



山东华致林医药科技股份有限公司

Shandong Huazhilin Pharmaceutical Technology Co., Ltd.

Company Profile

——Pharmaceutical Protection Specialists (Quality & Service) ——

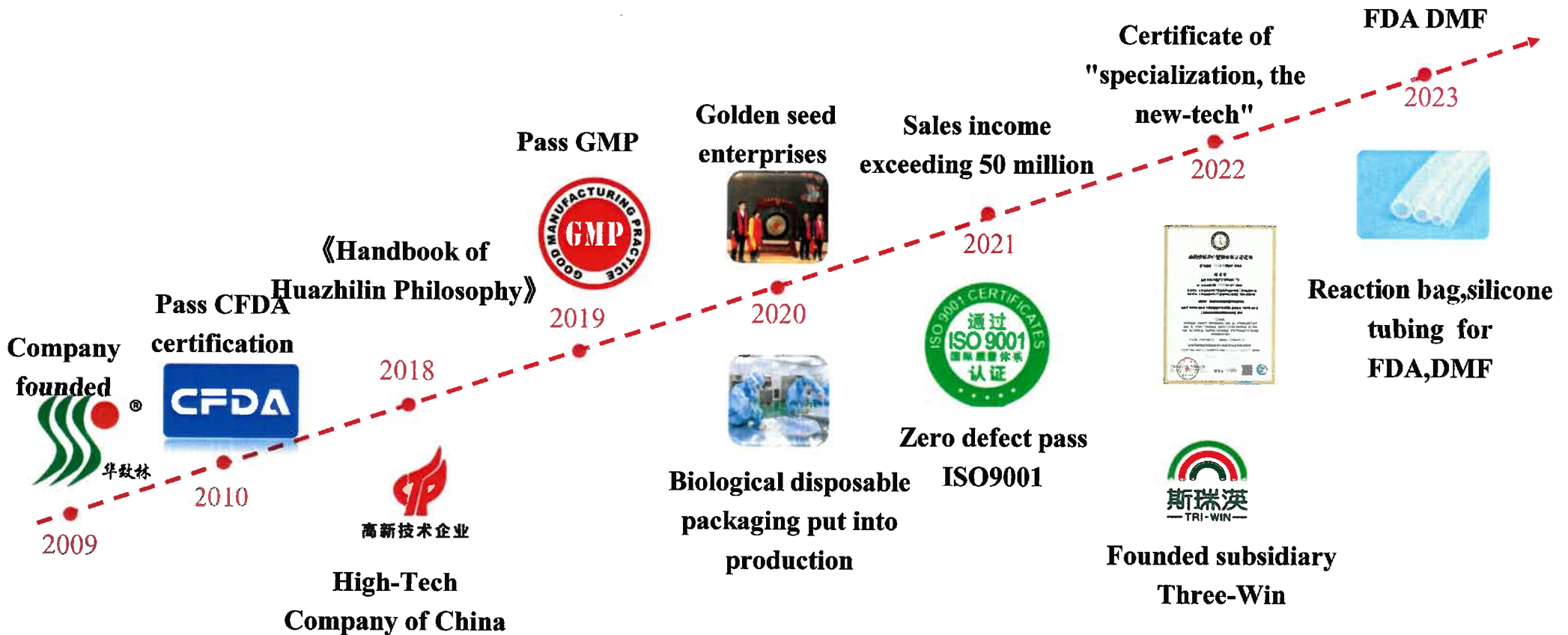


质量管理标准高
药袋认准华字标



- About Us
- Our Team
- Qualification
- Quality Control
- Main Products
- R&D Achievements

Company History



—Pharmaceutical Protection Specialists (Quality & Service)—

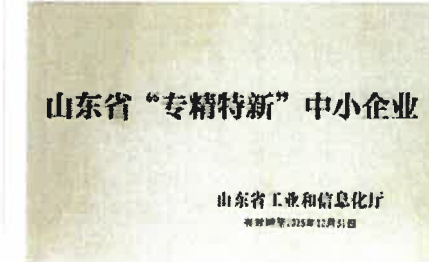
I、Company introduction -- Qualification



National high-tech enterprises



Shandong Gazelle enterprise



Shandong "specialized and special new" small and medium-sized enterprises



"Listed golden seed" enterprises



Zibo Gazelle enterprise

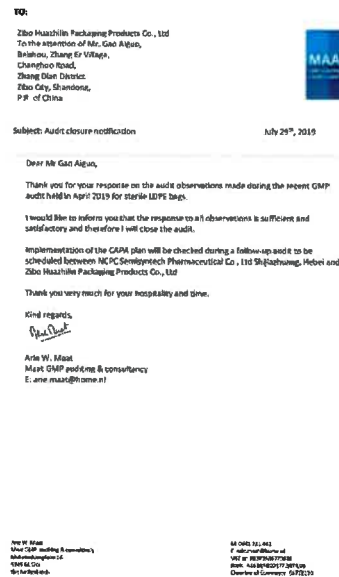


Zibo "specialized and special new" small and medium-sized enterprises

I、Company Certification



ISO 9001 certification



GMP



Performance excellence evaluation

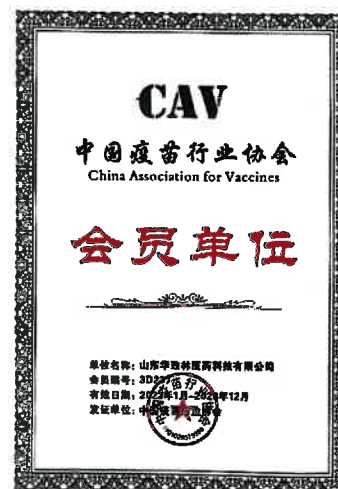
I、Company Industry Association



**China Medical
Equipment
Engineering
Association**



**China
Pharmaceutical
Packaging
Association**



**China
Vaccine
Association**

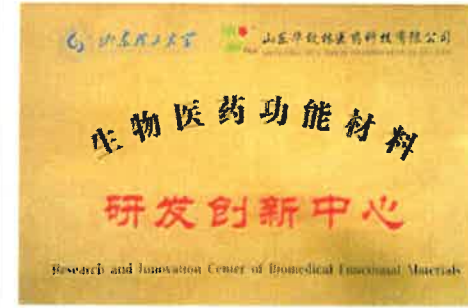


**Shandong
Pharmaceutical
Industry
Association**

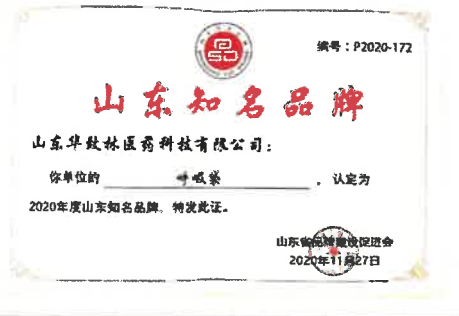
I、Company Brand & R&D



Shandong University of Technology teaching and research base



Biomedical functional materials research and development innovation center



Shandong famous brand - Tyvek steam sterilization bag

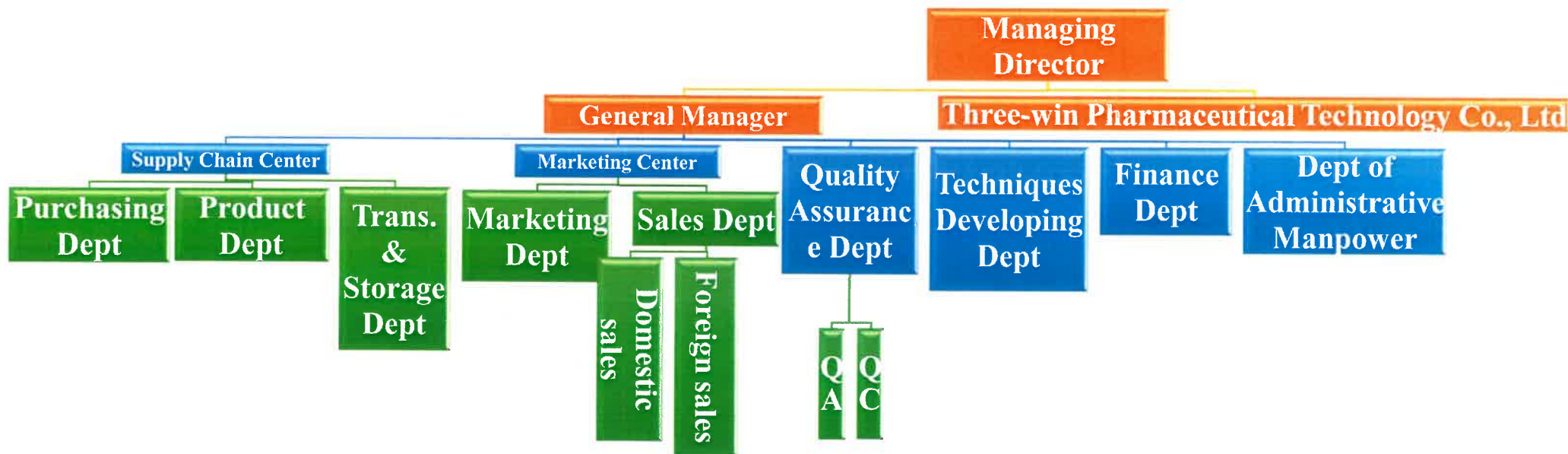


Shandong famous brand--Huazhilin



Medicine bag/sterile bag famous brand in Shandong

I、Organization Chart



I、Company introduction——Quality Management



II、Leading team



Founder and Chairman: Ni Huali

Mrs. Ni Huali graduated from Shandong University with a master's degree in pharmacy. She is a senior engineer, licensed pharmacist and a member of the Standardization Working Committee of China Vaccine Industry Association.



She was in charge of production and quality control in Xinhua Pharmaceutical, chief engineer in Qidu Pharmaceutical for 10 years, and was employed as an entrepreneurial mentor in Shandong University of Technology and Zibo City. In 2021, it was listed as "Shandong Warehousing Expert" by Shandong Industry and Information Department.

II、Leading team



李国栋
Guodong Li

- **Quality Manager, Shandong University microbiology major, postgraduate degree, has been engaged in quality management work for more than 20 years.**

张彬 Bin Zhang

- **PE product production director, graduated from Shandong Wanjie Medical College, medical major.**

张国锋 Guofeng
Zhang

- **General Manager of Biological Consumables Business Department, Pharmaceutical engineering major of Shandong University, master's degree, used to be responsible for production quality management in Qidu Pharmaceutical.**

许文东
Wendong Xu

- **General manager of Sunwin Pharmaceutical Silicone tube, Shandong University, pharmaceutical engineering major, postgraduate degree, used to be in charge of production quality management in Qidu Pharmaceutical.**

III、Qualification



登记号	品种名称	企业名称	企业地址	产品来源	包装规格	规格	更新日期	与制剂共同审评审批结果	备注
B20190004699	药用低密度聚乙烯袋	山东华致林医药科技股份有限公司; 山东华致林医药科技股份有限公司	山东省淄博市张店区昌国东路淄博耀鲁工贸创业园南6号	国产		—	2023-12-29	A	国药包字20150322
B20190004434	药用低密度聚乙烯无菌袋	山东华致林医药科技股份有限公司; 山东华致林医药科技股份有限公司	山东省淄博市张店区昌国东路淄博耀鲁工贸创业园南6号	国产		—	2023-12-29	A	国药包字20150727
B20190003189	药用低密度聚乙烯无菌膜	山东华致林医药科技股份有限公司; 山东华致林医药科技股份有限公司	山东省淄博市张店区昌国东路淄博耀鲁工贸创业园南6号	国产		—	2023-12-29	A	国药包字20170615

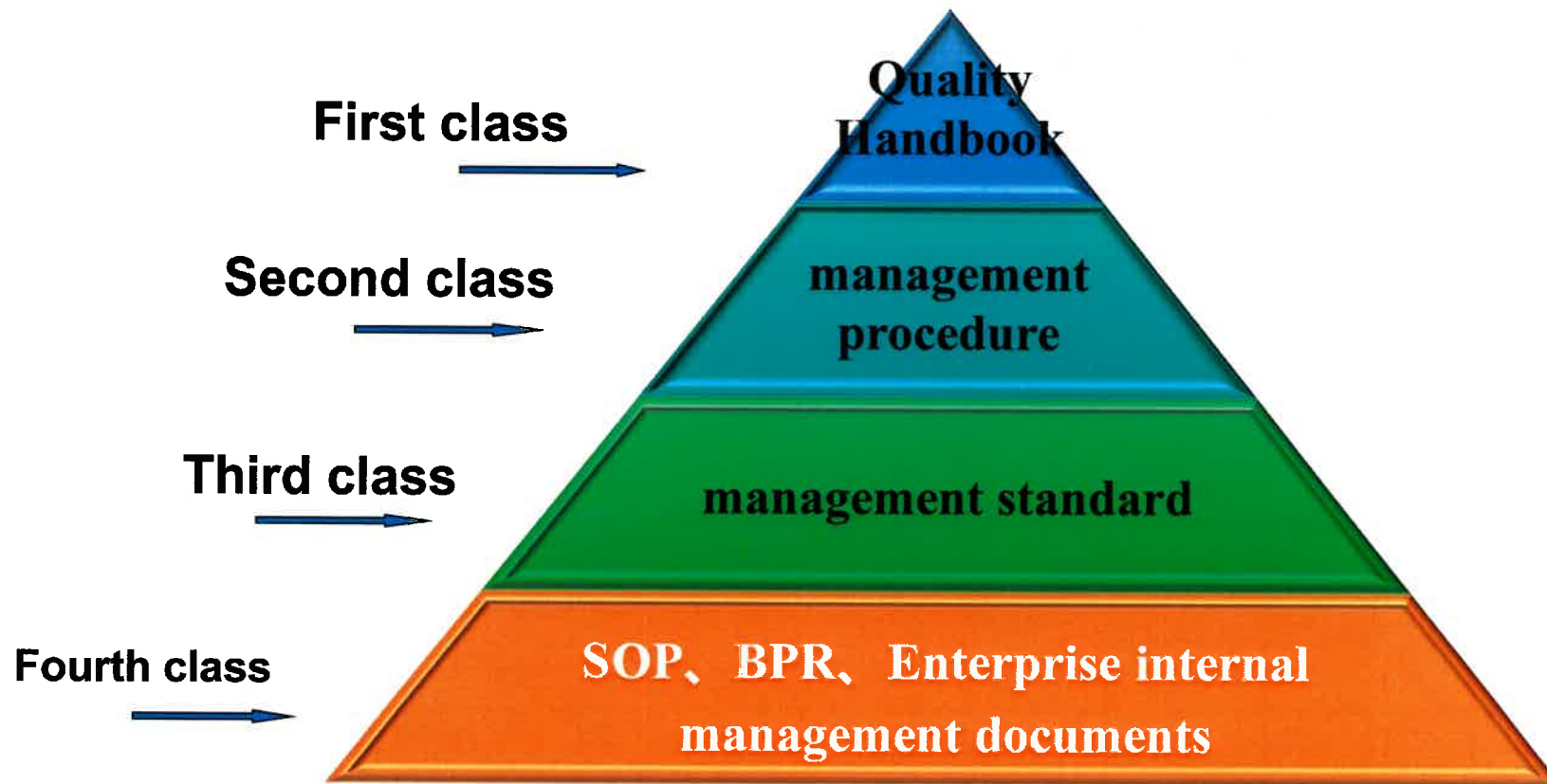


国家药品监督管理局药品审评中心
Drug Evaluation Center, State Drug Administration (CDE)

药用低密度聚乙烯袋
药用低密度聚乙烯无菌袋
药用低密度聚乙烯无菌膜
登记号信息可查询

状态均为“A”。

IV、Quality Management: How to control our quality



Whole production Quality Control process



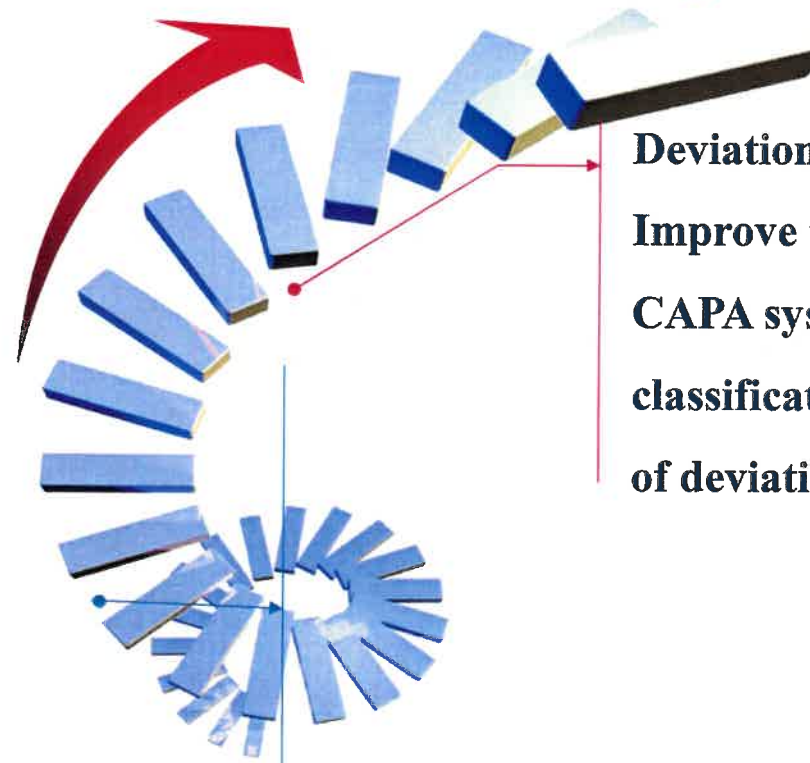
IV、Quality Control

Implement risk management, CCS (EU Foreign Matter Control Strategy) throughout the product life cycle)

Change management: Change initiation, application, approval, evaluation, implementation and tracking of all aspects of strict implementation of management procedures

Change, deviation, OOS and other normal operation; Annual product quality review

Quality management spiral



Deviation and CAPA:
Improve the deviation and CAPA system, clarify the classification and treatment of deviation.

Quality management - Advanced Production Equipment



SUS



Silicone tube/TPE



Film blowing machine



Bag machine



Square shape bag making machine

IV、Quality Control——Advanced Equipment



Blown film machine equipped with testing equipment industry first online black spots such as low equipment automation device is equipped with electrostatic eliminator to avoid electrostatic adsorption caused by foreign body risk

IV、Advanced and Complete Inspection Equipment



Gas transmission detector



Insoluble particle detector



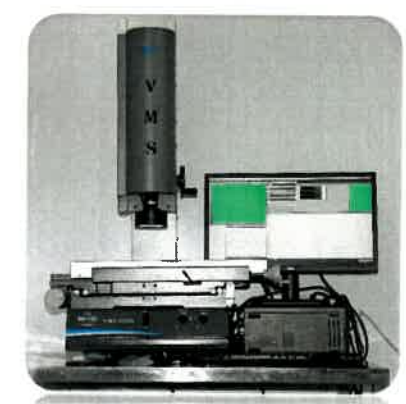
Static meter



Melt indexer



Electronic stripping tester



Silicone tube testing equipment

IV、 Inspection and raw materials



Daily inspection items are self-inspection, no commissioned inspection. Annual inspection third party inspection agency for all items. Antistatic effect with precise testing instrument, the realization of digital surveillance.

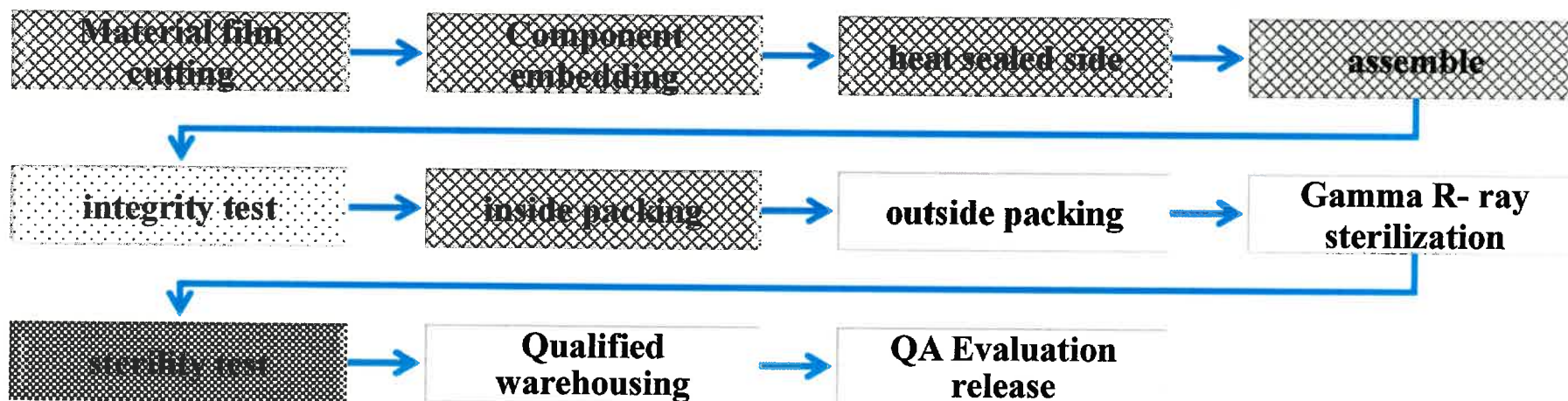


Stability stable quality raw materials imported raw materials suppliers perform strict inspection, inspection warehousing procedures after the inspection qualified rear can be used in the production of materials

Strict production process control



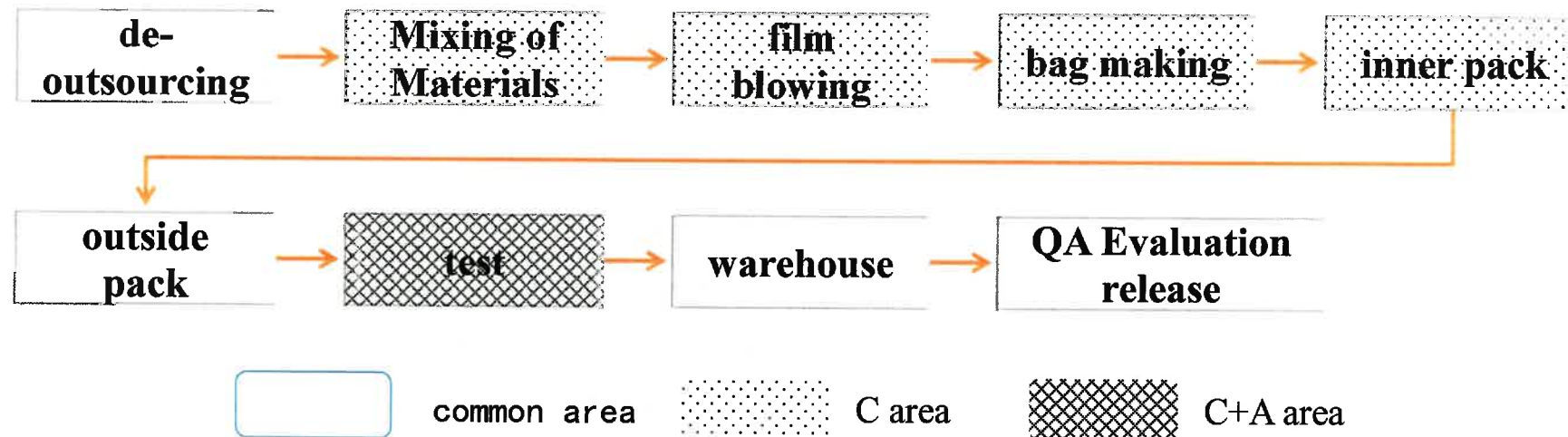
Single Using Bio-pharma system production process flow chart



Strict production process control



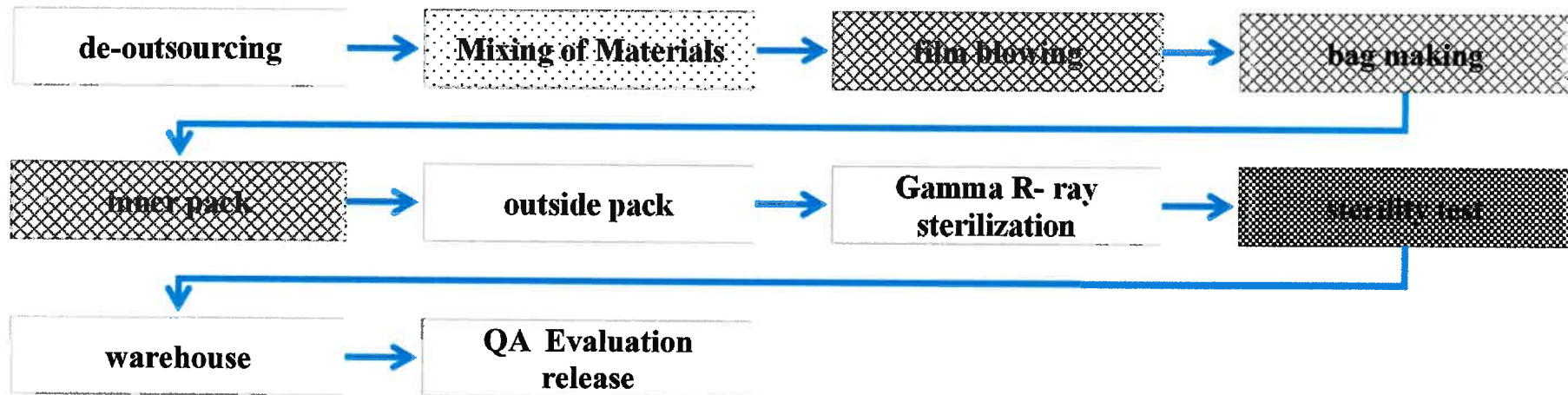
Pharmaceutical low density polyethylene bag(LDPE) production process flow chart



Strict production process control

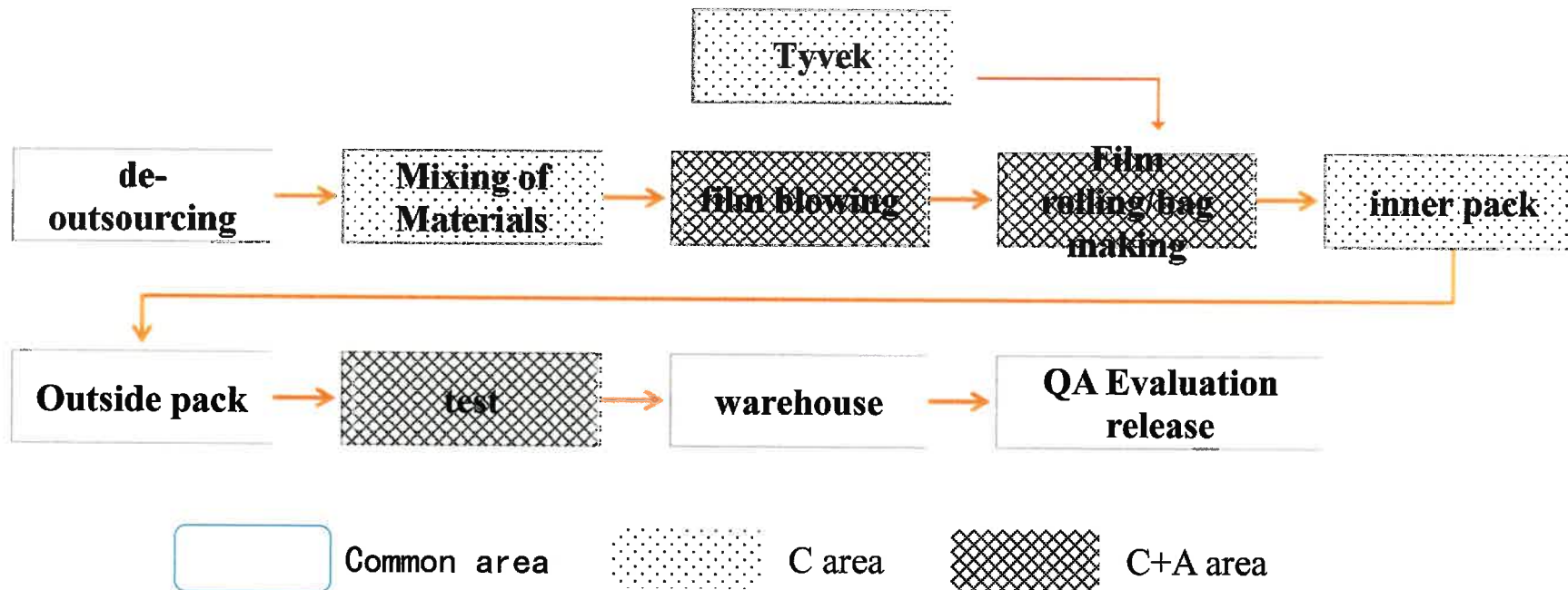


Production process flow chart of pharmaceutical low density polyethylene(LDPE) aseptic bag



Strict production process control

Production flowchart of Tyvek/ polyethylene clean steam bag for pharmaceutical used



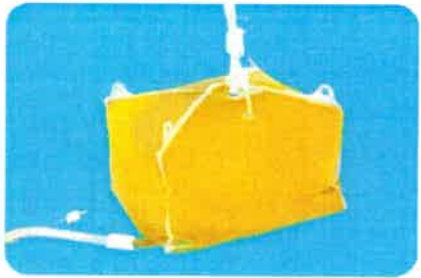
V、 Main product



- 1、 Single Using Bio-pharma System (SUS)
- 2、 Pharmaceutical Tyvek/HDPE Clean steam bag /rolls
- 3、 Biopharma tubing
- 4、 Pharmaceutical PE bag or rolls
- 5、 High barrier film series



V、Main Product——Single Using Bio-pharma System (SUS)



**3D Bio-pharma
Storage Bags**



**2D Bio-pharma
Storage Bags**



**Wave Cell
Culture Bags**



**Bio-pharma
Reaction
Bags**

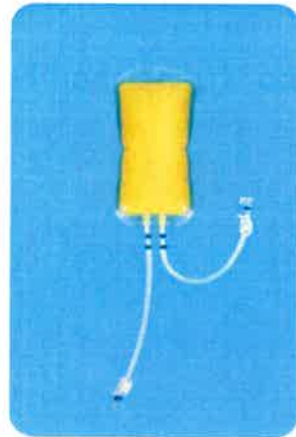


**Liquid Mixing
Bags**

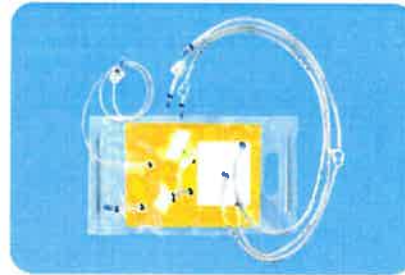
V、Main Product——Single Using Bio-pharma System (SUS)



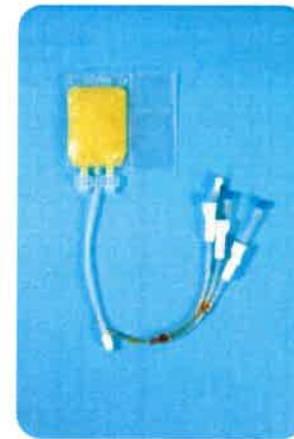
**Powder/Package
Material
Transportation
Bags**



**Sampling
Bags**



**Bio-pharma
Perfusion
Bags**



**Freezing
Bags**



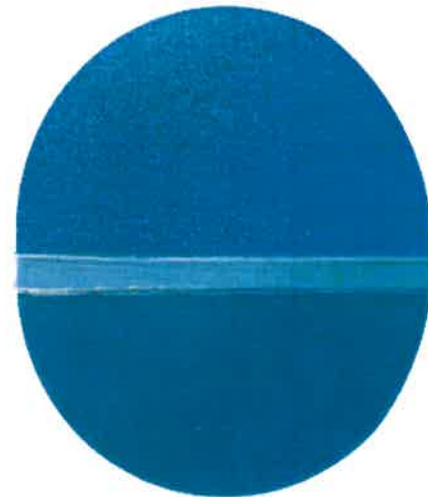
**Culture
Medium
Bags**

V、Main Product——Single Using Bio-pharma System (SUS)  华致林
H A G I L I N

Double weld process to
avoid liquid leakage



Huazhilin double weld process

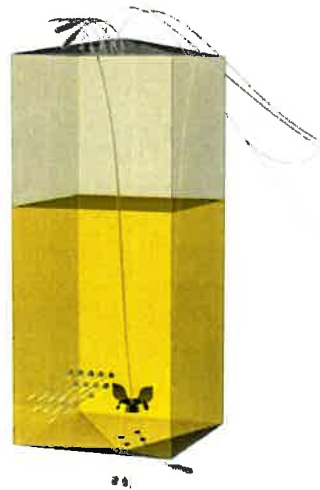


Other manufacturers single weld process

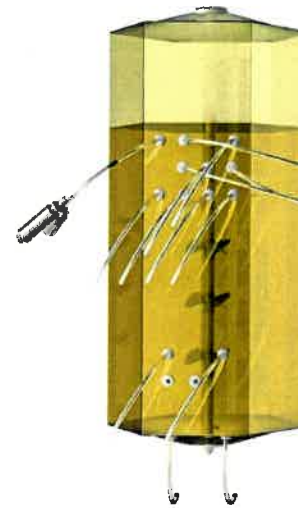
V、Main Product——Single Using Bio-pharma Reaction Bags



上搅拌S型



上搅拌M型



下搅拌A型



下搅拌G型

Various types of Single Using Bio-pharma Reaction bags can be perfectly fit to different model reactors.

V、Main Product——Single Using Bio-pharma Reaction Bags



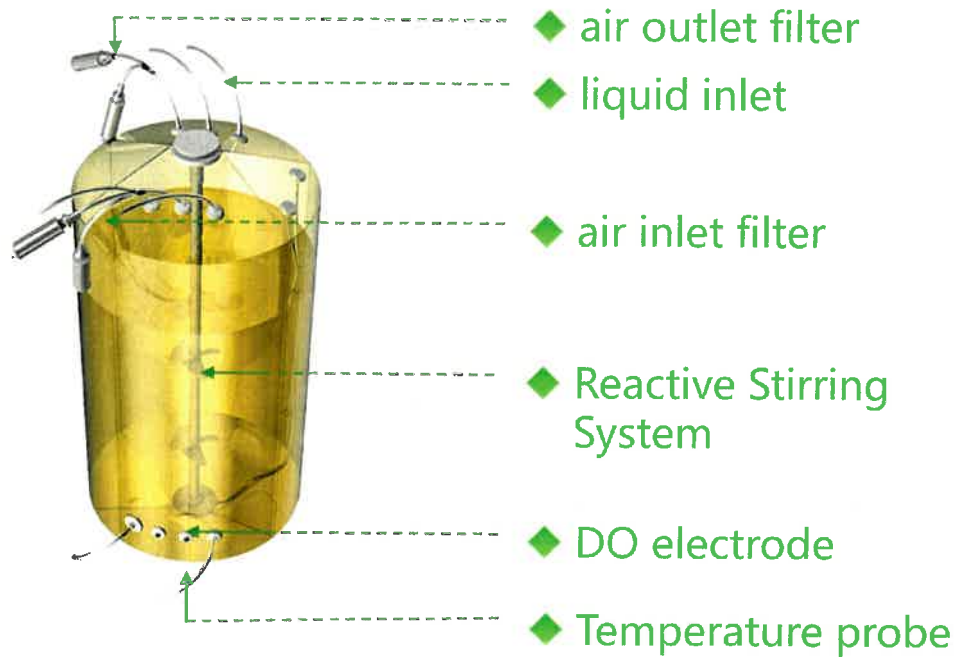
——Product Advantages

- ◆ Perfect for different brands of reactors.
- ◆ High Barrier Films, keep better cell growing condition
- ◆ Disposable patch pH、 DO sensors
- ◆ Double heat seal technology, avoid Liquid leak, 100% integrity test
- ◆ Model size:50L, 100L, 200L, 300L, 500L, 1000L, 2000L etc. According to customer customized standard fit to different model reactor.

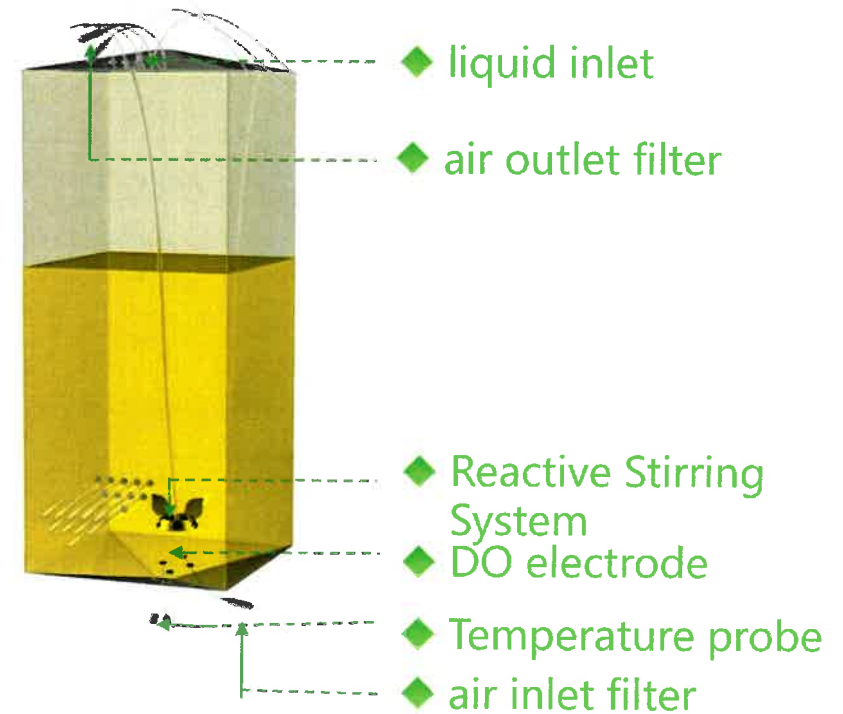
——Application

Cell/microbial culture field(antibody, vaccine, cell therapy/gene therapy, etc.)

V、Main Product——Single Using Bio-pharma Reaction Bags

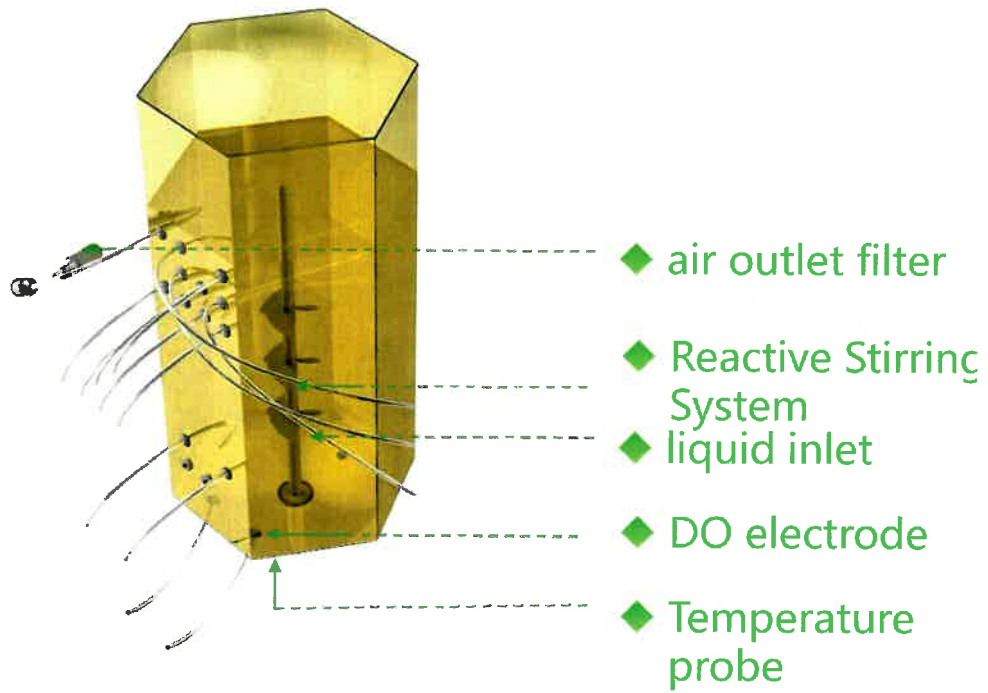


上搅拌S型

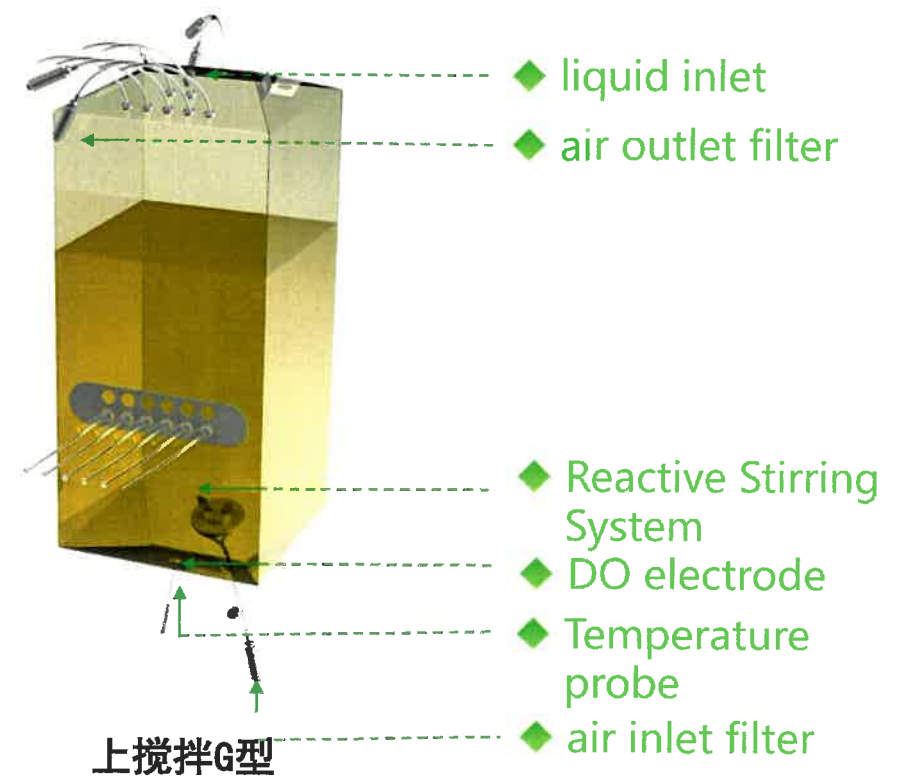


上搅拌M型

V、Main Product——Single Using Bio-pharma Reaction Bags

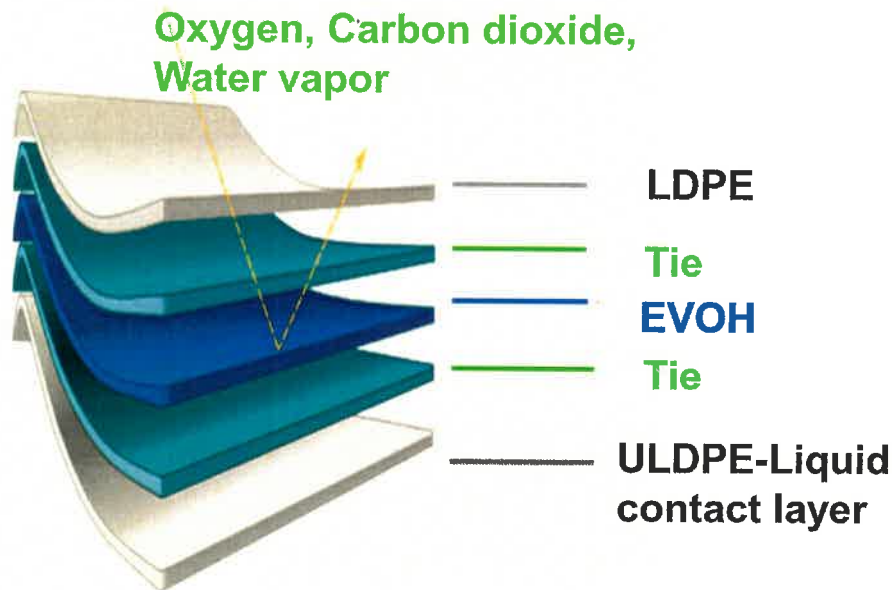


下搅拌A型
(High speed metal stirring rod, bacterial culture)



上搅拌G型

V、Main Product——Single Using Bio-pharma Reaction Bags



PE: Excellent chemical compatibility and biocompatibility, good physical properties.

EVOH: Gas barrier layer, with different permeability to various gas components

Tie: Adhesive layer, providing toughness

ULDPE: Fluid contact material

——Advantage Feature

The bag body is welded with high barrier film, film thickness between 0.325mm and 0.03mm, the film is divided into 5 layers, which can match our own brand and other brands.

V、Main Product——Single Using Bio-pharma Reaction Bags

Integrity test: Determine the detection parameters for different apertures.

No.	Aperture size	Initial pressure (mbar)	Final pressure (mbar)	Detection duration (min)	Standard detection duration (min)
①	30μm	50	49	18	20
②	20μm	50	49	30	40
③	10μm	50	49	60	70
④	5μm	50	49	80	90
⑤	1μm	50	49	100	120

Integrity test parameters : Pressure 50mbar, Detection duration 120min, Pressure attenuation less than 1mbar.

V、Main Product——Single Using Bio-pharma Reaction Bags

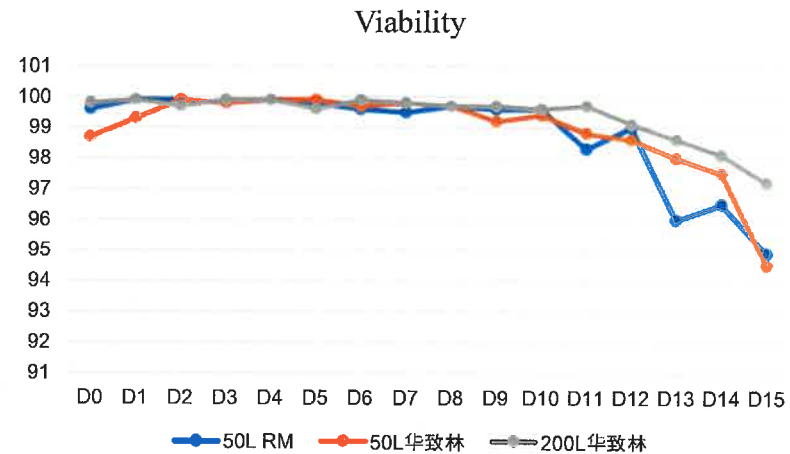
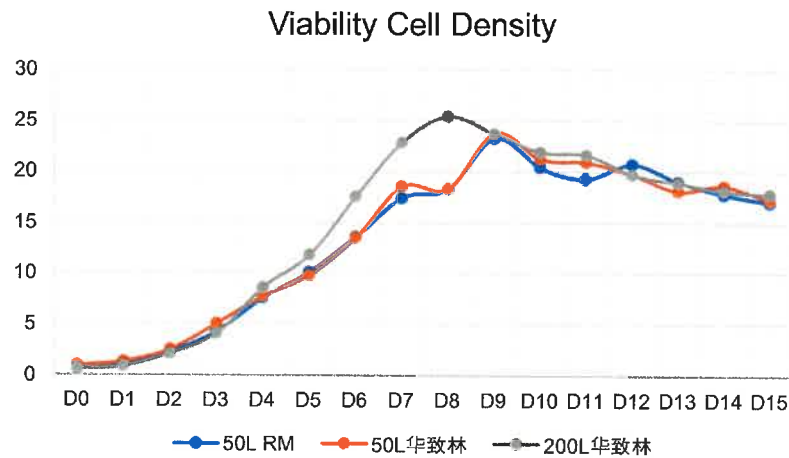


HA-D1054 item: Cell culture (CHO-K1) process solutions by client B

Item/process requirement	50L RM	50L Huazhilin	200L Huazhilin
Initial culture volume	17.07kg	17.01kg	149.79kg
Final culture volume	20.58kg	20.72kg	160.55kg
Inoculated cell density and cell viability ($0.6 \pm 0.2 \times 10^6$ cells/mL)	0.926×10^6 cells/mL, 98.7%	0.601×10^6 cells/mL, 99.6%	0.615×10^6 cells/mL, 99.8%
pH 7.0, DB \pm 0.2	6.92 (D4) -7.29 (D10)	7.00 (D5) -7.26 (D8)	7.00 (D4) -7.21 (D8)
DO \geq 20%	29.8-97	34.3-110.3	30.3-100.4

V、Main Product——Single Using Bio-pharma Reaction Bags

Results of cell culture(CHO-K1) by client B: Cell Density&Cell Viability



- 1、 During D0-D7 cell culture, the production trend of 200L Huazhilin Reaction Bags faster than 50L RM cell culture (50LSartorius reaction bags*1、 50LHuazhilin reaction bags*1) , but the overall trend is consistent.
- 2、 The growth trend of 50L Huazhilin reaction bags is consistent with that of 50L Sartorius reaction bags, the peak density of 50L Huazhilin reaction bags is slightly higher than that of 50L Sartorius reaction bags and reached the peak density on the same day.
- 3、 The overall trend of cell viability of the two bags is the same, all greater than 94%.

V、Main Product——Single Using Bio-pharma Reaction Bags



Cell culture (CHO-MGV) process solutions by client M

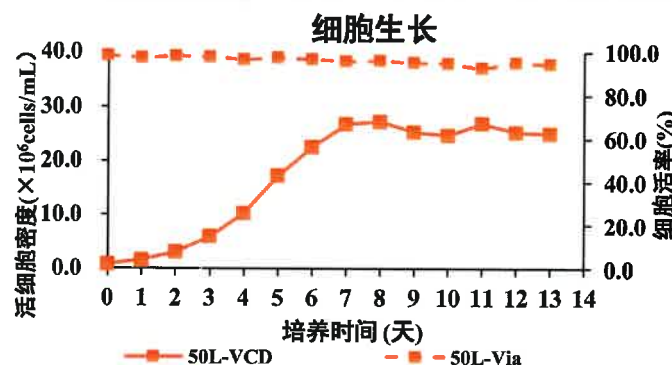
Test Content	Test Purpose	Inspect Materials
1.Test different liquid storage bags	Test the stability of the culture medium in the liquid storage bag. The culture medium stored for a certain period of time was used for subsequent 20L RM reactor and 50L reactor cell cultures	Bio-pharma Single Using Storage Bags No.: S230607
2.Test cell growth in 20L RM (WAVE) Cell Culture bags	inspect condition of cell growth and metabolism	Bio-pharma Single Using Wave Cell Culture Bags No.: S230609
3.Test cell growth in 50L Cell Culture bags	inspect condition of cell growth and metabolism	Bio-pharma Single Using Reaction Bags No.: S230610
4.Silicone Tube	inspect silicone tube whether is suitable for cell culture process. It's used in both 20L RM and 50L Cell Culture bags to cell culture test	Pharmaceutical Silicone Tube SY230150、 SY230151、 SY230149

V、Main Product——Single Using Bio-pharma Reaction Bags



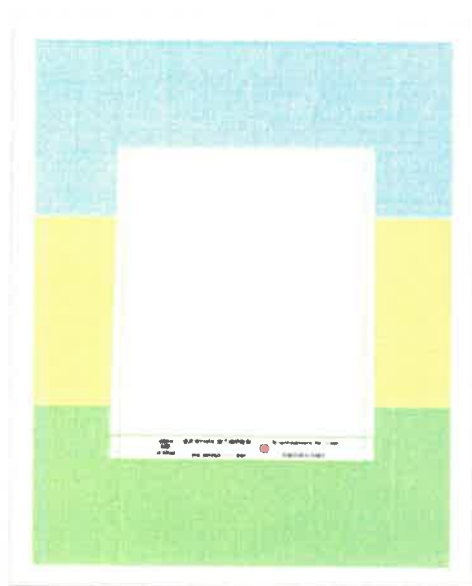
Results of cell culture performed by client M: Cell Density&Cell Viability

Day	Hour	VCD		Via	
		mc/mL		%	
		50L-VCD		50L-Via	
0	0	0.75		98.58	
1	24	1.52		97.5	
2	48	3.02		98.23	
3	72	5.89		97.89	
4	96	10.23		96.59	
5	120	17.23		97.56	
6	144	22.55		96.78	
7	168	26.78		95.92	
8	192	27.25		96.18	
9	216	25.33		95.31	
10	240	24.70		94.91	
11	264	26.90		92.75	
12	288	25.23		95.13	
13	312	25.00		94.52	

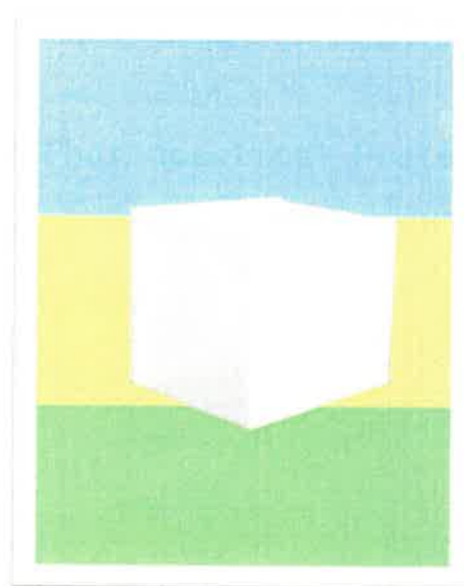


3、Conclusion: In this experiment, cells grew and metabolized normally in the test culture bag. The test bag can be used for cell culture, and the stability between batches can be further investigated. The growth and metabolism of the cells were in line with the normal Fed-batch trend. The maximum cell density reached 27×10^7 cells/mL, and the cell viability rate was 94.52% after 13 days of culture. The culture process was normal and in line with expectations.

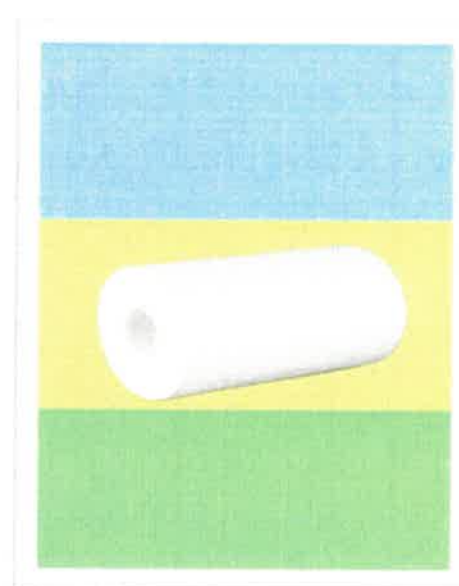
V、Main Product——Single Using Bio-pharma Reaction Bags——Tyvek/Polyethylene Cleansteam Bags for Medicine



Cleansteam bags



3D Cleansteam bags



Cleansteam films



Flexible Protective Cover

V、 Main Product——Single Using Bio-pharma Reaction Bags——Tyvek/Polyethylene Cleansteam Bags for Medicine



- **The first national brand**
- **"Well-know brand in Shandong, China"**
- **Obtained the national invention patent**
- **Can withstand 125°C pressure steam sterilization**
- **After sterilization, the contents can be placed for one year and still reach the sterile state**

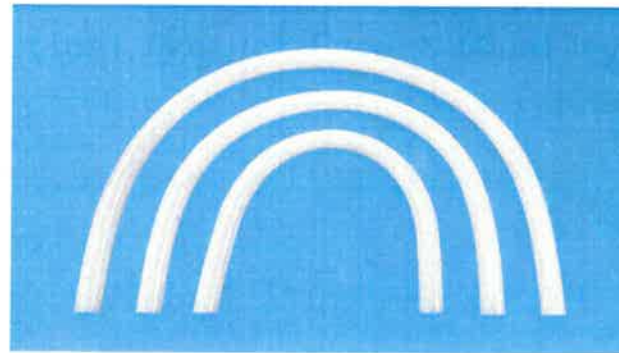
Application

- A、 **rubber stoppers/aluminum covers**
- B、 **Stainless steel tools and process equipment**
- C、 **canned needles、 silicone tube、 sealing ring**
- D、 **filter elements**
- E、 **clean clothes**
- F、 **penicillin bottles and container**
- G、 **medical equipment, such as syringe components**
- H、 **Interface ring, interface cover, etc**

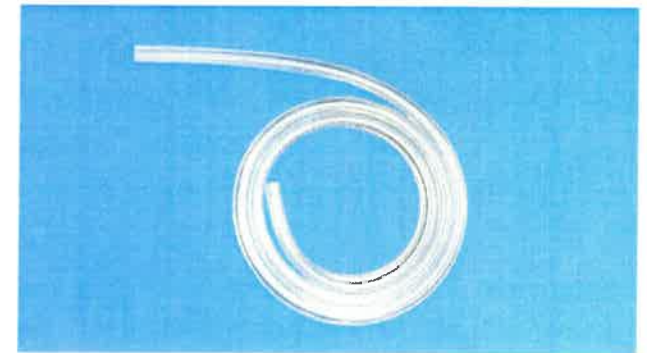
V、Main Product——Bio-pharma Tubing Series



**Pharma Silicone
Transferring Tube**

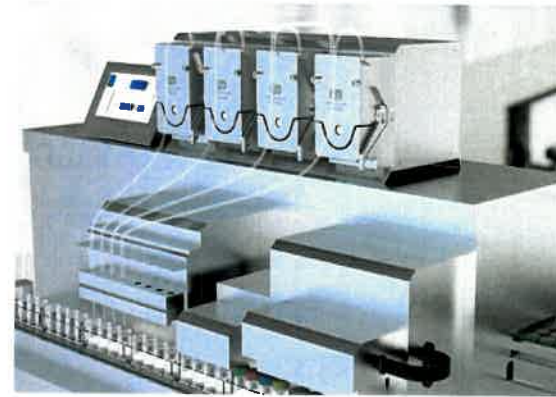


**Pharma Peristaltic
Pump Tube**



**Pharma TPE
Thermoplastic Tubes**

V、Main Product——Bio-pharma Tubing Series



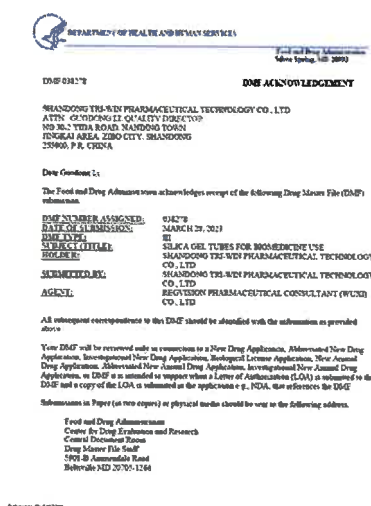
Application

- Specialized fluid transfer in pharmaceutical and biopharmaceutical fields.
- Precision filling.

Personalized control item

Biopharmaceutical silicone tube to detect insoluble particles, sterilization times (≥ 60 times) verification.
Filling with silicone tube for filling accuracy verification.

V、Main Product——Bio-pharma Tubing Series



**DMF备案
(DMF 038279)**

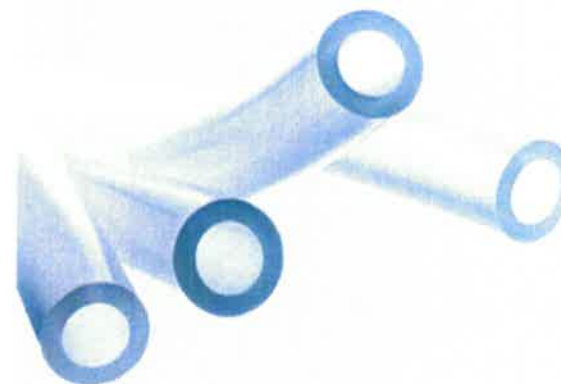
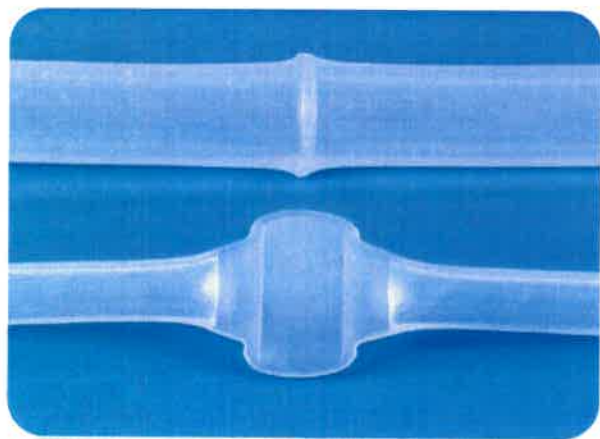
Based on Standard

- Chinese Pharmacopoeia
 - ASTM International Standard
 - ISO 10993 BC(biocompatibility)
 - USP85、USP87、USP88
 - Extracts can be used for experimental reference
- BPOG Guideline (2020)**
- Transmission tube benchmarking Saint-Gobain
 - Pump tube benchmarking Watson Marlow

V、Main Product——Bio-pharma Tubing Series



**Sanying's TPE thermoplastic tube realizes the
Perfect welding between imported brand TPE
thermoplastic tubes**



V、Main Product——Bio-pharma Tubing Series



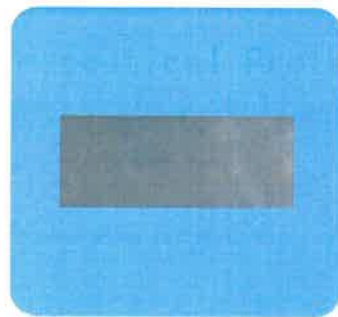
Main specification size (*Can be customized)

Items	Model Size	ID (In)	ID (mm)	OD (In)	OD (mm)	Thickness (mm)
0125-0250	16	1/8	3.2	1/4	6.4	1.6
0187-0312	25	3/16	4.8	5/16	8.0	1.6
0250-0375	17	1/4	6.4	3/8	9.5	1.6
0125-0312	20	1/8	3.2	5/16	8.0	2.4
0312-0437	18	5/16	8.0	7/16	11.1	1.6
0187-0375	15	3/16	4.8	3/8	9.5	2.4
0250-0437	24	1/4	6.4	7/16	11.1	2.4
0312-0500	35	5/16	8.0	1/2	12.7	2.4
0375-0562	36	3/8	9.5	9/16	14.3	2.4
0250-0500	26	1/4	6.4	1/2	12.7	3.2
0375-0625	73	3/8	9.5	5/8	15.8	3.2
0500-0750	82	1/2	12.7	3/4	19.1	3.2
0750-1125	191	3/4	19.1	9/8	28.7	4.8
1000-1375	92	1	25.4	11/8	35.0	4.8

V、Main Product——Pharmaceutical PE series



Pharma grade (sterile)
LDPE film/bag



Lyophilized film



PE Valve Bags



PE shrinking/bundling film

V、Main Product——Pharma grade LDPE film/bag



- Solid raw materials, pharmaceutical excipients and pharmaceutical intermediates
- Oral solid preparation production process and product packaging
- Film for drying Chinese medicine
- Internal packaging materials in direct contact with the drug (stopper, combination cap, etc.)
- Food, chemical products



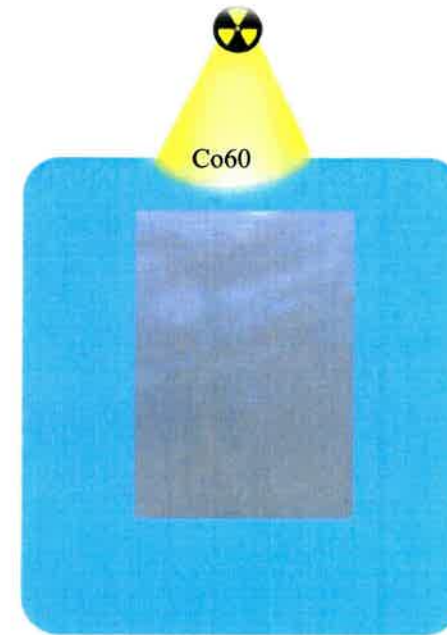
Based on Standard

- **Comply with YBB00072005-2015 national standard**
- **EP Standard**
- **USP Standard**
- **Meet the requirements of injection for insoluble particles and visible foreign bodies**

V、Main Product——Pharma grade Sterile LDPE film/bag



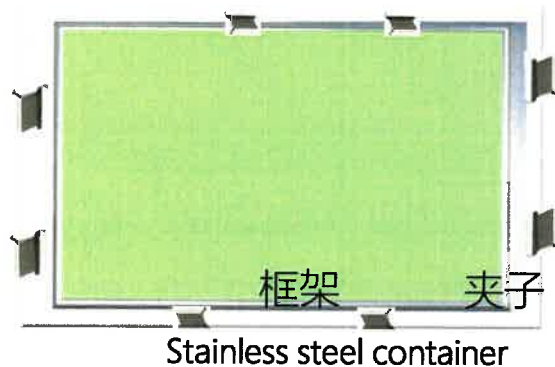
- Aseptic apis, aseptic preparations and other production processes as well as packaging of final products
- The transfer of aseptic packaging materials such as aseptic rubber plugs in the production process and the packaging of the final product
- Semi-finished products storage and transport of vaccines and other biological products
- Biopharmaceutical clean area material and waste transfer
- Packaging of sterile medical devices



Application

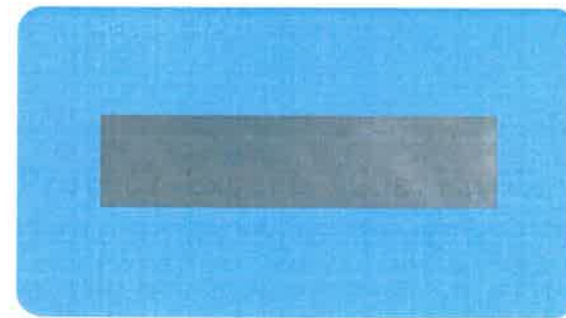
- Need freeze-dried apis
- Can withstand low temperature of -70°C

V、Main Product——Pharma grade sterile LDPE film (Lyophilized film)



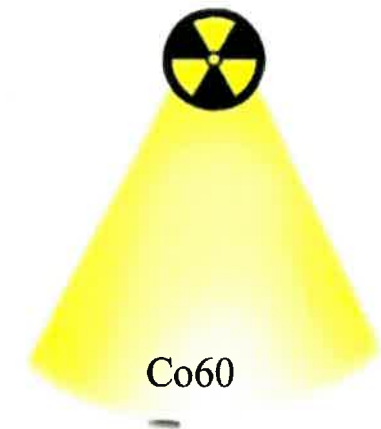
Advantages

- Instead of stainless steel container, to avoid operation risk of pollution.
- Reduce heavy cleaning.
- The material is light and easy to operate.
- Can be used repeatedly.



Based on Standard

- **Comply with YBB00072005-2015 national standard**
- **Business registration standard**
- **Meets the requirements of insoluble particles and sterility of injection**
- **Almost no discoloration after sterilization**



V、Main Product——PE Valve Bags



Advantages

- Can connect different shapes of PE bags
- To realize the whole process of material aseptic transfer, the valve port can choose different specifications.

Applications

- Aseptic transport of process items, rubber plugs, aluminum caps, raw materials and other products

V、Main Product——聚乙烯收缩膜、捆扎膜



Applications

Mainly used for injection, tablet, capsule, granule, pill and other drugs of multi-pill box cluster heat shrink packaging.

Based on Standard

GB/T 4456-2008 National Standard

Advantages

High tensile strength, good toughness; Good heat sealing; High softness; Good transparency; Strong tear resistance; Specifications according to customer requirements, customization.

V、Main Product——High barrier film Series



聚酯/铝、聚酯/镀膜、纤维素等多种材质

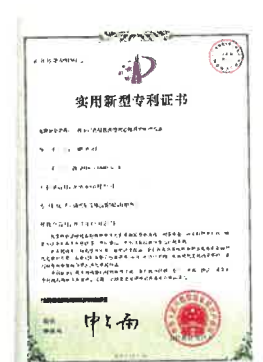
Advantages

- Solvent-free composite process
- Water vapor transmission rate is not higher $0.5\text{g} / (\text{m}^2 \cdot 24\text{h})$
- Oxygen transmission rate is not higher $0.5\text{cm}^3 / (\text{m}^2 \cdot 24\text{h} \cdot 0.1\text{MPa})$

Applications

Suitable for solid oral/liquid oral preparations, easy moisture absorption and easy oxidation of raw materials/traditional Chinese medicine preparations and other drug packaging

VI、 R&D Achievements——R&d cooperation and patents



Huazhilin pays attention to science and technology research and development, closely cooperates with many domestic universities, and has more than 30 national patents.



药用防护专家
Medical Protection Specialist

国家高新技术企业
National High-Tech Enterprise

质量管理标准高 药袋认准华字标



**有15年专业药包材生产管理经验的生产企业，
受国家药监局监管、飞检；
产品在市场上随机抽检，
洁净厂房由药监部门出具检测报告；
用药品GMP规范进行生产质量管理，
有在药厂从事多年生产质量管理经验的专业管理团队。**

战略定位



对原料药、无菌产品的企业而言，
华致林是生产药用内包装及无菌过程防护产品的公司，
它能提供专业安全的内包装及无菌过程防护个性化解决方案，
因为它拥有健全的质量保证体系和专业的服务团队。



Corporation Positioning
Pharmaceutical Protect Expert

Operation Philosophy
Contribute to the Development of the World Pharmaceutical Industry with the Pursuit
of Material and Spiritual Happiness of Employees.

Operation Philosophy
World-class Pharmaceutical Package Enterprise

Our Mission
Provide pharmaceutical packaging and process protection solutions for
pharmaceutical companies

Core Values
注重品质 持续创新 服务客户