

# FREEZE DRYER

for PHARMACEUTICAL

50 to 300kg/Batch



## [ 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 bGMP 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.

ILSHIN BIOBASE is proud to announce its commercial installation of **Automatic Loading/Unloading system, first among Korean manufacturers.** Integrated system supply shall enhance efficiency and productivity of your plant production.

## 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 ±1.5°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 Stopping, CIP and SIP: premium full function series

##### (2) bGMP/cGMP/SCADA

- **bGMP (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)

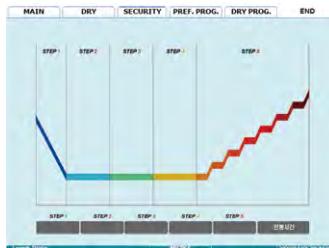
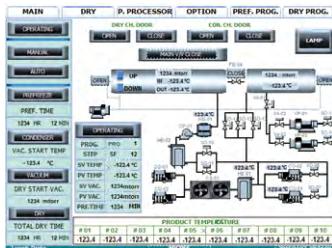
- **SCADA (Supervisory Control And Data Acquisition):** Supervisory Control And Data Acquisition

##### (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										DRY										PREF. PROG.										< >				
SECURITY					PREF. PROG.					DRY PROG.					END																			
PROG. 1	STEP 1	STEP 2	STEP 3	STEP 4	STEP 5	STEP 6	STEP 7	STEP 8	STEP 9	STEP 10	STEP 11	STEP 12	STEP 13	STEP 14	STEP 15	STEP 16	STEP 17	STEP 18	STEP 19	STEP 20	STEP 21	STEP 22	STEP 23	STEP 24	STEP 25	STEP 26	STEP 27	STEP 28	STEP 29	STEP 30	PASS	MANUAL		
TEMP. (C)	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	RST		
VAC. (mbar)	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234
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PROG. 2	Step 1	Step 2	Step 3	Step 4	Step 5	Step 6	Step 7	Step 8	Step 9	Step 10	Step 11	Step 12	Step 13	Step 14	Step 15	Step 16	Step 17	Step 18	Step 19	Step 20	Step 21	Step 22	Step 23	Step 24	Step 25	Step 26	Step 27	Step 28	Step 29	Step 30	STOP	STOP		
TEMP. (C)	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	RST	
VAC. (mbar)	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234
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PROG. 3	Step 1	Step 2	Step 3	Step 4	Step 5	Step 6	Step 7	Step 8	Step 9	Step 10	Step 11	Step 12	Step 13	Step 14	Step 15	Step 16	Step 17	Step 18	Step 19	Step 20	Step 21	Step 22	Step 23	Step 24	Step 25	Step 26	Step 27	Step 28	Step 29	Step 30	STOP	STOP		
TEMP. (C)	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	RST
VAC. (mbar)	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234
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PROG. 4	Step 1	Step 2	Step 3	Step 4	Step 5	Step 6	Step 7	Step 8	Step 9	Step 10	Step 11	Step 12	Step 13	Step 14	Step 15	Step 16	Step 17	Step 18	Step 19	Step 20	Step 21	Step 22	Step 23	Step 24	Step 25	Step 26	Step 27	Step 28	Step 29	Step 30	STOP	STOP		
TEMP. (C)	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	-12.3	RST
VAC. (mbar)	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234	1234
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## 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

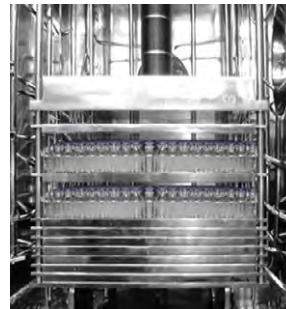
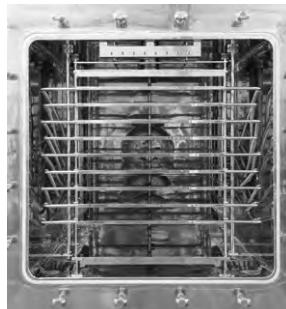
# DETAIL & FEATURES

for PHARMACEUTICAL



## Spiral oil path plate

Less than RA  $0.4\mu\text{m}$  surface roughness spiral design plate shelves provide the best efficiency and uniformity of temperature by internal heat exchange. Cooling from 20°C to  $\sim 40^\circ\text{C}$  less than 60 minutes by degree of 1°C. Uniformity of shelf temperature convinces reliable drying quality of samples.



## Stoppering system

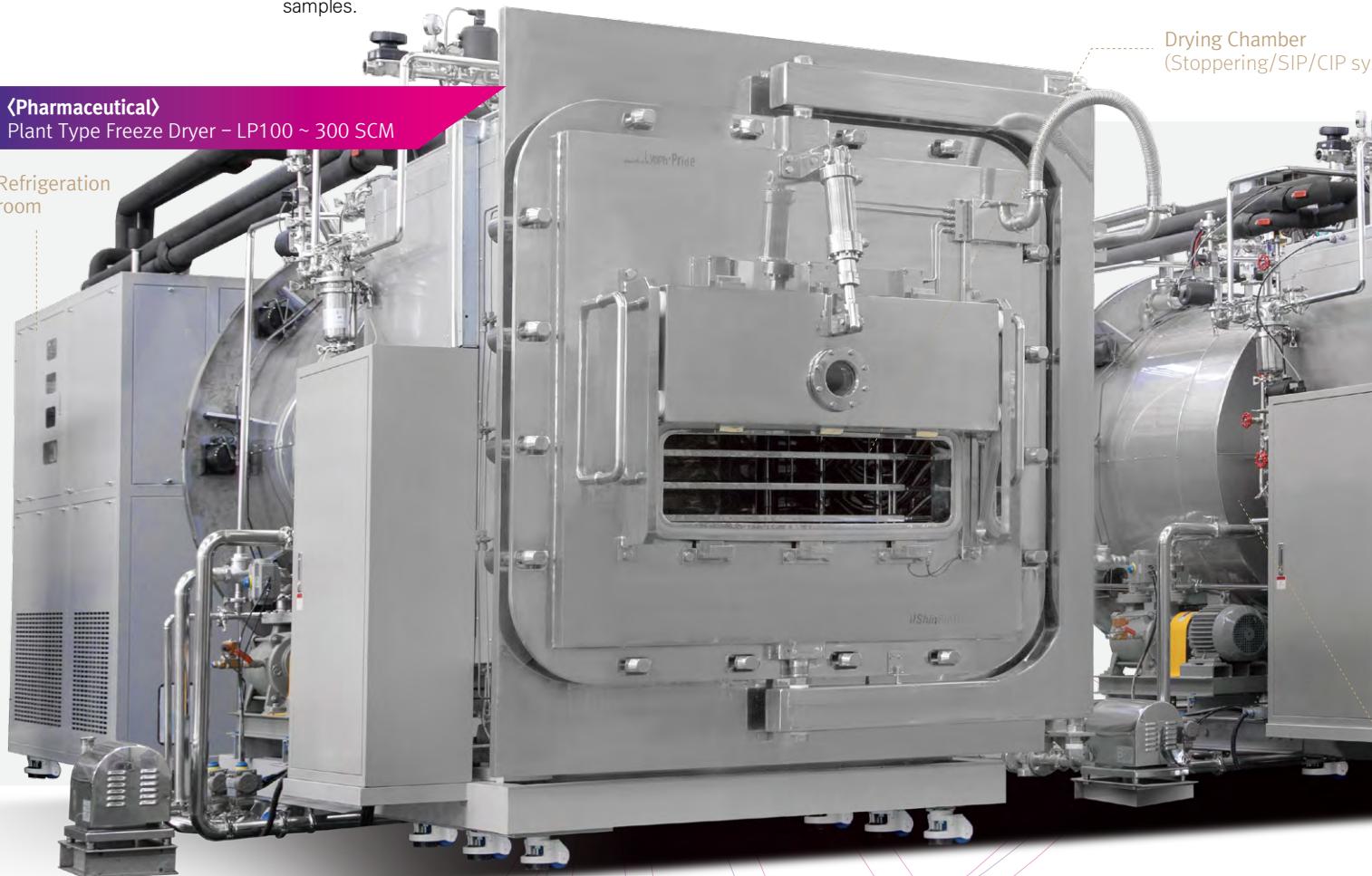
Sealing is completed under vacuum condition (0.3mBar) automatically.

- Stoppering devices are hydraulic cylinder and bellows type (anti-contamination)
- Hydraulic pressure: 70~110kgf/cm<sup>2</sup>

Drying Chamber  
(Stoppering/SIP/CIP sys)

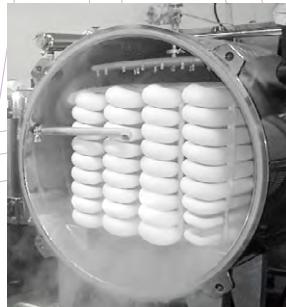
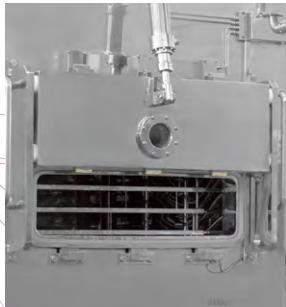
**〈Pharmaceutical〉**  
Plant Type Freeze Dryer – LP100 ~ 300 SCM

Refrigeration room



## 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.



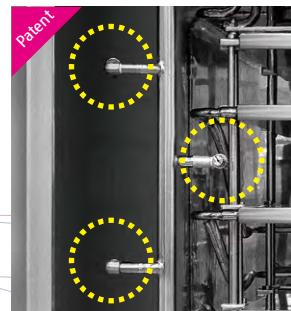
## Condenser Chamber

- STS316L interior
- Overlap door system for monitoring condensing process
- Low as  $-85^\circ\text{C}$  condenser temperature
- Cooling speed is within 30 minutes from 20°C to  $-70^\circ\text{C}$



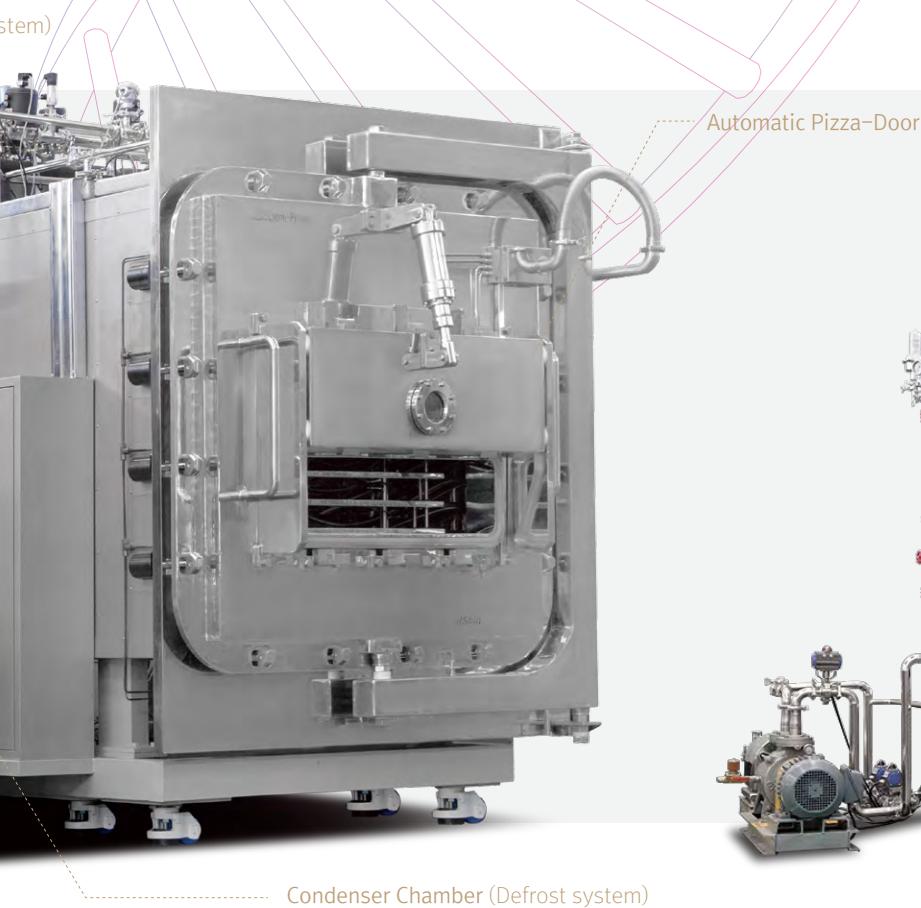
#### SIP(Sterilization In Place)

- 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: 0.001~0.0001μm
- Operating condition: +50 ~ +90°C, 2~5kgf/cm<sup>2</sup>
- 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



**《Pharmaceutical》**  
Plant Type Freeze Dryer – LP50 SCM



#### 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.

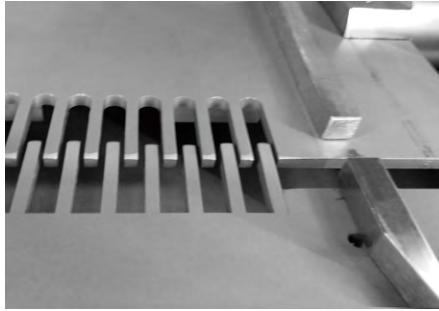
#### 1. 2) Vials StopperDevice

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.



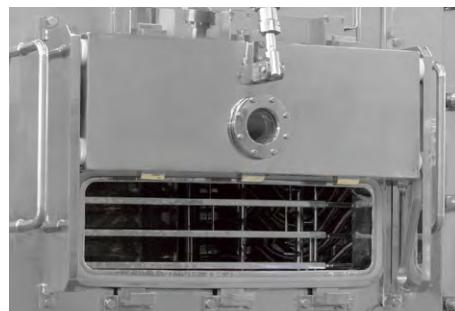
### 4. RABS/cRABS/Isolator(option)

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 benefit 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 ±1.5°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

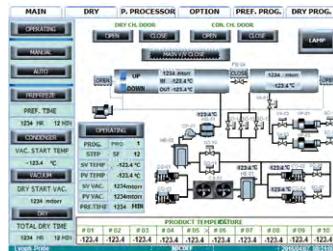
Automatic vacuum tester before starting freeze drying process

#### 3. Protection for Vacuum Pump

Automatic gas ballast system for protection from condensation and oil contamination

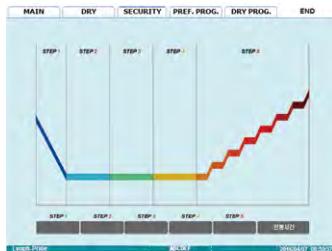
# CONTROL SYSTEM

10 to 12" TFT LCD TOUCH SCREEN - PLANT SERIES



## Main

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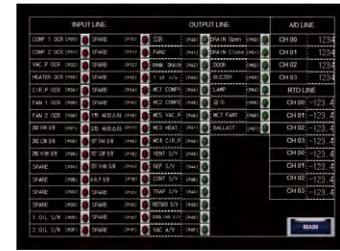
## Progress

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## Setting

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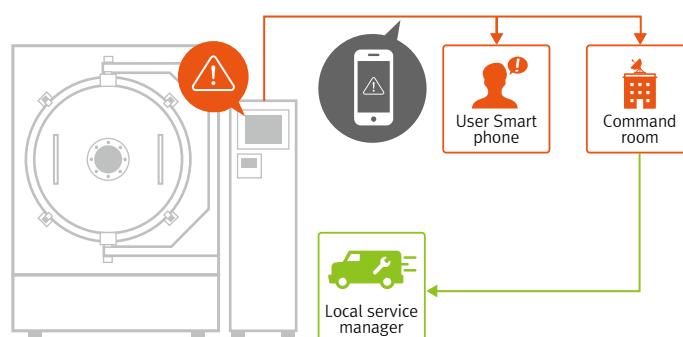


## IO Test

Each compartment of equipment is tested by sending electric signal for monitoring the process 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

# DETAIL & FEATURES

for BIO MATERIAL/FOOD INDUSTRY



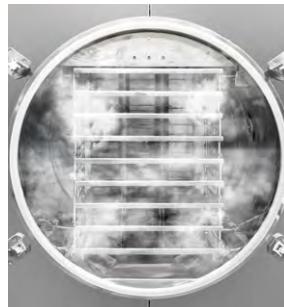
## Spiral oil path plate

Less than RA 0.4 $\mu$ 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 5x10<sup>-3</sup> 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

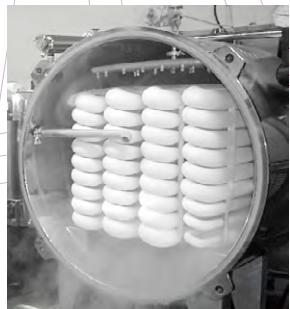
Refrigeration room

## 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

## Automatic Door Lock

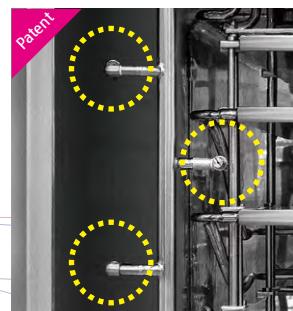
Complete sealing and vacuum protection are guaranteed by hydraulic power one touch door lock system.





#### 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



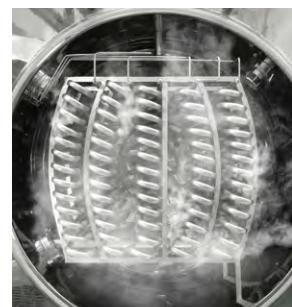
#### CIP(Clean In Place)

- RO water: 0.001~0.0001μm
- Operating condition: +50 ~ +90°C, 2~5kgf/cm<sup>2</sup>
- 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



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

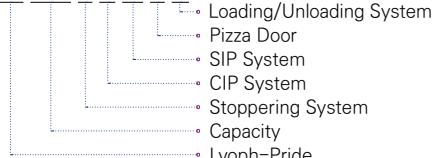
# SPECIFICATIONS

for PHARMACEUTICAL MATERIAL

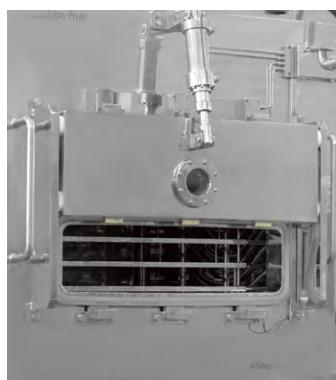
Pharmaceutical Industry	LP50	LP100	LP200	LP300	LP500
Totally ice capacity	50 liters	100 liters	200 liters	300 liters	500 liters
Vial quantity (10ml기준)	6,700 ea	13,300 ea	27,300 ea	41,000 ea	69,500 ea
Condenser temperature			Below -85°C		
Shelf temperature			-45(-55°C) to +80°C		
Shelf areas	3.2m <sup>2</sup> (0.4m <sup>2</sup> /EA)	6.4m <sup>2</sup> (0.8m <sup>2</sup> /EA)	13.2m <sup>2</sup> (1.2m <sup>2</sup> /EA)	19.8m <sup>2</sup> (1.8m <sup>2</sup> /EA)	33.6m <sup>2</sup> (2.5m <sup>2</sup> /EA)
Shelf quantity	8 + 1			11 + 1	14 + 1
Material		STS 316 (Chamber/Shelf) / Calibration service			
Shelf. Dimensions (WxDxH mm)	500 x 800 x 18	805 x 1005 x 18	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
Options	(1) Pizza door with automatic loading/unloading system (2) Stoppering system (3) CIP system (4) SIP system (5) Loading/Unloading System (6) Dual-safety system (7) Isolation system (8) Monitoring system (9) Validation support				

\*Feature in parenthesis is optional and selectable by customer.

\*Model name index: LP 200 S C M P U



## OPTIONAL DISCRIPTION



*Option (1)*  
**Automatic Pizza-Door System**

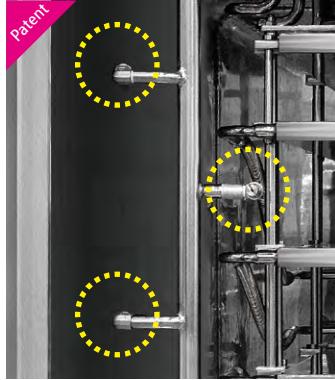
Automatic pizza door minimizes the exposure to external atmosphere during loading/unloading. Less chance of contamination and less energy consumption.



*Option (2)*  
**Stoppering system**

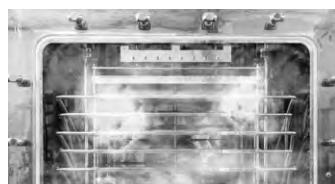
Sealing is completed under vacuum condition (0.3mBar) automatically.

- Stoppering devices are hydraulic cylinder and bellows type (anti-contamination)
- Hydraulic pressure: 70~110kgf/cm<sup>2</sup>



**Option (4)  
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



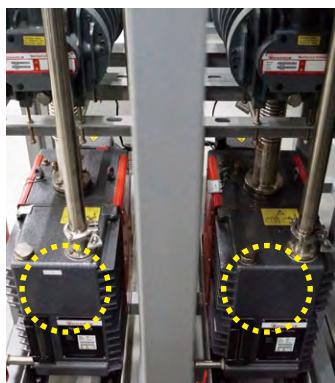
**Option (3)  
CIP(Clean In Place)**

- 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



**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**

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



**Option (8)  
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.



**Option (9)  
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.

# SPECIFICATIONS

for BIO SCIENCE/FOOD INDUSTRY

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°C				
Shelf temperature	-45 to +80°C				
Shelf areas	3.2m <sup>2</sup> (0.4m <sup>2</sup> /EA)	6.4m <sup>2</sup> (0.8m <sup>2</sup> /EA)	13.2m <sup>2</sup> (1.2m <sup>2</sup> /EA)	19.8m <sup>2</sup> (1.8m <sup>2</sup> /EA)	33.6m <sup>2</sup> (2.5m <sup>2</sup> /EA)
Shelf quantity	8 + 1		11 + 1		14 + 1
Shelf. Dimensions (WxDxH mm)	500 x 800 x 18	805 x 1005 x 18	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

## CONTROL SOFTWARE

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

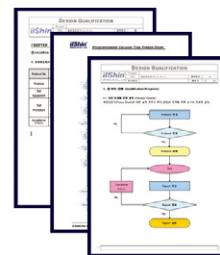
- **Process monitoring:** Comprehensive data supply through entire drying process allows you to have optimal condition and best recipe.
- **Recipe management:** Automatic operation is available by selection of saved recipe that can be expanded further.
- **Audit Trail:** All data from system is traced 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 management 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.

# QUALIFICATION & VALIDATION SUPPORTING

for PHARMACEUTICAL MATERIAL & BIO SCIENCE/FOOD INDUSTRY

## ◆ Design Qualification

- Project Master Plan Supporting
- URS Supporting
- Functional & Design Specification Development
- Risk Analysis & Risk Assessment
- DQ Protocol Supporting



## ◆ Installation Qualification

- IQ Protocol Development
- SOP Development
- IQ Execution & Supporting
- Calibration Program Established



## ◆ Operation Qualification

- OQ Protocol Development
- OQ Execution & Supporting
- Final Report Writing
- Corrective Action & Preventive Action Supporting



## ◆ Computerized System Validation

- Computerized System Design Supporting
- CSV Master Plan Supporting
- DQ, IQ, OQ Protocol Development
- DQ, IQ, OQ Execution & Supporting