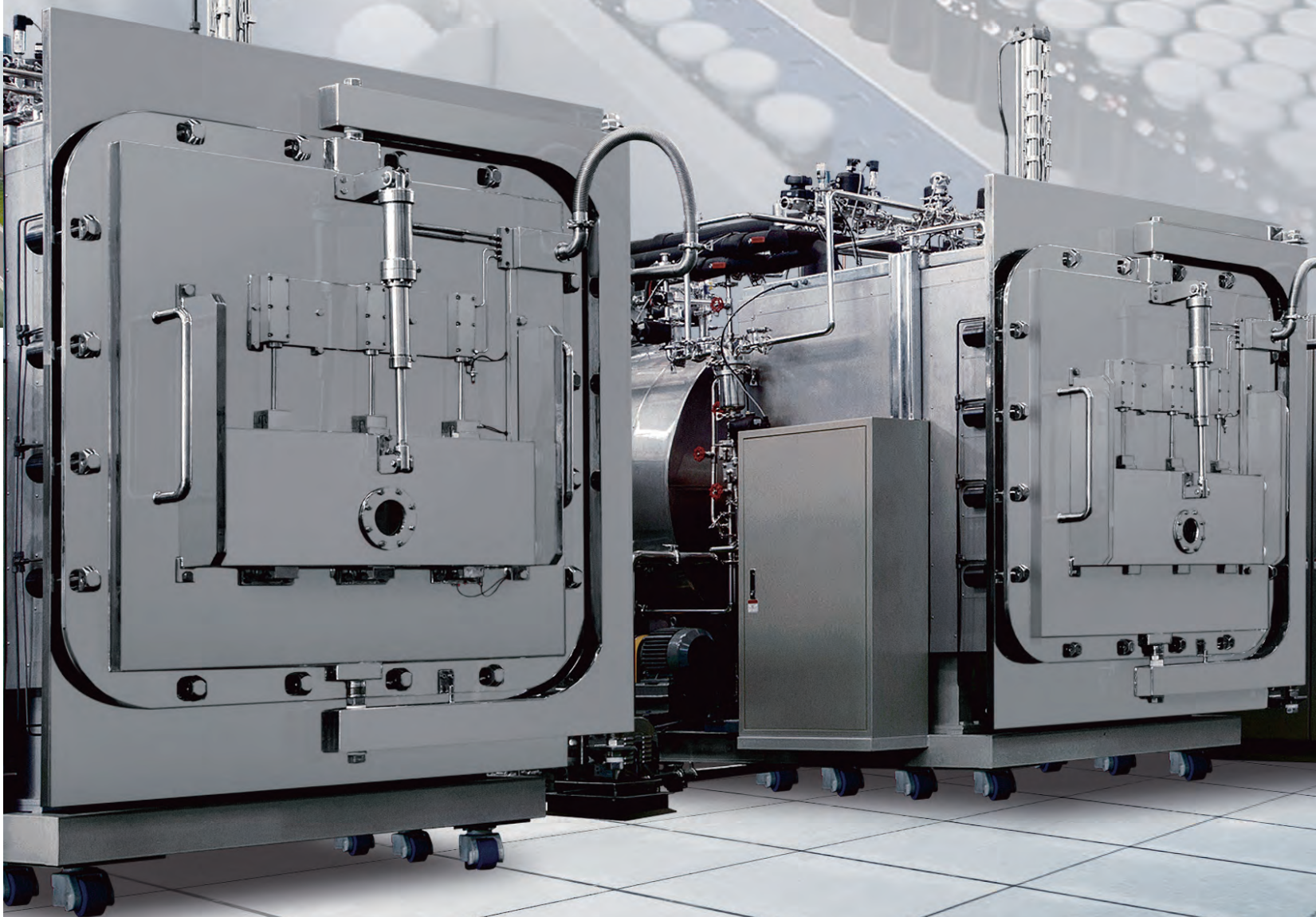


FREEZE DRYER

for PHARMACEUTICAL &
BIO SCIENCE/FOOD INDUSTRY



ilShinBioBase
Since 1988

FREEZE DRYER 50 to 300kg/Batch

for PHARMACEUTICAL

[Pharmaceutical Plant]

Industrial Scale Freeze Dryer with automatic loading/unloading system

Lyoph-Pride SCM series provide satisfaction for specific customer's needs. SCM series are designed upon various user requirements complying with vGMP and cGMP. From small scale to large scale, SCM series perform ultimate completion of freeze drying with uniformity and efficiency. Verified in-house technology of Cleaning in place and Sterilization in place guarantees perfect execution and SCADA control provides precision of standard control complying with 21 CFR11.

Being a great partner of your successful future, authentic **full-automated loading/unloading system** of ILSHIN BIOBASE shall improve your productivity.



SPECIFICATION

LP50-300 SCM SERIES

◆ Process Control

1. Lyophilization process

CIP → SIP → Loading → Freezing → Primary Freezing → Secondary Freezing

2. **Manual control:** Pre-Freeze ~1st/2nd Drying process parameter setup. Process is completed manually by user verification

3. **Automatic control:** Select recipe. Parameters of Pre-Freeze ~1st/2nd Drying process are automatically setup. Process is completed by P-rise test system inside of chamber after whole process is finished

◆ Recording parameters

Sample temperature/shelf temperature/Condenser temperature/ CIP, SIP data/Vacuum level

◆ Drying Chamber

1. **Surface roughness:** Less than 0.4 μm
2. **Cooling speed:** Within 60 minutes from 20°C to -40°C (1°C/min)
3. **Shelf temperature uniformity:** Less than $\pm 1.5^\circ\text{C}$

◆ Cold Trap Chamber; Condenser

1. **Cooling speed:** Within 30 minutes from 20°C to -70°C
2. **Defrosting System:** Hot gas solenoid method. Fast defrosting by steam and hot water

◆ Vacuum System

1. **Pull down time:** Within 45 minutes from 760Torr to 100mTorr. Lower than 20mTorr eventually
2. **Primary Vacuum Tester:** Automatic vacuum tester before starting freeze drying process
3. **Protection for Vacuum Pump:** Automatic gas ballast system for protection from condensation and oil contamination

◆ Remark

(1) SCM

SCM stands for Stoppering, CIP and SIP: premium full function series

(2) vGMP/cGMP/SCADA

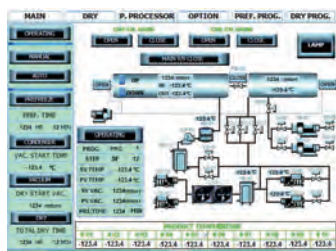
- **vGMP (Bulk Good Manufacturing Practices):** standard of process and quality control complying with pharmaceutical material production requirements
- **cGMP (Current Good Manufacturing Practice):** standard of quality control on pharmaceutical goods by the US FDA (Food and Drug Administration)
- **SCADA (Supervisory Control And Data Acquisition):** Supervisory Control And Data Acquisition

(3) CIP testing method

- Spray by Riboflavin solution (10g/L). After CIP process, no residue must be found by Ultra Violet device.

CONTROL SYSTEM

12" TFT LCD TOUCH SCREEN - PLANT SERIES



Main

Selection between Auto and Manual mode. Alarms, Lamp, Temperature set up are displayed. Entire process time, shelf temperature, cold trap temperature, vacuum level is monitored. The whole progress is visually monitored.



Progress

Current status must be monitored. Any event must be recorded and reported. Program status is displayed.



Setting

User can set up its own recipe step by step with each parameter along with duration of time. Programs can be saved so each recipe can be chosen by user anytime.

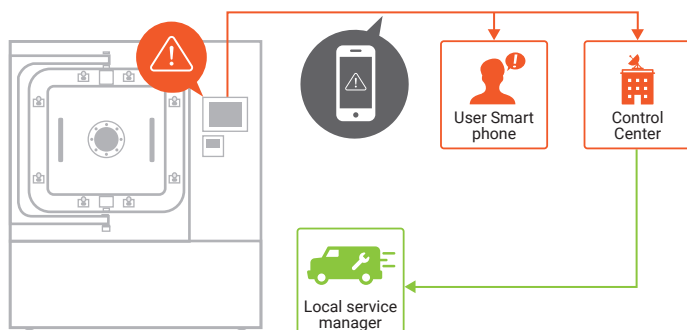


Auto loading/unloading system

Automatic shelf control is available. Both manual and automatic process can be selected for user's convenience.

BLACK BOX

GLOBAL REAL TIME CARE SERVICE



IoT remote monitoring service

Internet of things technology. 24/7 monitoring service by manufacturer's server as well as user's smart phone. Real time diagnosis and data keeping.

Proactive service

Process data can be monitored all the time by smart phone application. Any incident shall be reported to authorized manager and service action can be instructed without visiting installation site. *App. OS: Android 2.3 (Gingerbread or latter), IOS 9.2 or latter.

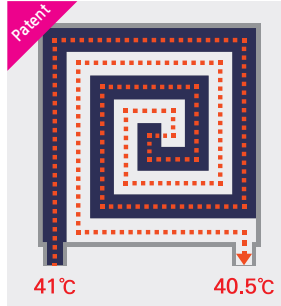
Command room data monitoring

- Temperature: Sample, shelves, condenser, refrigeration system
- Pressure: Vacuum, chamber
- Alarms: Sensor failure, condenser overheat, over current, oil circulation failure, motor overheat, heater malfunction, condenser temperature error, vacuum failure, heat media circulation problem
- General data: Process status including pre-freezing, vacuum status, 1st or 2nd drying process

*Refer to page no.16 for more details.

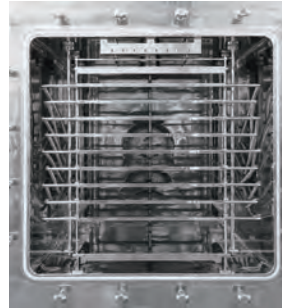
DETAIL & FEATURES

for PHARMACEUTICAL



Spiral oil path plate

Less than RA 0.4 μ m surface roughness spiral design plate shelves provide the best efficiency and uniformity of temperature by internal heat exchange. Cooling from 20°C to -40°C less than 60 minutes by degree of 1°C. Uniformity of shelf temperature convinces reliable drying quality of samples.



Stoppering system

Sealing is completed under vacuum condition (0.3mBar) automatically.

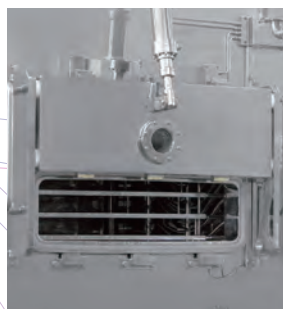
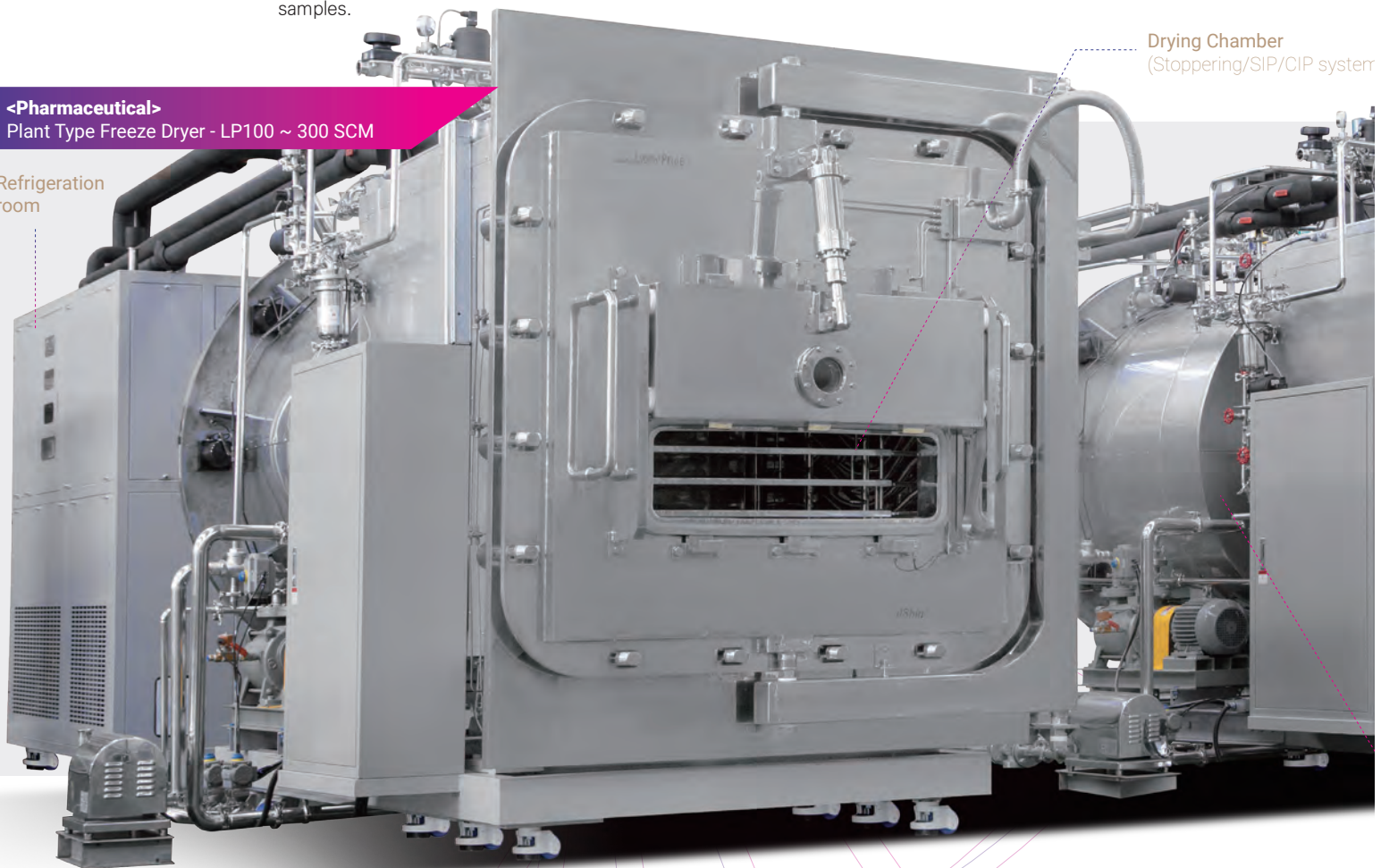
- Stoppering devices are hydraulic cylinder and bellows type (anti-contamination)
- Hydraulic pressure: 70~110kgf/cm²

<Pharmaceutical>

Plant Type Freeze Dryer - LP100 ~ 300 SCM

Refrigeration room

Drying Chamber
(Stoppering/SIP/CIP system)



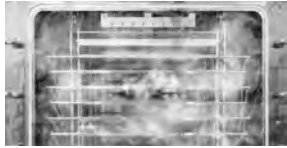
Automatic Pizza-Door System

Minimizing chance of contamination from external atmosphere during loading/unloading process as well as energy loss by automatic control of Pizza door.



Condenser Chamber

- STS316L interior
- Overlap door system for monitoring condensing process
- Low as -85°C condenser temperature
- Cooling speed is within 30 minutes from 20°C to -70°C



SIP (Sterilization In Place)

- Sterilizing temperature at 122°C with more than 20 minutes duration by steam from PSG (Pure Steam Generation)
- Air Pocket Exhaust more than 3 times
- Initial ventilation completes within 1 hour

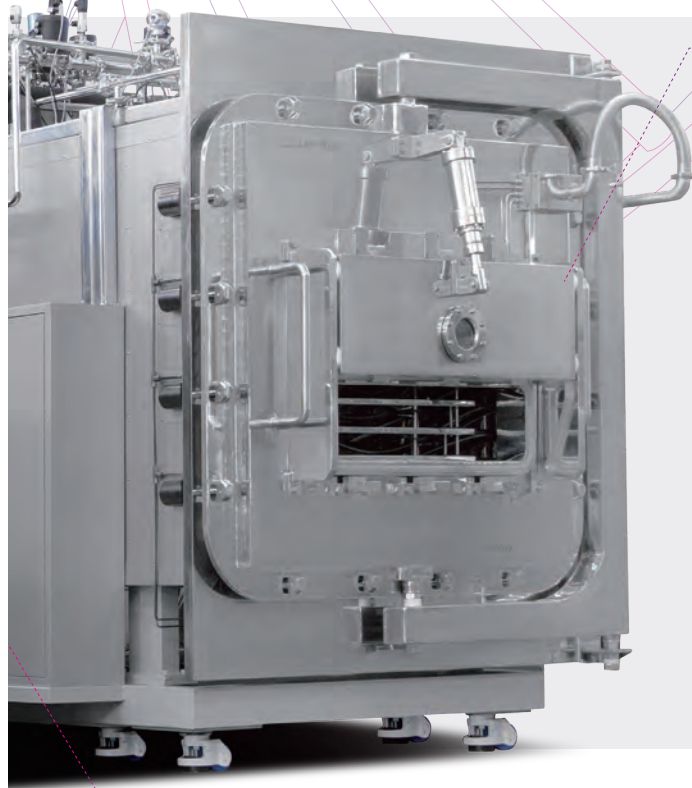


CIP (Clean In Place)

- RO water: 0.001~0.0001 μm
- Operating condition: +50 ~ +90°C, 2~5kgf/cm²
- Automatic rotating spray nozzle method by water pressure
- Spray by Riboflavin solution (10g/L). After CIP process, no residue must be found by Ultra Violet device



(stem)



Automatic Pizza-Door

Condenser Chamber (Defrost system)

<Pharmaceutical>
Plant Type Freeze Dryer - LP50 SCM



Control Panel

Recorder



Defrost system

Prompt and efficient defrosting process by combination of steam and hot water with hot gas solenoid method. Process completes within 60 minutes.



Vacuum system

- Primary Vacuum Tester is equipped for automatic testing on vacuum status before freeze drying process.
- Pull down time: within 45 minutes from 760Torr to 100mTorr. Eventually maintained lower than 20mTorr

AUTOMATIC LOADING & UNLOADING SYSTEM

for PHARMACEUTICAL



AUTOMATIC LOADING/UNLOADING SYSTEM (Row By Row)

1. Loading System

- 1) Loading Array Device
- 2) Vials Stopper Device
- 3) Vials Positioner Counter Device
- 4) Docking Device
- 5) Buffering Device

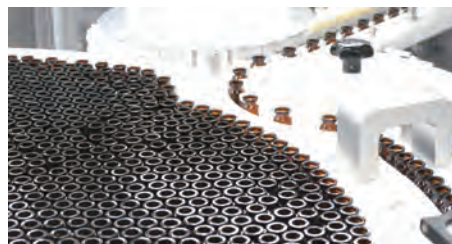
2. Loading/Unloading Device

3. Pusher Device

4. RABS/cRABS/Isolator(option)

5. Flexible liner

6. Automatic Pizza Door



1. 1) Loading Array Device

Vials are safely lined up and standby at buffer zone before and after drying process.

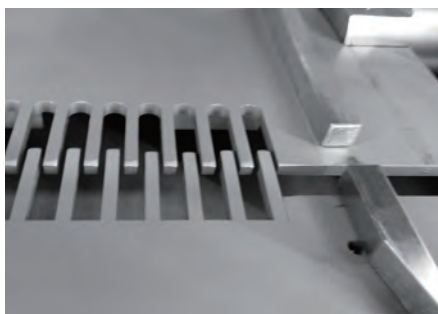
1. 2) Vials StopperDevice

Complete sealing with rubber cap is executed without chance of contamination from external atmosphere.



1. 3) Vials Positioner/Counter Device

Specially designed vial location controller and positioner with photo optical sensor. Precision control is guaranteed with 0% counter error rate.



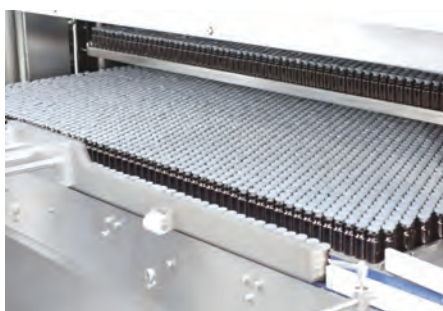
1. 4) Docking Device

Within $\pm 0.1\text{mm}$ deviation, docking device insures safe and precise transportation between shelves and conveyor belt.



1. 5) Buffering Device

Buffer device provides enough space for vials in order to maintain optimal flow of production process without chance of congestion or over filling.



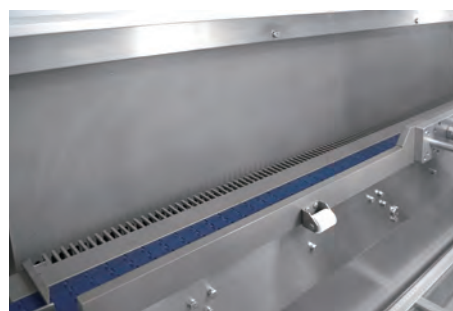
2-1. Loading Device

Loading device lines up vials from conveyor belt and delivers through bridge by cylinder.



2-2. Unloading Device

Unloading device brings vials back to conveyor belt by cylinder.



3. Pusher Device

Pusher system moves vials between shelves and conveyor belt by docking device before and after drying process without chance of error.



4. RABS/cRABS/Isolator(option)

Contamination protection system to guarantee germ/bacteria free production.



5. Flexible liner

Flexible liner provides flexibility on vial transportation: from 2ml to 100ml.



6. Automatic Pizza Door

Automatic pizza door minimizes the exposure to external atmosphere during loading/unloading. Less chance of contamination and less energy consumption.

Row By Row Method

Comparing to AGV method, row by row type requires less space. Convenient maintenance and economical management bring more bene-fit to customers.



FREEZE DRYER 50 to 500kg/Batch

for BIO SCIENCE/FOOD INDUSTRY

[Bio/Food Industry] Plant Type Lyophilizer

Industrial scale freeze dryer for Bio/Food application. Equipped with high quality stainless interior/exterior, automatic process program with various recipes, powerful refrigeration system and low energy consumption, Bio/Food plant type lyophilizer is optimal solution for your application on probiotics, extract mixture, functional food and long term storage adaptation.



SPECIFICATION

LP50-500 SERIES

◆ Process Control

1. Lyophilization process

Loading → Freezing → Primary Freezing → Secondary Freezing

2. **Manual control:** Pre-Freeze ~1st/2nd Drying process parameter setup. Process is completed manually by user verification

3. **Automatic control:** Select recipe. Parameters of Pre-Freeze ~1st/2nd Drying process are automatically setup. Process is completed by P-rise test system inside of chamber after whole process is finished

◆ Recording parameters

Sample temperature/shelf temperature/Condenser temperature/
CIP, SIP data/ Vacuum level

◆ Drying Chamber

1. **Surface roughness:** Less than 0.4 μm
2. **Cooling speed:** Within 60 minutes from 20°C to -40°C (1°C/min)
3. **Shelf temperature uniformity:** less than $\pm 1.5^\circ\text{C}$

◆ Cold Trap Chamber: Condenser

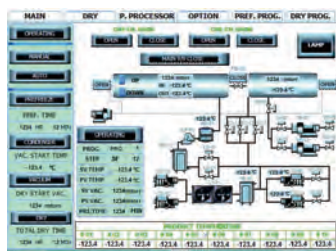
1. **Cooling speed:** Within 30 minutes from 20°C to -70°C
2. **Defrosting System**
Hot gas solenoid method. Fast defrosting by steam and hot water

◆ Vacuum System

1. **Pull down time:** Within 45 minutes from 760Torr to 100mTorr.
Lower than 20mTorr eventually
2. **Primary Vacuum Tester**
Automatic vacuum tester before starting freeze drying process
3. **Protection for Vacuum Pump**
Automatic gas ballast system for protection from condensation and oil contamination

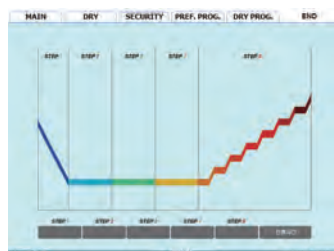
CONTROL SYSTEM

10 to 12" TFT LCD TOUCH SCREEN - PLANT SERIES



Main

Selection between Auto and Manual mode. Alarms, Lamp, Temperature set up are displayed. Entire process time, shelf temperature, cold trap temperature, vacuum level is monitored. The whole progress is visually monitored.



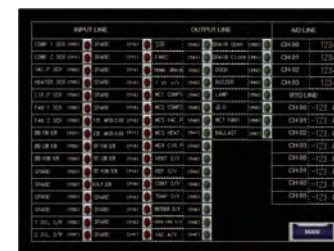
Progress

Current status must be monitored. Any event must be recorded and reported. Program status is displayed.



Setting

User can set up its own recipe step by step with each parameter along with duration of time. Programs can be saved so each recipe can be chosen by user anytime.



IO Test

Each compartment of equipment is tested by sending electric signal for monitoring the pro-cess and functionality.

BLACK BOX

GLOBAL REAL TIME CARE SERVICE



IoT remote monitoring service

Internet of things technology. 24/7 monitoring service by manufacturer's server as well as user's smart phone. Real time diagnosis and data keeping.

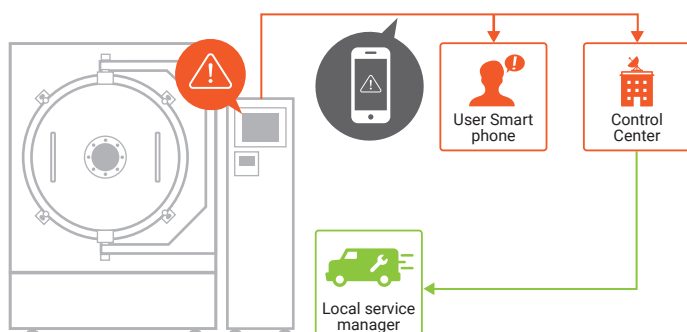
Proactive service

Process data can be monitored all the time by smart phone application. Any incident shall be reported to authorized manager and service action can be instructed without visiting installation site. *App. OS: Android 2.3 (Gingerbread or latter), IOS 9.2 or latter.

Command room data monitoring

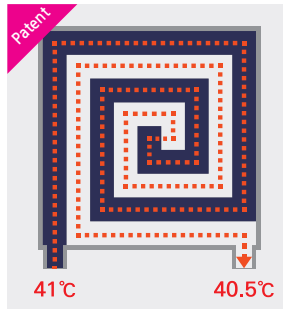
- Temperature: Sample, shelves, condenser, refrigeration system
- Pressure: Vacuum, chamber
- Alarms: Sensor failure, condenser overheat, over current, oil circulation failure, motor overheat, heater malfunction, condenser temperature error, vacuum failure, heat media circulation problem
- General data: Process status including pre-freezing, vacuum status, 1st or 2nd drying process

*Refer to page no.16 for more details.



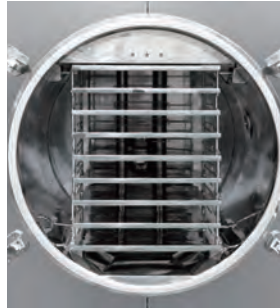
DETAIL & FEATURES

for BIO SCIENCE/FOOD INDUSTRY



Spiral oil path plate

Less than RA 0.4 μ m surface roughness spiral design plate shelves provide the best efficiency and uniformity of temperature by internal heat exchange. Cooling from 20°C to -40°C less than 60 minutes by degree of 1°C. Uniformity of shelf temperature convinces reliable drying quality of samples.



Drying Chamber

- STS304
- Vessel pressure standard: qualified chamber under vacuum gauge pressure lower than 5×10^{-3} Torr
- Illuminator is installed for visual inspection of inside of chamber



<Bio/Food Industry>
Plant Type Freeze Dryer - LP50

Control Panel
(10" TFT Touch Screen)

Recorder

Drying Chamber
(CIP system)

Automatic Door Lock

Refrigeration room



Automatic Door Lock

Complete sealing and vacuum protection are guaranteed by hydraulic power one touch door lock system.



Condenser Chamber

- STS316L interior
- Overlap door system for monitoring condensing process
- Low as -85°C condenser temperature
- Cooling speed is within 30 minutes from 20°C to -70°C

Optional

SIP(Sterilization In Place)

- Sterilizing temperature at 122°C with more than 20 minutes duration by steam from PSG (Pure Steam Generation)
- Air Pocket Exhaust more than 3 times
- Initial ventilation completes within 1 hour



Optional

CIP(Clean In Place)

- RO water: 0.001~0.0001 μ m
- Operating condition: +50 ~ +90°C, 2~5kgf/cm²
- Automatic rotating spray nozzle method by water pressure
- Spray by Riboflavin solution (10g/L). After CIP process, no residue must be found by Ultra Violet device



<Bio/Food Industry>
Plant Type Freeze Dryer - LP100 ~ 500

Condenser Chamber (Defrost system)

Refrigeration room

Defrost system

Prompt and efficient defrosting process by combination of steam and hot water with hot gas solenoid method. Process completes within 60 minutes.



Vacuum system

- Primary Vacuum Tester is equipped for automatic testing on vacuum status before freeze drying process.
- Pull down time: within 45 minutes from 760Torr to 100mTorr. Eventually maintained lower than 20mTorr



SPECIFICATIONS

for PHARMACEUTICAL & BIO SCIENCE/FOOD INDUSTRY

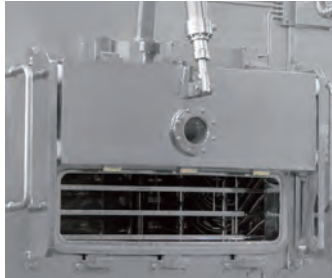
Pharmaceutical Industry		LP50	LP100	LP200	LP300	LP500
Totally ice capacity		50 liters	100 liters	200 liters	300 liters	500 liters
Vial quantity (10ml기준)		6,700 ea	13,300 ea	27,300 ea	41,000 ea	69,500 ea
Condenser temperature		Below -85℃				
Shelf temperature		-45(-55℃) to +80℃				
Shelf areas		3.2m ² (0.4m ² /EA)	6.4m ² (0.8m ² /EA)	13.2m ² (1.2m ² /EA)	19.8m ² (1.8m ² /EA)	33.6m ² (2.5m ² /EA)
Shelf quantity		8 + 1		11 + 1		14 + 1
Material		STS 304 / 316 (Chamber/Shelf) / Calibration service				
Shelf. Dimensions (WxDxH mm)		500 x 800 x 20	805 x 1005 x 20	1005 x 1205 x 25	1210 x 1510 x 25	1510 x 1650 x 25
Ext. Dimensions (WxDxH mm)		1450 x 2003 x 2140	1600 x 2415 x 2210	2970 x 2855 x 2160	3500 x 3390 x 2375	3516 x 4616 x 2347
Electrical		380/400/440/480V 3Ph 50/60Hz				
Refrigeration system		7.5HP x 2EA	10HP x 2EA	30HP x 2EA	40HP x 2EA	30HP x 4EA
Vacuum Vol. (LPM)		841	1,600	4,000	6,680	14,000
Black box		Optional	Optional	○	○	○
Options	(1)	Pizza door		(11)	Monitoring system	
	(2)	Stoppering system		(12)	Validation support	
	(3)	CIP system		(13)	Safe Guard system	
	(4)	SIP system		(14)	Calibration service	
	(5)	Loading/Unloading System		(15)	CIP return system and Injection of detergent	
	(6)	Dual-safety system		(16)	CIP Tank	
	(7)	Isolation system		(17)	Tray (For vial)	
	(8)	Particle Separation System-PS		(18)	Tray (For bulk)	
	(9)	Tray cart-TR				
	(10)	Tray hook for lyophilizer (LP200 ~ 500)				

Bio/Food Industry		LP50	LP100	LP200	LP300	LP500
Totally ice capacity		50 liters	100 liters	200 liters	300 liters	500 liters
Condenser temperature		Below -85℃				
Shelf temperature		-45 to +80℃				
Shelf areas		3.2m ² (0.4m ² /EA)	6.4m ² (0.8m ² /EA)	13.2m ² (1.2m ² /EA)	19.8m ² (1.8m ² /EA)	33.6m ² (2.5m ² /EA)
Shelf quantity		8 + 1		11 + 1		14 + 1
Shelf. Dimensions (WxDxH mm)		500 x 800 x 20	805 x 1005 x 20	1005 x 1205 x 25	1210 x 1510 x 25	1510 x 1650 x 25
Ext. Dimensions (WxDxH mm)		1450 x 2003 x 2140	1600 x 2415 x 2210	2970 x 2855 x 2160	3500 x 3390 x 2375	3516 x 4616 x 2347
Electrical		380/400/440/480V 3Ph 50/60Hz				
Refrigeration system		7.5HP x 2EA	10HP x 2EA	30HP x 2EA	40HP x 2EA	30HP x 4EA
Vacuum Vol. (LPM)		841	1,600	4,000	6,680	14,000
Black box		Optional	Optional	○	○	○

*Feature in parenthesis is optional and selectable by customer.

OPTIONAL DESCRIPTION

GLOBAL REAL TIME CARE SERVICE



Option (1)

Automatic Pizza-Door System

Automatic pizza door minimizes the exposure to external atmosphere during loading/unloading. Less chance of contamination and less energy consumption.



Option (2)

Stoppering system

Sealing is completed under vacuum condition (0.3mBar) automatically.

- Stoppering devices are hydraulic cylinder and bellows type (anti-contamination)
- Hydraulic pressure: 70~110kgf/cm²



Option (3)

CIP (Clean In Place)

- RO water: 0.001~0.0001μm
- Operating condition: +50~+90℃, 2~5kgf/cm²
- Automatic rotating spray nozzle method by water pressure
- Spray by Riboflavin solution (10g/L). After CIP process, no residue must be found by Ultra Violet device
- Providing a Chamber Drying after finished CIP process

Option (4)

SIP (Sterilization In Place)

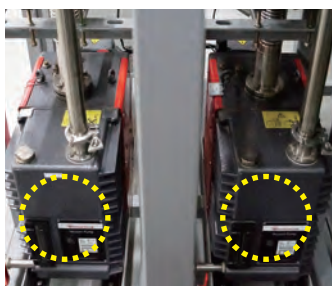
- Sterilizing temperature at 122℃ with more than 20 minutes duration by steam from PSG (Pure Steam Generation)
- Air Pocket Exhaust more than 3 times
- Initial ventilation completes within 1 hour



Option (5)

Loading/Unloading system

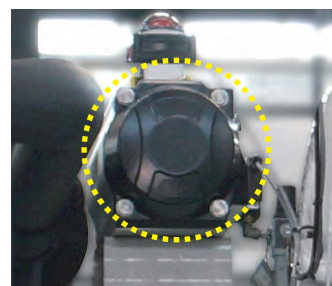
1. Loading Integration System
2. Loading System
 - 1) Loading Array System
 - 2) Vials Stopper System
 - 3) Vials Position Half-shift System
 - 4) Flexible Bridge System
 - 5) Transition System
3. Unloading System
4. Unloading Integration System
5. RABS/cRABS/Isolator(option)



Option (6)

Dual-safety system

Dual safety system protects your production from any chance of failure with independent pre-freezing and refrigeration system. It brings best efficiency during production process and easy maintenance for long term use.



Option (7)

Isolation system

Butter fly or Mushroom type isolation protects system from any chance of cross over contamination by black out during process or condenser malfunction.



Option (8)

PS System- AAPS0001

PS filtration system prolongs lifetime and stability of vacuum pump by preventing pump from accumulation of oil sludge.



Option (9) ◀

Tray Cart-AATR0006

Using for Loading, moving bulk tray.

Option (10) ▼

Tray hook for lyophilizer

- AAPVG50100 / AAPVG200500

Using for unload bulk tray.





Option (11) Monitoring system

Internet of things technology. 24/7 monitoring service by manufacturer's server as well as user's smart phone. Real time diagnosis and data keeping are available.

*Refer to page no.16 for more details.



Option (12) Validation support

Lyophilization requires precise control and management especially for sensitive samples. Based upon accumulated experience and GMP standard, ILSHIN BIOBASE shall bring successful solution with verified validation complying with user specification.

LP MASTER – LYOPH-PRIDE Software



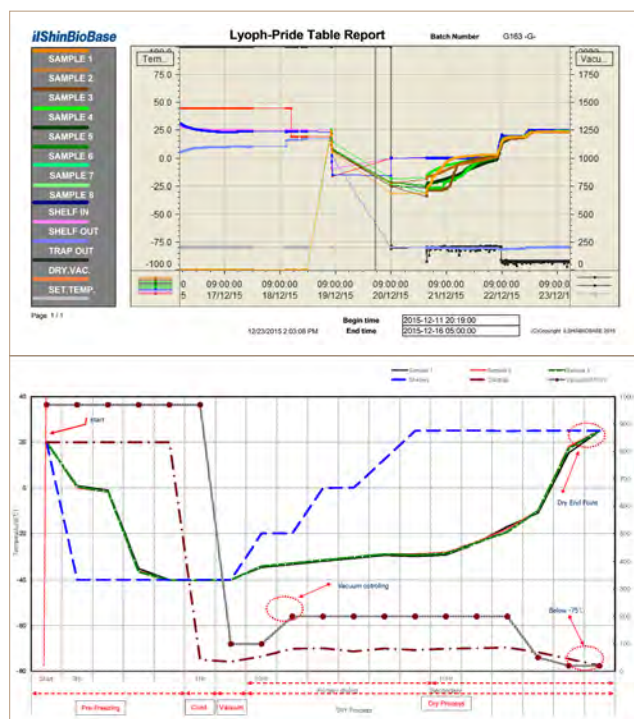
Why LP MASTER

Stability and credibility are first priority for biological and pharmaceutical application of freeze drying. Therefore precise and reliable control and monitoring are very critical for successful freeze drying process and such precise monitoring software must be required.

Our authentic monitoring/control software is designed to comply with FDA guideline with flexibility to meet various changes. It also gives abundant libraries to meet satisfactory compliance for user's various requirements.

Software Library

- **Process monitoring**
Comprehensive data supply through entire drying process allows you to have optimal condition and best recipe.
- **Recipe management**
Automatic operation is available by selection of saved recipe that can be expanded further.
- **Audit Trail:** All data from system is traced and monitored.
- **User Access**
Only authorized user can manage operation, control and monitoring by security library access.
- **SCADA System**
Choice of data management and record nagement period are available.
- **Vacuum Integrity Test Library**
Test on vacuum of chamber before drying process.
- **Trend:** Graphic data management of accumulated real time data (drying / SIP / CIP – Conductive)
- **21 CFR Part 11 compliance.**



BLACK BOX

GLOBAL REAL TIME CARE SERVICE



◆ CONTROL CENTER

With IoT (Internet of things) technology, our control center can provide remote monitoring through WAN connection at real time basis. System event is to be notified to each user's mobile phone.

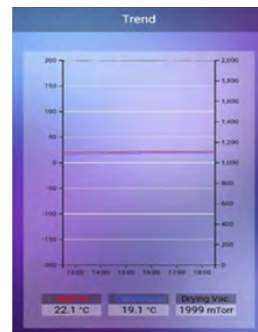
Blackbox is the ultimate tool to help user's management on machine with integrated ICT (Information and Communications Technologies) for prompt diagnosis.

Main Content of **MOBILE APPLICATION**



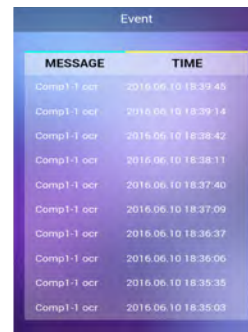
◆ Main window

General view on operation status. Current process is indicated. Process data is displayed at real time.



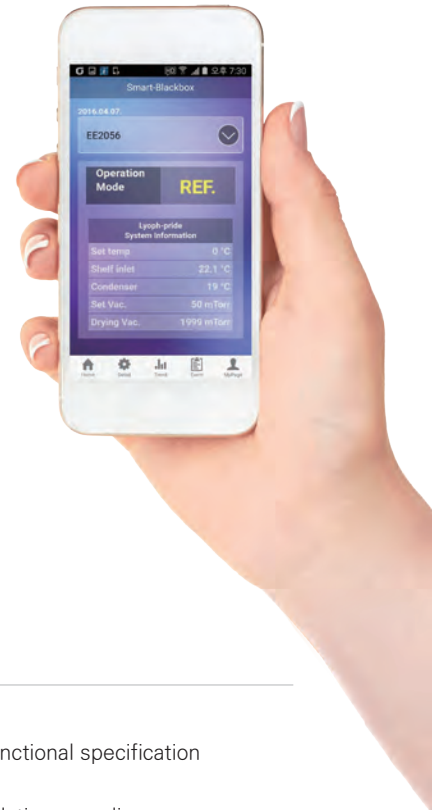
◆ Trend window

Variation of drying process is displayed. 24 hours previous trend can be reviewed.



◆ Event window

Real time event is displayed for observation on any malfunction.



QUALIFICATION & VALIDATION SUPPORTING

◆ Design verification

- Verification/documentation service for system design compliance with user's requirement
- Master plan support service for project
- User's requirement specification support service
- Specification and design development service
- Risk analysis service
- Evaluation protocol support for design compliance

◆ Operation verification

- Verification service for each operational condition and category
- * Evaluation protocol/execution support for operation compliance (Empty, Full-load, cooling, uniformity, etc)
- * Worst Case simulation service
- * CAPA (Corrective action & Preventive action) support

◆ Installation verification

- Installation verification for design/functional specification
- * SOP development support
- * Evaluation protocol support for installation compliance
- * Calibration support service
- Maintenance/training support service

◆ Software system verification

- Software system verification for design/functional specification
- Master plan support service
- Protocol development for design/installation/operation compliance
- Verification & validation on execution for design/installation/operation compliance
- Program risk analysis support service

ilShinBioBase
Since 1988



Product Inquiry

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수원지사	경기도 화성시 봉담읍 갈담초교길 113	031-298-8147	031-298-8149
대전지사	대전시 유성구 학하북로 25	042-824-1145/6	042-824-1147
영남지사	대구광역시 동구 동호로 75, 4F	070-4354-3977/5000	070-7950-3941
호남지사	전라북도 전주시 덕진구 안전로 108-4(중동)	063-237-5122	063-237-5123

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