaX® hydroxyapatite chromatography resin, BaronCMT type I and BaronCMT type II, have the following characteristics:

- Unique separation characteristics
- Prolonged service life
- High dynamic binding capacity
- Excellent inter-batch repeatability

Characteristics of ChromaX® BaronCMT type I and type II :

Product	Describe
Type of chromatography resin	Multimodal chromatography resin:cation exchange,calcium affinity
Ligand	Ca ²⁺ , PO ₄ ³⁻ , -OH
Mean particle size (D50)	Available in a variety of particle: 20, 40, 60, 80 μm
Dynamic binding capacity	25-60 mg mAb / ml resin* (I type) 15-25 mg mAb / ml resin* (II type)
Recommended flow velocity	50-400 cm/h
Max.back pressure	Type I:3 MPa;Type II:4MPa



Spherical appearance and typical crystal structure of hydroxyapatite

ChromLinX® Empty Chromatography Column ▶▶



Main features of ChromLinX® empty chromatography column:

- The column is made of glass, with a clear view of column bed position
- Easy to disassemble and clean
- Supporting axial movement of the screw rod by rotating the column head, making it easy to compress resins
- With different diameters and heights to meet different test needs
- Optional diameters: 10, 16, 26, 50 mm
- Optional heights: 200, 400, 700, 1000 mm
- Pore diameter of sieve: 10 μ m

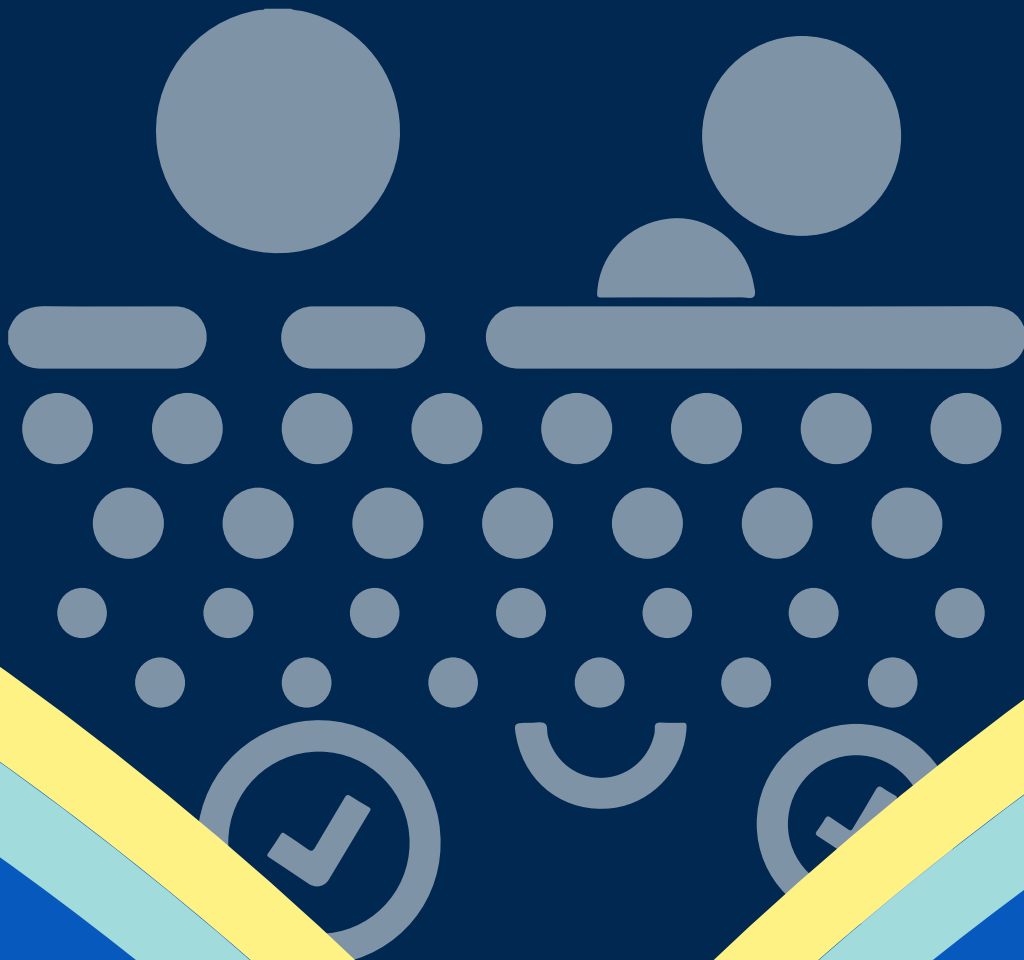
1 mL/4.7 mL/5 mL Chrom-Trap™ & Chrom-Screen™ Prepacked Chromatography Column ▶▶

The body and inner plug of the prepacked column are made of PP material with internal and external polishing, and the sieve plate is made of HDPE material. Generally, the column has excellent physical properties and chemical tolerance, resistance to corrosion and aging, long service life, and good safety.

- 1) Out of the box, convenient and fast
- 2) Compatible with syringes, peristaltic pumps, or chromatography systems
- 3) Supporting serial connection to increase the sample treatment capacity



Filtration Products



TFFNOVA® Hollow Fiber Membrane ▶

TFFNOVA® hollow fiber filter produced by SMAX is made of modified polyethylene inkstone (mPES), which is suitable for filtration of various processes in the pharmaceutical industry (such as biopharmaceuticals, chemical drugs, traditional Chinese medicine, etc.) and the food industry. It can provide stable and reliable filtration performance.

TFFNOVA® hollow fiber membrane made of modified polyphenol is an asymmetric structure. The membrane layer is dense, and the outer layer is relatively open. Its unique structural design can result in lower bioburden, lower non-specific adsorption, faster filtration rate, higher throughput, and shorter filtration time, so it is very suitable for the pharmaceutical and food industries.

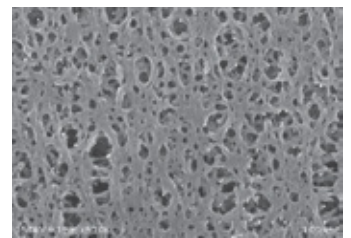
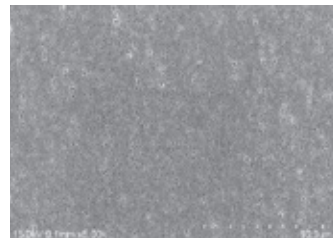
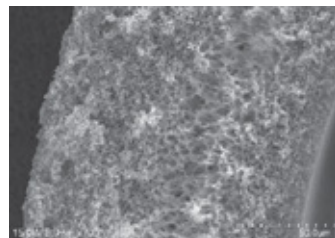
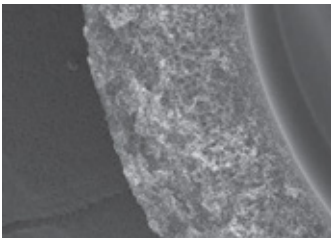
Common applications:

- Upstream cell perfusion culture
- Inclusion body clarification and renaturation
- Nanoparticle Diafiltration and Separation
- Lysate clarification
- Cell concentration, clarification, diafiltration
- Purification, concentration, diafiltration of proteins and nucleic acids
- Virus purification, concentration, diafiltration
- Liposome concentration and diafiltration



Quality assurance

- USP <88> Class VI Testing: All flow path materials have been tested confirmed to the USP <88> Class VI biocompatibility standards
- Pyrogen: Hollow fiber filter production and assembly lines are under strictly control of endotoxin contamination, but they are not pyrogen-free
- Free of Animal Origin: All raw materials used in these filter productions do not contain any animal or animal derived substances
- Shipping and Packaging Verification: SMAX has verified product shipping/packaging configurations to ISTA 3A (2008) requirements to ensure that sterile products are adequately protected from damage during shipping
- Product Validity: Non-sterile filters are valid for 5 years from the date of manufacture



Cassettes and virus removal products are under development testing

Optional pore diameters: 0.65, 0.45, 0.2, 0.1 μm

Optional molecular cut offs: 750, 500, 300, 100, 50, 30, 10, 5, 3, 1 kD

FiltraLinX® Series Depth Filter Holder ▶▶

M series



- Compatible with the prevalent square deep filtration cassettes on the market;
- Suitable for laboratory research and development, pilot-scale production, and large-scale production;
- Suitable for various types of primary and secondary clarification filtration;
- Resistant to the disinfection by acid, alkali, organic solvents, and other disinfectants, meeting the requirements of CIP and cleaning validation

PC-3 series



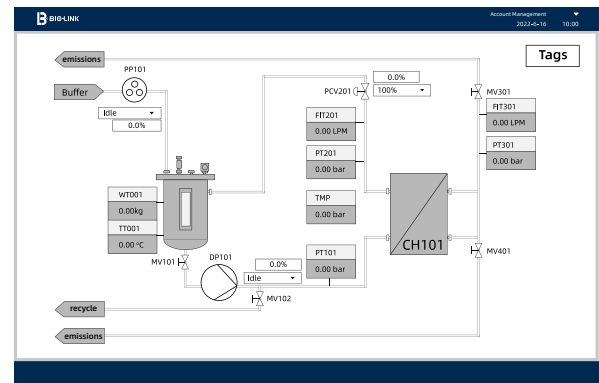
- Compatible with the prevalent round deep filtration cassettes on the market
- With ergonomic design, by which the operator can load, filter, and disassemble in the vertical direction
- Resistant to the disinfection by acid, alkali, organic solvents, and other disinfectants, meeting the requirements of CIP and cleaning validation
- Easy to install, use, and operate for production

Filtration-Related Hardware (desktop) ▶▶

Hardware configurations



Software functions



Virus Removal Holder — VFH Series ▶▶

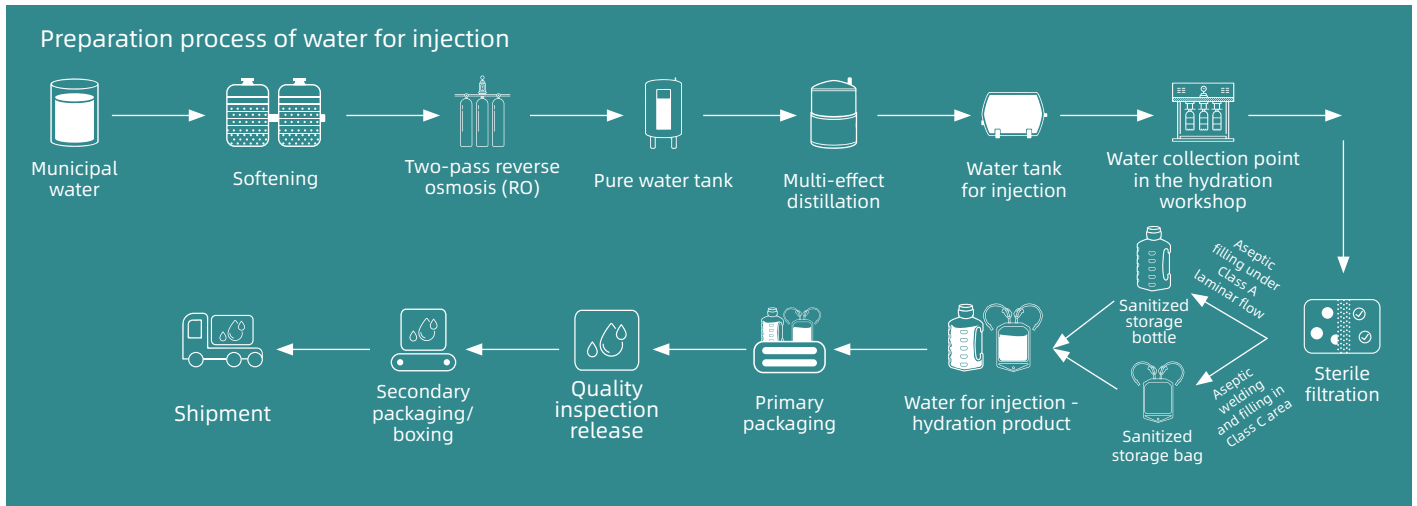
Compatible with Merck cassettes

Number of layers	Single tower design	Double tower design
Loading capacity of 0.51 m ² cassettes	1-12	1-42
Loading capacity of 1.53 m ² cassettes	1-6	1-14
Loading capacity of Modus cassettes	-	Yes
Dimension: L × W × H (cm)	88.6 × 60 × 120	135 × 104 × 77
Weight	142	142
Maximum total weight (Kg)	192	192
Material composition	SS 304/316L	SS 304/316L
Manual hydraulic pressure	Yes	Yes
Cart handle	Yes	Yes
Pressure gauge	Yes, before and after VF filtration	Yes, before and after pre-filtration + before and after VF filtration = 3
Hand valve	No	Yes, before VF and after pre-filtration, behind the pressure gauge
CIP design of blank tube	Optional	Optional
Ordering no.	VFH-S07	VFH-D07

Hydration Products



Hydration Products



Phase I

Water for injection

- Bottle (100mL-2L) + 2D storage bag (500mL-20L)
- Supporting customer-supplied container + filling service
- Bags - Aseptic connection/welding and filling in Class C area
- Bottles - Filling under Class A laminar flow

Phase II

Water for injection

- Water for injection Stored in 3D storage bags (50 L to 1,000 L)
- collapsible bins + dollies

Phase III

Buffer liquid

- Storage bottles (standard) + 2D storage bags (standard) + 3D storage bags (customized)
- Custom product available



Bottled



2D Bagged



3D Bagged

Services



Suzhou R&D Center ▶

Upstream process development

- Cell culture process development
- Stepless scale-up
- Process optimization

Downstream process development

- Protein chromatography process development
- Stepless scale-up
- High-throughput process development
- Validation of resin service life

Training

- Application training
- Operation training



Accelerate process innovation, enrich product portfolio, and continuously improve products quality.

Bio-Link Validation and Analysis Center ▶▶

Located in Nantong, Jiangsu, this center was established in February, 2022 and covers an area of 1,400 sqm. It is equipped with all kinds of large precision instruments, including inductively coupled plasma mass spectrometer, liquid mass spectrometer, gas mass spectrometer, TOC detector, automatic microplate reader, infrared detector, etc..

The center supports the analysis and detection of extractables and leachables, with a detection precision of up to PPT level. The platform is operated and managed in accordance with CMA and CNAS systems.



Extractable/Leachable study (E&L)

- Extractable study with BPOG & USP standard methods
- Leachable study of customers' feed liquid
- Risk assessment
- 1,500+ E&L-related databases



Microbiology test (BSL2)

- Bacterial viability test
- Bacterial challenge test of virus removal filter
- Microbial limit test
- Sterility test



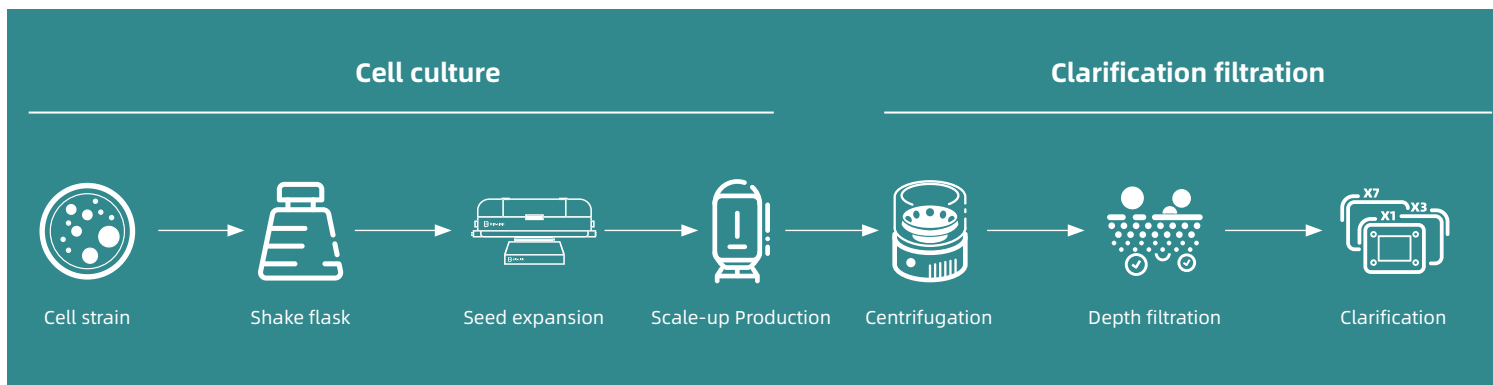
Filter validation

- Chemical compatibility study
- Product-wet integrity test
- Adsorption study
- Integrity test





"Intelligent" Made-in-China Bioprocessing Solutions ▶

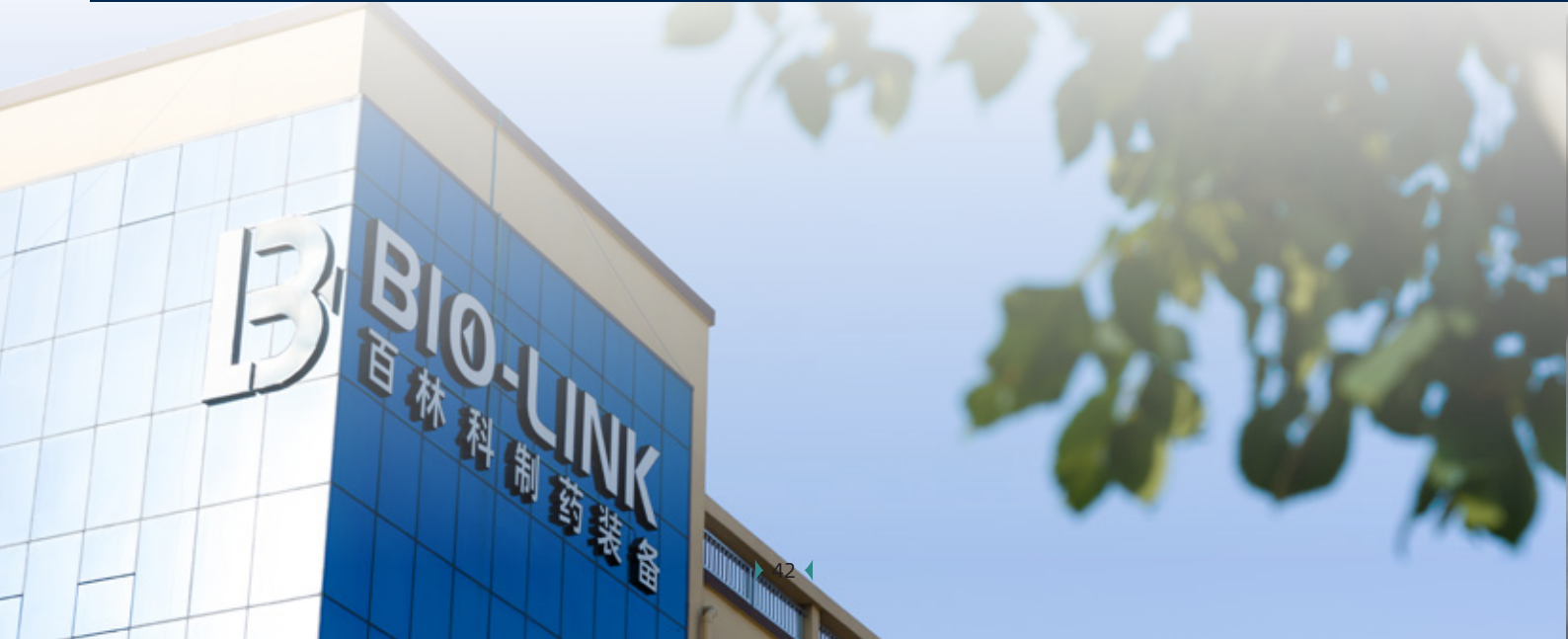


Bio-Link Offerings



Validation service Validation of single-use biopharmaceutical consumables

Process development service Application training Equipment operation training



Products capture

Preparation purification



Validation of resin service life

Validation of resin cleaning

Process development

Process bridging service

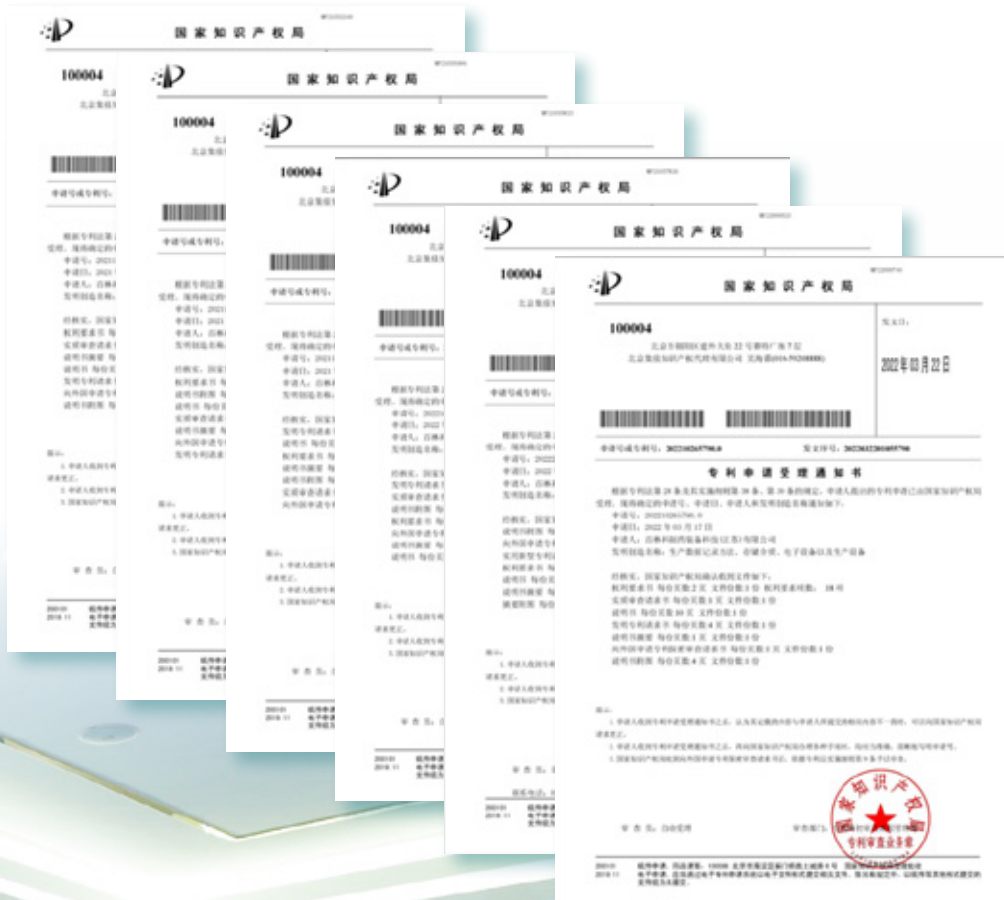


Take Innovation as the First Driving Force for Enterprise Development

As innovation is the power to drive enterprise development, Bio-Link has always given priority to scientific and technological innovation, to improve the core competitiveness of products and enterprise.

By gathering experts and scientists from the industry, Bio-Link possesses strong capability of independent research and development in bioprocessing solutions covering upstream and downstream.

So far, 14 patent technologies from Bio-Link have been approved, with more than 20 in the review stage.



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About Bio-Link

Bio-Link Biological Applied Technologies (Shanghai) Co., Ltd. (Bio-Link) is a group of technology-driven businesses that provide products and process solutions in the life sciences industry.

The company focuses on the development and production of the key processing equipment and materials for vaccines, antibodies, cell therapies, gene therapies and other biological products. Bio-Link's portfolio of offerings cover the entire upstream and downstream bioprocess such as cell culture, single-use mixing and storage, chromatography purification, filtration and ultrafiltration, as well as process development services. Bio-Link is committed to providing customers with high-quality, innovative products and solutions and strives to build an efficient, safe and competitive biopharmaceutical supply chain eco-system.

 info@biolink.com

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