BIO-SUPPORT × TAILIN

Introduction of Aseptic & Contamination Isolator for Production and QC

For Korean PharmaBio Customers

Tailin Technology × Bio-Support GMP Expertise
From Product Supply to GMP-Ready Implementation

2026-11-06 · Ver 00
Proposed by: Bio-Support

gmp@biosupport.co.kr

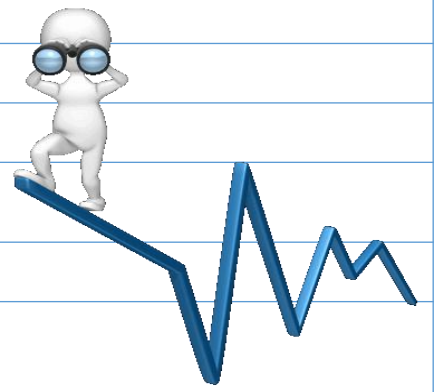
Bio-Support, Your Trusted GMP Value Chain Integrator
Leading Value. Connecting with Trust. Realizing the Future.



Bio-Support: Company Overview

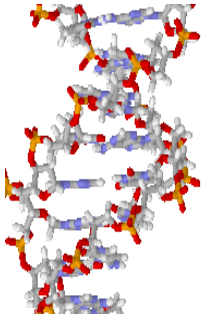
제약·바이오 고객의 GMP와 글로벌 기술을 연결하는 통합 실행 파트너

ITEM	DECSRIPTION
Name	Bio-Support Co,. Ltd
Founded	Apr. 19, 2000
CEO	Kim Kyung-min
Address	65, Dongpyeon-ro 13beon-gil, Dongan-gu, Anyang-si, Gyeonggi-do, Republic of Korea
Employee	61 Persons(GMP Consultant 50, GEP Engineer 2)(as of Aug 2026)
Main business	• [GMP & Validation Solution Consulting Biz] • [PharmaBio Value Chain Collaboration Biz] • [GMP Design & Modular Construction Biz] • [PharmaBio Knowledge & Competency Development Biz] • [Global BioTech Gateway Collaboration Biz] • GMP (Good Manufacturing Practices, pharmaceutical manufacturing management and quality control standards) for pharmaceuticals, biopharmaceuticals, ATMP, veterinary drugs, medical devices, and health functional foods
Main Certificates	• Venture Business Verification (2006~), Gov. Promising SME Certification (2008) • Technology Innovation SME (Innobiz) Verification (2008~) • Professional Research Biz. Certificate(Ministry of Science & ICT)(2007~) • ISO 9001 Quality Management System (2009~), • Ministry of Employment and Labor SME Verification (2024~)
Contact us	www.biosupport.co.kr, gmp@biosupport.co.kr



Bio-Support: Company Overview

제약·바이오 고객의 GMP와 글로벌 기술을 연결하는 통합 실행 파트너



한 장으로 보는 바이오써포트

고객사가 GMP 프로젝트를 더 빠르고, 더 안전하게, 더 확실하게 실행하도록 지원합니다.

26년	1,306+	392+	111+	202+
GMP & Validation 컨설팅 역사	총 프로젝트 수행 건수	함께한 고객사	Turnkey 프로젝트 실적	GMP 제조소 설계 프로젝트

Bio-Support의 고객 가치

규정·기술·엔지니어링·운영을 하나의 실행체계로 연결하여 GMP 리스크를 낮추고 프로젝트 성공 가능성을 높입니다.

고객과 함께 만드는 성과

신축·개축 GMP 제조소, PQS, DI, CCS, Qualification/Validation, 글로벌 GMP 대응까지 고객사의 목표 GMP 수준에 맞춰 수행합니다.

Global Technology × Global GMP Expertise × Integrated Realization

[GMP & Validation Solution Consulting]

Bio-Support x TAILIN

New/Remodeling GMP Facility Consulting(Turnkey Project); [Conceptual Design Execution, VMP, QRM(RA), URS, DQ, IQ, OQ, PQ, CSV, CV, PV and/or PQS Consulting]	
GMP Facility Design Solution (Conceptual Design)	GMP Facility for Oral Solid Dosage Form, Liquids, Ointments, Eye Drops, Injections
	GMP Facility for API
	GMP Facility for Biopharmaceuticals, Cell Therapy & Gene Therapy(ATMP, CGT)
	GMP Facility for Health Functional Food & Medical Devices
Good Engineering Practice(GEP) Solution	Enhanced Design Review of Basic & Detailed Design/Facility Design
	GMP Facility Commissioning Consulting + Planning Execution & Reporting
	Utility System and Equipment Functional & Design Specification(FDS) Analysis & Documentation
	FAT / SAT and Pre-Delivery Inspection Planning, Execution & Reporting
	GMP Facility Engineering Management & Supervision Service
Qualification Consulting	Validation Master Planning + Quality Risk Management Master Planning
	QRM Planning, Execution & Reporting(Facility, Utility System, Equipment, Process etc.)
	URS & Design Qualification Execution & Documentation
	Installation & Operational Qualification Execution & Documentation
	Performance Qualification Consulting, Execution & Documentation
	Requalification & Revalidation Consulting, Execution & Documentation
Validation Solution	Cleaning Validation Consulting & Documentation
	Process Validation Consulting & Documentation
	Computerized System Validation Consulting, Execution & Documentation
GMP Solution Consulting	Validation Management System & Quality Risk Management System Consulting & Documentation
	GMP & Validation Training + Survival GMP Workshop(Knowledge Sharing)
	Data Integrity Management System & SOPs Consulting + Data Integrity Mock Inspection
	GMP Mock Inspection/ Vendor Audit
	Pharmaceutical Quality System(PQS) Consulting(Policy, SOPs, Form; Preparation, Review, Training)
GMP Innovation	QbD Consulting(Partnership)
	Contamination Control Strategy (CCS) + Advanced EMP & Bioburden Control Consulting
	GMP Digital Transformation Solution Consulting



"Bio-Support", The Leader in GMP Solution Consulting, Our Valued 392 Customers!!



Bio-Support PharmaBio Value Chain Collaboration Biz

단순 제품 공급이 아니라 고객의 GMP 과제와 글로벌 파트너 기술을 실제 적용 솔루션으로 구현



Bio-Support 수행 역할

- GMP Requirement Review
- Application & Product Selection
- URS / Technical Specification Review
- Design & Interface Review
- Qualification Review or Execution
- Training & Lifecycle Support

고객 기대효과

- 제품 도입 목적과 GMP 요구사항 정렬
- 초기 단계에서 Spec·Interface·Validation 리스크 확인
- 공급자 기술자료와 고객 SOP·Validation 체계 연결
- 도입 후 운영·점검·Lifecycle Support 가능

BIO-SUPPORT × TAILIN

Integrated Aseptic, Contamination Control & QC Solutions for PharmaBio

TAILIN Technology

- Isolator
- Sterile Transfer
- VH_2O_2 Bio-decontamination
- Microbiology QC
- TOC / Filter Integrity / CCIT

×

Bio-Support GMP Expertise

- GMP Requirement Review
- URS / Specification
- Design & Interface Review
- Qualification / Validation
- Training & Lifecycle Support

=

Customer Value

- Better CCS
- Faster Implementation
- Stronger GMP Evidence
- Lifecycle Support

바이오써포트는 Tailin의 한국 공식 대리점으로서
국내 GMP 환경에 적합한 제품 도입과 Qualification을 지원합니다

Bio-Support x TAILIN

TAILIN: Integrated Life Science Solution Provider

무균격리, Bio-decontamination, Microbiology QC, Water Quality, Integrity Test를 연결하는 Life Science Solution Provider

Aseptic Isolation & Containment	Sterile Transfer	VH_2O_2 Bio-decontamination	Barrier Integrity Testing
Microbiology QC	TOC Analysis	Filter Integrity / PUPSIT	CCIT

One Connected Contamination Control & Quality Control Value Chain

Website: tailinscitech.com/
YouTube: youtube.com/@tailinbioengineering/videos

Bio-Support
TAILIN

BIO-SUPPORT × TAILIN

Technology from Tailin. GMP Expertise from Bio-Support. One Integrated Solution for PharmaBio.

Your Partner for Aseptic & Contamination Isolator for Production and QC

Global Technology × Global GMP Expertise

Thank you so much!!!

Bio-support has been growing together with our valued customers and partners since 2000!!!.

Official Website
https://www.tailinscitech.com/

YouTube Channel
https://www.youtube.com/@tailinbioengineering/featured

Bio-Support Role
Korean official distributor,
GMP Value Chain Integrator

CONTACT US : 바이오써포트 담당임원 김지민 상무 / www.biosupport.co.kr / gmpkjm@biosupport.co.kr



Sterility Test Isolator

ZHEJIANG TAILIN BIOENGINEERING CO., LTD

Zhejiang Tailin Scitech Co., Ltd
Fully owned subsidiary of Zhejiang Tailin Bioengineering Co., Ltd
No.2930 Nanhuan Road, Binjiang, Hangzhou, Zhejiang, China.

TEL: 0086-571-86589087 **FAX:** 0086-571-86689998
E-MAIL: marketing@tailingood.com **WEB:** www.tailinscitech.com

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Integrated Solution Provider in Life Science

Zhejiang Tailin Bioengineering (Tailin), an integrated solutions provider in the life sciences, was established in 2002. The company operates across a range of vital sectors, including biotechnology, precision medicine, pharmaceutical engineering, radiopharmaceuticals, food safety, and advanced materials.

Our core strength lies in developing customized solutions tailored precisely to our clients' needs. Our products are widely applied in pharmaceutical companies, labs, cleanrooms, hospitals, and research institutes. Notable offerings include aseptic isolators, glove integrity testers, VH2O2 decontamination systems, sterile pass boxes, sterility test pumps & canisters, filtration membranes, TOC analyzers, filter integrity testers, and beyond.

Our team consists of nearly 1,000 employees, including 200 R&D engineers. We hold over 300 national patents and actively participate in drafting national and industry standards to advance our field.

We have strong partnerships with pharmaceutical companies and laboratories in over 50 countries. Tailin aims to continue growing and improving our services for our customers while contributing to health and safety.

Tailin Brand: Established in 1993
Tailin Bioengineering(Tailin): Established in 2002
Tailin IPO: 2020 (Stock Code: SZ300813)
Tailin Sictech: a subsidiary of Tailin, responsible for overseas business



HTY Series

The Sterility Test Isolator is a custom-designed cGMP Class A/ISO 5 isolator system, specifically engineered to provide the safest and most ergonomic working conditions for quality control operations. Tailin hard-wall laminar flow sterility test isolator HTY series features a rigid structure made of stainless steel and tempered glass, creating a dynamic Class A internal environment. Operations within the isolator are conducted using gloves, available in two versions: a thick, tear-resistant model and a thin, highly tactile option. The system incorporates a Siemens Programmable Logic Controller (PLC) for fully automated control of pressure and airflow volume and includes a pressure loss alarm function. Comply with GMP, USP, EP.



+ Built-in Sterility Test Pump + Built-in Vaporized Hydrogen Peroxide Sterilization System + Customized

Application

For GMP inspections of sterile pharmaceuticals, including sterile preparations and sterile active pharmaceutical ingredients.

For sterility tests, sampling, weighing, dispensing, etc.

The sterility test, aseptic preparation and filling could be conducted in an isolator located whithin Class C/D, according to EU GMP Annex 1 and PIC/S<Recommendation on Sterility Testing> 8.1.1

Sterility Test Isolator



Features

Sterile Assurance

HTY series isolators ensure the highest air quality within the isolation environment:

- Engineering filtration system comprising H14 High-Efficiency Particulate Air (HEPA) filters.
- The integration of the latest generation of vaporized hydrogen peroxide sterilizers developed by Tailin, coupled with precise hydrogen peroxide gas concentration/saturation control technology, which rapidly steriizes the internal environment of the chamber, guaranteeing a sterile environment during sampling processes.
- Inflatable seals made of GMP-approved silicone ensure the tightness of the chamber.
- A fully enclosed physical barrier avoids direct contact between operators and products, addressing the issue of microbial contamination.
- Real-time monitoring of settling microorganisms, temperature, humidity, pressure, and airspeed within the chamber ensures the production environment remains continuously controlled.

Automatic Leak Testing

HTY series isolator is equipped with an automatic leak testing system that individually tests each chamber for leaks using the pressure decay method as described in international standard ISO 10648-2. Leakage rate is less than 0.5% /vol/hour under 2 times working pressure test .

Glove Integrity Testing

HTY series isolators are equipped with an integrated automated glove leak testing system (GIT Series) which performs an independent leak test on each glove installed on the isolator system according to the positive pressure decay method described in the international standard ISO 14644-7. It detects holes as small as 100μm in diameter.

Data Management

Comply with 21 CFR Part 11 electronic records and signature requirements.

Sterility Test Isolator

Sterility Test Isolator

Model Selection

Model	Description	Overall Dimensions	Operating Space	Inner Pass box
HTY-1250G2	Operating chamber with Pass box-2Gloves	2300x870x2420mm	1240x680x700mm	600x550x700mm
HTY-1650G3	Operating chamber with Pass box-3Gloves	2700x870x2420mm	1640x680x700mm	600x550x700mm
HTY-1800G4	Operating chamber with Pass box-4Gloves	2850x870x2420mm	1790x680x700mm	600x550x700mm
HTY-1800G8	Operating chamber with Pass box-8Gloves(Double Side)	2650x1240x2420mm	1750x1200x650mm	600x650x600mm
HTY-1250AG2	Operating chamber-2 Gloves	1675x870x2420mm	1250x680x700mm	NIL
HTY-1650AG3	Operating chamber-3 Gloves	2075x870x2420mm	1640x680x700mm	
HTY-1800AG4	Operating chamber-4 Gloves	2225x870x2420mm	1790x680x700mm	
HTY-1800AG8	Operating chamber-8Gloves (Double Side)	2370x1240x2420mm	1750x1200x650mm	

Size Can Be Customized:

*Some models



HTY-1650AG3



HTY-1650AG3(RTP)



HTY-1250AG2



HTY-1800G4



HTY-1800AG4



HTY-1800G8

Technical Parameters

Power Supply: AC380V/50Hz	Max.Power: 3000W-4000W
Cleanliness: GMP Class A	Chamber Pressure Range: From -80Pa to +80Pa
Airflow Direction: Laminar flow	Velocity: 0.36~0.54m/s
Built-in Sterility Test Pump: 1 or multiple	Compressed Air Supply: 0.4MPa-0.6MPa clean and dry
Killing Rate: ≥log6	Noise: ＜75dB(A) when in pressure hold stage
Touch Screen: 12" Tablet PC	Leakage Rate: ＜ 0.5% /vol/hour under 2 times working pressure test
Vaporized Hydrogen Peroxide Residual Concentration: ＜1ppm	Cabin Illumination: 500 lux, LED light source

Optional Accessories of Isolator



Half-Suit Integrity Tester



Glove Integrity Tester



Air Sampler



Particle Counter



H_2O_2 Concentration Sensor



RTP Integrity Tester



Buit-in Sterility Test Pump



Barcode Printer



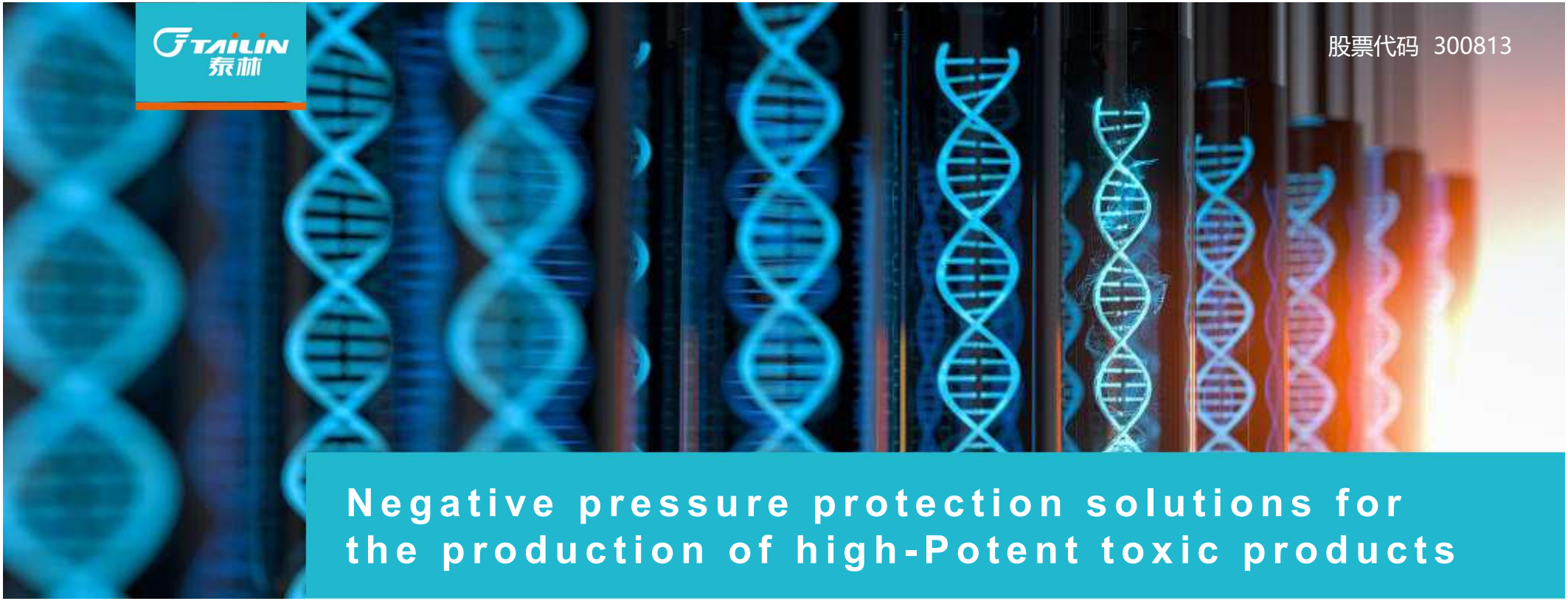
Barcode Scanner



Video Monitor

Validation & Serivices

- DQ/IQ/OQ Documents
- Samples Safety Test
- Chemical Indicators(CIs)
- Biological Indicators(BIs)
- H_2O_2 Residue Test
- SAT/FAT and Training
- Bio-decontamination Effectiveness Report
  - BIs incubation result
  - CIs indication result
  - Bio-decontamination parameters and process data
  - Layout and place points of BIs and CIs



Negative pressure protection solutions for the production of high-Potent toxic products

Zhejiang Tailin Medical Engineering Co., Ltd

Content

Content

1. Negative pressure protection solutions for the production of high-activity toxic products
2. Design Features & Advantages

1

1. Negative pressure protection solutions for the production of high-activity toxic products

Solutions for the production of high-potency solid dosage forms







Solid preparation closed isolation system operation process:

1. Start the isolator, and test the internal environment self-cleaning and sealing performance of the isolator inside;
2. The material is conveyed to the isolation chamber in a closed manner through a continuous bagging system;
3. After weighing and batching, the operator feeds the material through the isolation glove for crushing or screening (after crushing and collecting dust, the air is filtered by a high-efficiency filter and discharged into the designated treatment device) and other material pretreatment operations;
4. The pre-treated material can be conveyed under negative pressure or fed into the granulation system by the operator's glove for granulation, drying and granulation (the dry air is discharged through the HEPA filter and discharged into the designated treatment unit);
5. The granules are put into the mixing equipment by the operator through gloves for mixing, and after the mixing is completed, they are discharged to the designated closed container;
6. The mixed material is continuously bagged into a tablet pressing or capsule filling isolation chamber for tableting or capsule filling;
7. The tablets are coated by continuous bagging into a coating isolation chamber;
8. The coated tablets or capsules are passed through RTP to the isolation room of the inner packaging equipment for packaging (the dry air is filtered through a high-efficiency filter and discharged into the designated treatment unit);
9. After the end of production, the equipment and isolation room are cleaned and disinfected, and the cleaning liquid is discharged to the designated device.

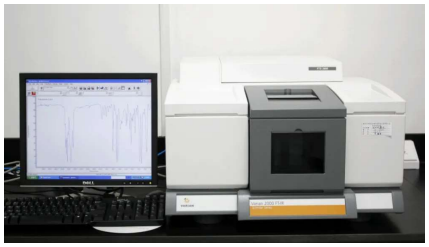
Solutions for high-activity analytical laboratories

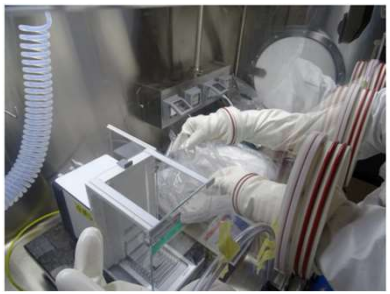








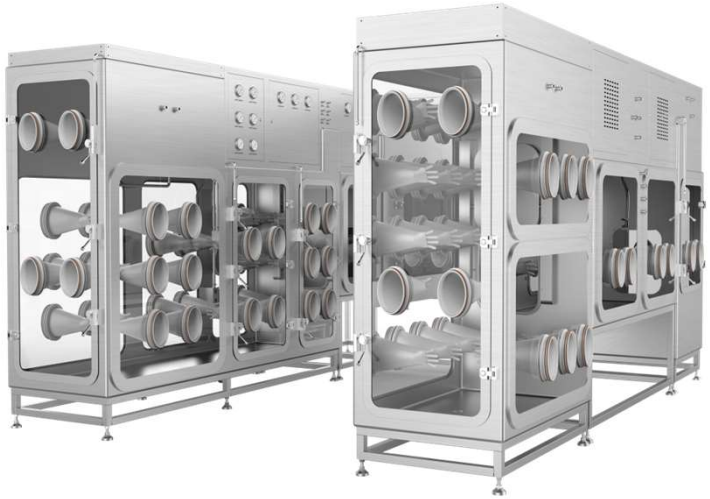




The commonly used equipment in the high-activity analysis laboratory includes: water titration, analytical balance, oven, muffle furnace, infrared analysis, tablet press, XRD diffractometer, laser particle size analyzer, etc., and the main purpose is to analyze samples.

Design features:
1. Mechanical sealing;
2. Satisfy OEB5 requirement
3. Equipped with INS-GIT
4. Equipped with 316L waste liquid container
5. Equipped with siemens touch screen and PLC
6. Equipped with Shock-proof suspension platform, for better measuring accuracy.

Small molecule synthesis workshop solutions















The commonly used equipment in the small molecule synthesis workshop includes: glass reactor, rotary steaming, magnetic stirring, ultrasonic cleaning, layer drying oven, freeze dryer, etc.

Design features:
1. Mechanical sealing;
2. Satisfy OEB5 requirement;
3. Equipped with GIT04;
4. The whole machine adopts explosion-proof design;
5. Equipped with Siemens touch screen and PLC.

Small and medium-sized pilot plant solutions













The commonly used equipment in the small and medium-sized test workshop includes: reaction crystallization kettle, drying oven, filter tank, crusher, centrifuge, three-in-one, etc

For isolators for this type of application, design features include:

1. The isolator is sealed for a long time in the case of power failure.
2. The isolator is well integrated with drying ovens, filter tanks, pulverizers and other production equipment.
3. To meet the design requirements of OEB5, third-party test reports can be provided. Leakage rate: Acceptable packing pressure -200 to 250pa benchmark, leak rate ≤0.25%Vol/h.
4. Equipped with an integrated integrity glove tester, the test data can be exported and printed.
5. The whole machine adopts explosion-proof design, equipped with imported explosion-proof fan, pressure sensor, etc.
6. Equipped with Siemens touch screen and PLC, the negative pressure state is controlled throughout the process to protect the safety of operators and the environment.

Third Party Containment Assessment

5.0 ASSESSMENT RESULTS

The assessment results are shown in the tables below.

Table 1: XRPD Sample Preparation in Hard-walled Isolator (Dec. 3, 2019)

Operator / area location	Test Run 1			Test Run 2			Test Run 3		
	Sample ID	Sampling duration (min)	Measured concentration (ng/m³)	Sample ID	Sampling duration (min)	Measured concentration (ng/m³)	Sample ID	Sampling duration (min)	Measured concentration (ng/m³)
Background sample before operation	267473	25 (13:47-14:12)	<0.995	267457	25 (15:35-16:00)	<1.00	267451	25 (17:05-17:30)	<1.00
Left passing chamber door	267436	65 (14:25-15:30)	<0.385	267437	62 (16:00-17:02)	<0.403	267489	58 (17:30-18:28)	<0.431
Between left two gloves of operating chamber	267493	65 (14:25-15:30)	<0.385	267477	62 (16:00-17:02)	<0.403	267429	58 (17:30-18:28)	<0.431
Lower edge of operating chamber	267485	65 (14:25-15:30)	<0.385	267454	62 (16:00-17:02)	<0.403	267519	58 (17:30-18:28)	<0.431
Between right two gloves of operating chamber	267503	64 (14:25-15:29)	<0.388	267507	62 (16:00-17:02)	<0.402	267481	57 (17:30-18:27)	<0.435
Right passing chamber door	267450	65 (14:25-15:30)	<0.383	267433	62 (16:00-17:02)	<0.404	267470	58 (17:30-18:28)	<0.431
Operator 1#	267501	65 (14:25-15:30)	<0.382	267517	62 (16:00-17:02)	<0.400	267494	58 (17:30-18:28)	<0.431
Operator 2#	267510	65 (14:25-15:30)	<0.384	267509	62 (16:00-17:02)	<0.403	267476	57 (17:30-18:27)	<0.433
Background sample during operation	267435	65 (14:25-15:30)	<0.384	267462	62 (16:00-17:02)	<0.401	267515	58 (17:30-18:28)	<0.431

2

1. Design Features & Advantages

In-line rinsing spray gun (corrosion resistant, acid and alkali resistant, PFA material)



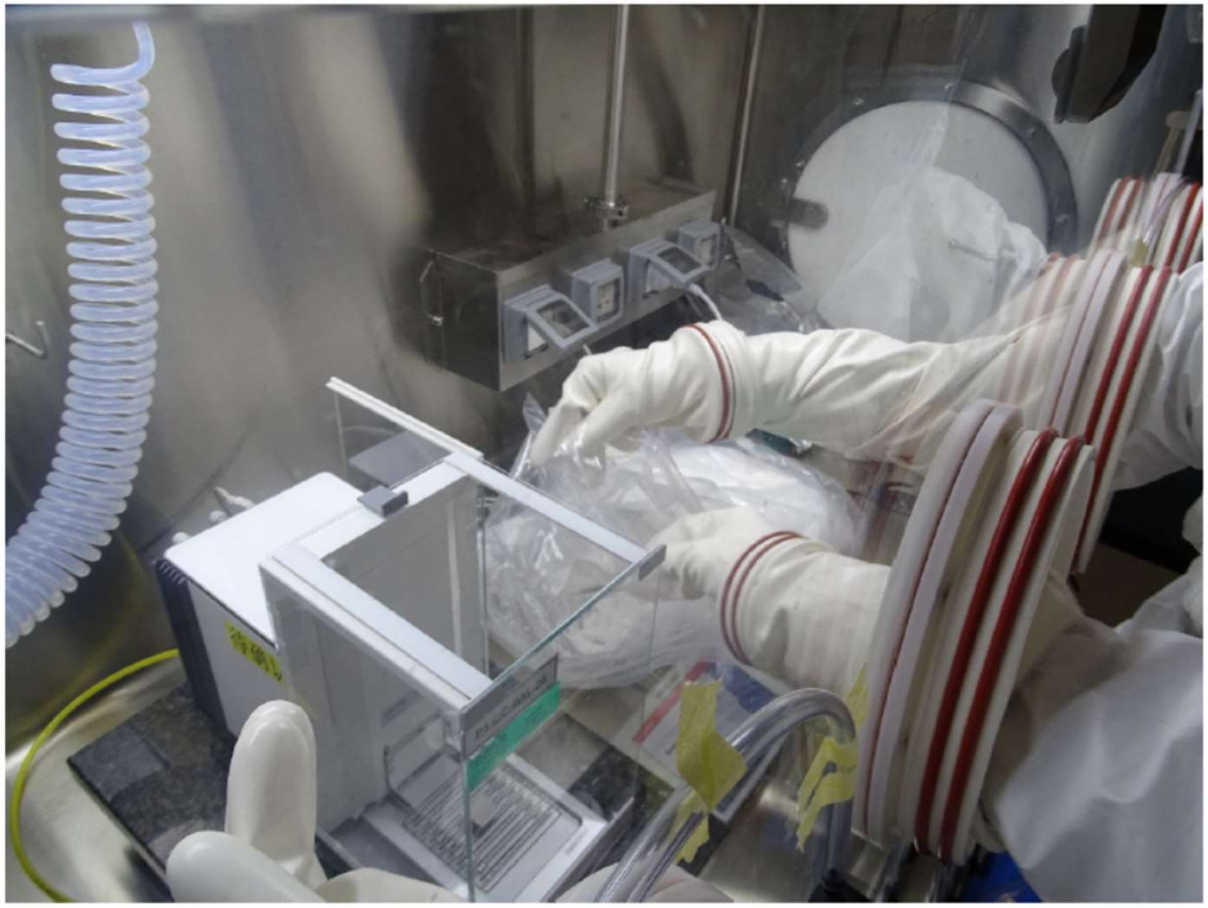


High-precision weighing shockproof suspension platform

(Suitable for high-precision weighing, 1/10,000, 1/100,000, 1/million)



Shock-proof suspension platform



PUSHPUSH HEPA filter device



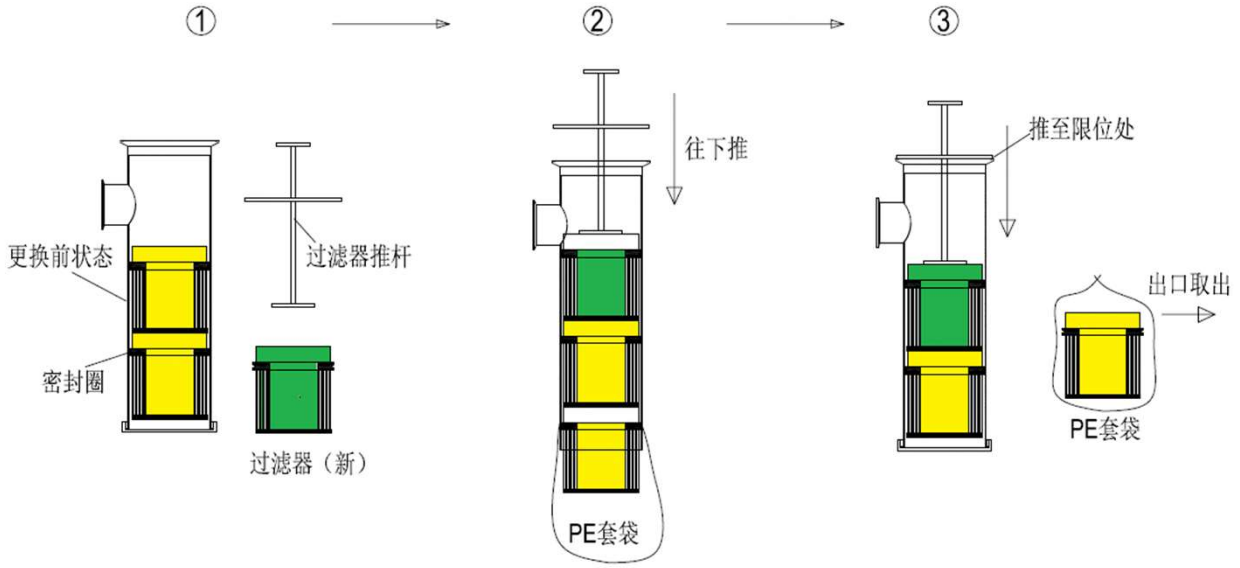
Waterproof cover



Filter changing device



Install the barrel



Safe replacement process

Gloves are safe and can be changed online



1.remove first rubber band



2. remove second rubber band



3. put on the new glove



4. put first rubber band on the new glove



1. tidy up new glove



2. remove old glove



3. remove old glove from inside



4. put on second rubber band

Continuous bagging device

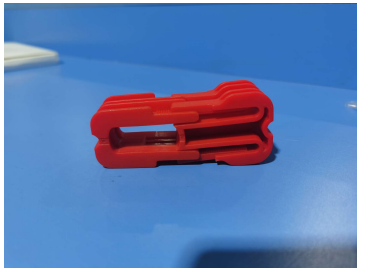
(Equipped with special tools, the material can be transferred in a closed manner)



Crimping tool



Cutting tool



Bag clips



传出-1



传出-2



传出-3



传出-4



传出-5



传出-6



传出-7



传出-8



传入-1



传入-2



传入-3



传入-4



传入-5



传入-6



传入-7



传入-8

THANKS